ACC/AHA/ESC PRACTICE GUIDELINES

ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) Developed in Collaboration With the European Heart Rhythm Association and the Heart Rhythm Society

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rhythmias and SCD and the following subtopics: mechanisms, substrates, clinical presentations, ECG, exercise testing, echocardiography, imaging, electrophysiological (EP) testing, drug therapy (antiarrhythmic and nonantiarrhythmic), implantable and external cardioverter devices, ablation, surgery, acute specific arrhythmias (e.g., acute coronary syndrome [ACS], heart failure [HF], stable sustained monomorphic ventricular tachycardia [VT], torsades de pointes), specific pathology (e.g., congenital heart disease, myocarditis, endocrine disorders, renal failure), cardiomyopathies, genetic arrhythmias, structurally normal hearts, athletes, elderly, gender, pediatric, and drug-induced arrhythmias. The complete list of keywords is beyond the scope of this section. The committee reviewed all compiled reports from computerized searches and conducted additional manual searching. Literature citations were generally restricted to published manuscripts appearing in journals in the Index Medicus. Because of the scope and importance of certain ongoing clinical trials and other emerging information, published abstracts were cited in the text when they were the only published information available.

The final recommendations for indications for a diagnostic procedure, a particular therapy, or an intervention for management of patients with ventricular arrhythmias and prevention of SCD summarize both clinical evidence and expert opinion. Once recommendations were written, a Classification of Recommendation and Level of Evidence grade was assigned to each recommendation.

Classification of Recommendations and Level of Evