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Does the abnormal signal-averaged electrocardiogram predict future appropriate therapy in patients with implantable cardioverter-defibrillators?☆

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Abstract

Background: Several studies have documented the prognostic significance of the signal-averaged electrocardiogram (SAECG) both after myocardial infarction and nonischemic cardiomyopathy. However, whether the SAECG can identify patients with implantable cardioverter-defibrillator (ICD) who receive appropriate therapy has not been hitherto completely investigated.

Methods: Between August 2002 and August 2004, 83 consecutive ICD patients who had had SAECGs recorded were enrolled in this study. All patients were followed up in the outpatient ICD clinic, and interrogated electrograms were collected.

Results: Over 9.0 ± 2.8 months of follow-up, 27 (32%) patients had appropriate ICD therapy for ventricular tachycardia or fibrillation; 15 (55.6%) patients had abnormal; and the remaining 12 (44.4%) had normal SAECGs. Of the 56 patients with no appropriate therapy, 27 (48.2%) and 29 (51.8%) patients had abnormal and normal SAECGs, respectively. There were no statistically significant differences between the 2 groups in SAECG findings ($P = .41$). A Cox regression analysis showed that the left ventricular ejection fraction was the only predictor of appropriate therapy ($P = .02$). Subgroup analysis of the patients with coronary artery disease and spontaneous monomorphic ventricular tachycardia indicated that left ventricular ejection fraction ($P = .03$) and abnormal SAECG ($P = .02$) were predictors of appropriate therapy.

Conclusions: Our data demonstrate that except for the subgroup of patients with coronary artery disease presenting with monomorphic ventricular tachycardia, the SAECG did not predict ventricular tachyarrhythmia recurrence and, hence, appropriate ICD therapy. Thus, SAECG findings should generally not be a factor in decision for ICD implantation.

Keywords: Signal-averaged electrocardiography; Implantable cardioverter-defibrillator; Appropriate therapy

1. Introduction

Several studies have investigated the role of the signal-averaged electrocardiogram (SAECG) in patients after myocardial infarction [1-5] and in those with nonischemic dilated cardiomyopathy (DCM) [6-10]. In these patients, the SAECG has been reported to identify patients at risk for ventricular tachyarrhythmias and, hence, an adverse prognosis. There has also been considerable interest in use of the SAECG in management of the patients with unexplained syncope [11-13]. This technology has been further extended to those patients who are candidates for electrophysiologic evaluation despite the absence of a clinical history of life-threatening ventricular arrhythmias or symptoms suggesting an arrhythmia [14,15].

Because patients with implantable cardioverter-defibrillators (ICDs) are at high risk for arrhythmic events, they should also be expected to have a high incidence of abnormal SAECGs.

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However, whether the SAECG can identify patients who receive appropriate ICD therapies has not been thoroughly investigated. This study sought to determine the role of the SAECG in separating patients with appropriate ICD therapy due to ventricular arrhythmia recurrence from those patients who had no appropriate ICD therapy after implantation.

2. Methods

2.1. Study population

Between August 2002 and August 2004, 83 consecutive patients with ICD who had had SAECGs recorded were enrolled in this study. The study was approved by the local ethics committee, and written informed consents were obtained from all the patients before SAECG recording and ICD implantation. In all the patients, the SAECG was recorded before ICD implantation. Mean age at implantation was 50.0 ± 17.3 years (range, 31-75 years), and 76% of the patients were men. Implantable cardioverter-defibrillator was implanted for secondary prevention of sudden cardiac death in 73.5% and as primary preventive measure in 26.5% of patients. At the time of ICD implantation, structural heart disease was present in 83.7% of the patients. Coronary artery disease (CAD) or a history of coronary artery bypass grafting was present in 45.2% of the patients (all patients with CAD were studied at least 14 months after myocardial infarction). Dilated, hypertrophic, and arrhythmogenic right ventricular cardiomyopathies were underlying disorders in 21.7%, 12.2%, and 2.2% of the patients, respectively. The remaining patients (2.4%) suffered from tetralogy of fallot. Primary electrical disorders, including the Brugada syndrome (6.0%), idiopathic ventricular fibrillation (VF) (6.0%), long QT syndrome (3.1%), and catecholaminergic polymorphic ventricular tachycardia (VT) (1.2%), constituted the underlying diagnosis in the remaining (16.3%) patients. Inclusion criteria of this study were the candidates for ICD implantation who had had SAECG recorded. The patients who had left or right bundle branch block or who had permanent ventricular pacing were excluded from participation.

2.2. Signal-averaged electrocardiography

The SAECG was recorded using a commercially available system (Hellige EK 56; Marquette Hellige, Freiburg, Germany). Before SAECG recording, the skin was prepared by shaving, removing skin debris with alcohol, and abrading the skin with gauze. The SAECG was recorded with standard bipolar X, Y, and Z orthogonal leads. Signals were amplified, averaged, and filtered with a bidirectional filter at frequencies of 40 to 250 Hz. About 200 beats were averaged to a noise level of <0.5 μV before signal amplification and filtering. The filtered signals were combined into a vector magnitude V and the QRS duration, the duration of low-amplitude signals <40 μV (LAS 40), and the root mean square voltage of the signals in the last 40 milliseconds of the filtered QRS (RMS 40) were calculated.

The SAECG was considered to be abnormal if 2 of the following 3 criteria were met: (1) total filtered QRS duration >114 milliseconds, (2) RMS 40 <20 μV, and (3) LAS 40 >38 milliseconds. Otherwise, the SAECGs were classified as normal [16].

2.3. Follow-up

All the patients recruited were visited regularly (every 3 months) and upon receiving ICD discharges in our outpatient ICD clinic. At each visit, all the interrogated data were recorded on diskettes.

2.4. Implantable cardioverter-defibrillator data retrieval

All the ICD electrograms were reviewed by 2 independent electrophysiologists (MH and AA). If there was discrepancy in diagnosis, the final diagnosis of the arrhythmia was made by a consensus of 3 electrophysiologists (MH, AA, and MAS). Intracardiac stored electrograms with spontaneous sustained VT/VF requiring therapy with antitachycardia pacing or direct-current cardioversion were identified as appropriate ICD therapy.

2.5. Data analysis and statistics

Continuous data are presented as mean ± SD. Differences between continuous variables were compared by independent sample student t test. In case of categorical data, the groups were compared by using the χ^2 test (or Fisher exact test if applicable). A 2-tailed P value <.05 was considered statistically significant. Multivariate analysis of predictors of subsequent appropriate ICD therapy was tested by Cox regression analysis with the forward selection method. Appropriate therapy-free probability of patients with abnormal and normal SAECGs over a 12-month period was assessed by the Kaplan-Meier survival curve and log-rank test. The SPSS 13.0 for windows (SPSS Inc, Chicago, Ill) was used for data analysis.

3. Results

3.1. Characteristics of study population

Baseline characteristics of the study population are summarized in Table 1. The studied patients were categorized into 2 groups (group I, patients with appropriate ICD therapy; group II, patients without appropriate therapy). Group I patients were distinguished from group II patients by having lower left ventricular ejection fraction (LVEF) (29.6 ± 13.1% vs 38.6 ± 16.2%, P = .009). There were no other significant differences between the 2 groups of patients regarding age, sex, underlying heart disease, mode of presentation, antiarrhythmic drug use, and follow-up period.

Table 1
Baseline characteristics of population study

Variables	All patients (n = 83)	(+)Appropriate ICD therapy (n = 27)	(−)Appropriate ICD therapy (n = 56)	P
Age (y) (mean ± SD)	50.0 ± 17.3	50.9 ± 16.3	49.5 ± 18.0	.73
Male sex (%)	76	74.1	76.8	.49
LVEF (%) (mean ± SD)	33.2 ± 13.0	29.6 ± 13.1	38.6 ± 16.2	.009
Underlying heart disease (%)				
CAD	45.2	47.6	40.8	.44
Dilated cardiomyopathy	21.7	27.0	18.3	.23
Hypertrophic cardiomyopathy	12.2	10.7	14.3	.56
Arrhythmogenic Right ventricular dysplasia	2.2	2.4	1.8	.41
Primary electrical disorders	16.3	12.3	20.5	.52
Mode of presentation (%)				
Sudden cardiac death	21.7	29.6	17.8	.17
Monomorphic VT	55.4	59.3	53.6	.24
Inducible VT/VF	7.2	0	10.7	.086
Syncope/presyncope	15.7	11.1	17.9	.32
Medications (%)				
Amiodarone	40	38	42	.41
β-Blockers	45	43	46	.53
Other antiarrhythmics	15	17	12	.38
Follow-up duration (mo)	9.0 ± 2.8	9.3 ± 2.2	8.7 ± 3.2	.46

3.2. Follow-up data

Over 9.0 ± 2.8 months of follow-up, of the 83 ICD patients followed up in our outpatient ICD clinic, 27 (32%) had appropriate ICD therapy (antitachycardia pacing and or cardioversion) for VT or VF. Inappropriate therapy for sinus tachycardia, atrial fibrillation, T-wave oversensing, and electromagnetic interference were detected in 13 of the recorded ICD electrograms. No ICD therapy was delivered in the remaining 43 patients. We had no mortality in our patients during follow-up.

3.3. Signal-averaged electrocardiogram findings in study population and its relation to appropriate ICD therapy

Of the 83 patients enrolled in the study, abnormal SAECGs were detected in 42 (51%) of the cases. Total filtered QRS duration, RMS 40 voltage, and LAS 40 duration were 123.2 ± 33.2 milliseconds, 20.3 ± 23.7 μV, and 43.8 ± 24.1 milliseconds, respectively.

Of the 27 patients in group I, 15 (55.6%) and 12 (44.4%) had abnormal and normal SAECGs, respectively. Of the 56 patients in group II, 27 (48.2%) and 29 (51.8%) had abnormal and normal SAECGs, respectively. There were no statistically significant differences between the 2 groups with respect to SAECG findings (P = .41). Fig. 1 shows a Kaplan-Meier curve of appropriate therapy-free probability over a 12-month period after device implantation based on SAECG results (log-rank P = .52). In group I patients, total filtered QRS duration, RMS 40 voltage, and LAS 40 duration were 122.0 ± 34.4, 24.0 ± 26.4, and 44.3 ± 30.8, respectively. In group II patients, total filtered QRS duration, RMS 40 voltage, and LAS 40 duration were 122.2 ± 31.2, 30.7 ± 33.0, and 41.0 ± 23.0, respectively. In a similar vein, no differences were observed between the 2 groups regarding the measured data of any SAECG parameter (all P > .05). Results of SAECG in the 2 groups of patients are listed in Table 2.

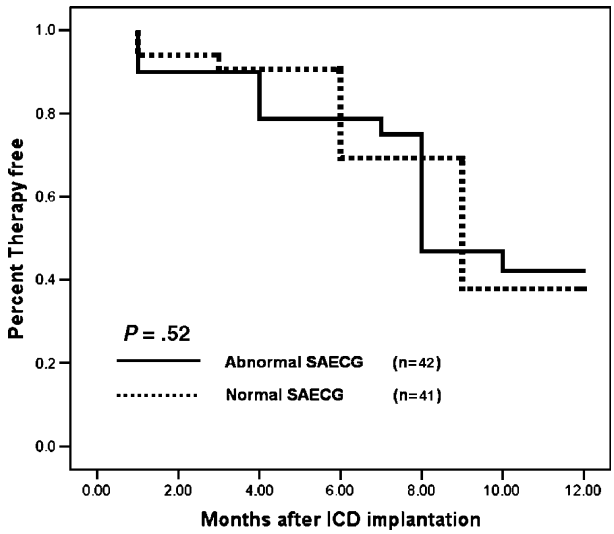

Fig. 1. Kaplan-Meier survival plot of appropriate therapy-free probability for 12 months in patients with abnormal and normal SAECGs after ICD implantation.

3.4. Effects of different modes of presentation, underlying heart disease, age, sex, LVEF, and prior exposure to antiarrhythmic drugs on the results of SAECG analysis

Of a total of 83 patients, abnormal SAECGs were detected in a higher proportion of patients who presented with spontaneous sustained monomorphic VT (MMVT)

Table 2
Signal-averaged electrocardiogram findings in 2 groups of patients with and without appropriate ICD therapy

Variables	(+)Appropriate ICD therapy (n = 27)	(−)Appropriate ICD therapy (n = 56)	P
Filtered QRS duration (milliseconds)	122.0 ± 34.4	122.2 ± 31.2	.97
RMS 40 voltage (μV)	24.0 ± 26.4	30.7 ± 33.0	.31
LAS 40 duration (milliseconds)	44.3 ± 30.8	41.0 ± 23.0	.58
SAECG result			.41
Abnormal	55.6	48.2	
Normal	44.4	51.8	

Table 3
Comparison of SAECG results and parameters in different modes of presentation

Variables	Presentation with MMVT (n = 46)	Other mode of presentation (n = 37)	P
Filtered QRS duration (milliseconds)	128.3 ± 30.6	115.4 ± 32.4	.07
RMS 40 voltage (μV)	20.3 ± 25.4	32.3 ± 31.0	.06
LAS 40 duration (milliseconds)	50.4 ± 27.9	33.2 ± 20.0	.002
SAECG result			.033
Abnormal	69.8	47.5	
Normal	30.2	52.5	

(69.8% vs 47.5%, $P = .033$) than in those with other modes of presentation (Table 3). Among the SAECG parameters, only LAS 40 duration was significantly greater in patients with spontaneous MMVT ($P = .002$).

Other variables, including underlying heart disease, age, LVEF, sex, and prior exposure to antiarrhythmic drugs, had no relation to the SAECG results (all $P > .05$).

3.5. Predictors of appropriate ICD therapy

A Cox regression analysis with the forward selection method showed that LVEF was the only predictor associated with future appropriate ICD therapy ($P = .02$). Other parameters such as age, sex, mode of presentation, underlying heart disease, and number and type of antiarrhythmic drug use could not predict subsequent appropriate ICD therapy after implantation. Subgroup analysis of the patients with CAD and spontaneous MMVT indicated that 2 variables, including LVEF ($P = .03$) and abnormal SAECG ($P = .02$), were predictors of future appropriate ICD therapy. An abnormal SAECG was not a predictor in other subgroups of the study population.

4. Discussion

The SAECG has been reported to identify high-risk patients for arrhythmic events after myocardial infarction and in the setting of nonischemic DCM [1-11]. Reliability of this technology was documented in predicting inducibility of VT both in patients with unexplained syncope and in patients with no symptoms suggesting arrhythmia [12-15,17]. However, the role of SAECG in predicting subsequent ICD therapy has not been studied satisfactorily.

Most published works in SAECG have been performed in post–myocardial infarction patients. A pioneering study by Simson [1] provided the initial clues about the role of the SAECG analysis in identifying patients with ventricular tachyarrhythmia after myocardial infarction, and this was further substantiated by Breithardt et al [2]. Subsequent studies tried to compare the SAECG with other indices of post–myocardial infarction risk stratification, such as Holter monitoring, radionuclide ventriculography, and cardiac catheterization [3-5]. The encouraging results in the setting of CAD paved the pathway for extension of these studies in patients with DCM or unexplained syncope [6-13]. The strength of the SAECG in all settings is the high negative predictive value (>90%). Consequently, it is the choice of many physicians to apply the SAECG as a screening tool to avoid electrophysiologic study [12-15,17]. Despite these encouraging results, the SAECG has been applied in few studies for the prediction of future ICD therapy. Epstein et al [18] tried to determine whether the SAECG could discriminate patients who would have arrhythmia recurrence and receive appropriate ICD shocks from those who would have no recurrence and no shocks. Of an entire group of 50 patients, 16%, 24%, and 60% had normal, abnormal, and indeterminate SAECGs, respectively. Of the 22 ICD users, 5%, 23%, and 73% patients had normal, abnormal, and indeterminate SAECGs, respectively. Of the 28 ICD nonusers, 25%, 25%, and 50% patients had normal, abnormal, and indeterminate SAECGs, respectively. Implantable cardioverter-defibrillator users had lower LVEFs ($P = .0002$), a higher incidence of VT ($P = .04$), prior exposure to a greater number of antiarrhythmic drugs ($P = .04$), and a lower likelihood for survival ($P = .02$) compared with the ICD nonusers. There was no statistically significant difference between the ICD users and nonusers as stratified by SAECG classification regardless of whether the indeterminate studies were included or excluded from the analysis. Although final conclusions of this work are in agreement with those in our study, there are important differences in subgroup analysis. Although all SAECG parameters were abnormal in ICD users, Epstein et al [18] could not demonstrate a predictive role of the SAECG in their subset of patients with CAD and sustained MMVT. Our difference may be related to the smaller sample size and relatively high proportion of patients with indeterminate results in Epstein et al study. In this group of patients with CAD and sustained spontaneous MMVT, the patient population for whom SAECG should be most informative [19-21], the SAECG statistically separated patients with ventricular arrhythmia recurrence and appropriate therapy from those without recurrence and no appropriate device use.

In another study, Tebbenjohanns et al [22] evaluated the predictive role of clinical parameters, SAECG, and electrophysiology study for the occurrence of future appropriate ICD discharges and mortality. In their study, 76 patients with ICDs were followed up for 18.2 ± 6.4 months. During the follow-up period, 29 patients (38.6%) experienced at least 1 episode of appropriate ICD discharges. Although the SAECGs were more often abnormal in patients with appropriate ICD discharges, the differences were not significant. On the other hand, lower ejection fraction and inducible sustained MMVT were predictors of future ICD discharge after implantation. We did not find a similar relation between induced MMVT and appropriate device therapy.

Zareba et al [23] reported results of the SAECG recording in 595 patients enrolled in MADIT II trial. In

MADIT II patients with a narrow QRS, prolonged filtered QRS duration (but not late potentials) was slightly predictive of appropriate therapy; within the entire MADIT II population, including those with bundle branch or wide QRS, SAECG was not predictive. Although this study had greater numbers than our study and, of course, had all patients with CAD, our patients with CAD (all with narrow QRS and sinus rhythm) had a greater risk for experiencing ventricular tachyarrhythmias than those in the study of Zareba et al (all of our patients with CAD were treated by ICD because of spontaneous or inducible VT/VF). Taken together, these studies indicated the greater role of the SAECG in predicting ventricular tachyarrhythmias as the higher-risk patients with CAD were analyzed.

There are several explanations for the inability of the SAECG to predict future arrhythmia recurrence in our group as a whole. First, because all the studied patients already had sufficient risk for experiencing ventricular tachyarrhythmias, risk stratification by SAECG could not necessarily be expected to offer further prognostic information. Second, given that SAECG is demonstrated to be less predictive in patients presenting with VF than VT [19-21], the inclusion of patients who suffered from VF in the final analysis may have contributed to the inability of the SAECG in predicting subsequent arrhythmia recurrence and device therapy. To test this hypothesis, we separately analyzed the patients with CAD and sustained MMVT to determine whether SAECG could provide any further prognostic information in this group of patients. Multivariate analysis confirms our hypothesis. Despite this new finding, we believe that the SAECG should generally not be a factor in the decision for ICD implantation because patients with CAD presenting with MMVT already had sufficient indication for implantation (according to results of several published trials and American College of Cardiology/American Heart Association/North American Society for Pacing and Electrophysiology guidelines [24]) such that the result of SAECG would not be decisive. Nonetheless, it should be noted that the underlying characteristics of our CAD patient with MMVT may not necessarily apply to all other groups of patients with CAD and MMVT.

5. Conclusion

Our data demonstrated that except for the subgroup of patients with CAD presenting with MMVT, SAECG did not predict future ventricular tachyarrhythmia recurrence and, hence, appropriate ICD therapy. Thus, the results of the SAECG should generally not be a factor in decision for ICD implantation.

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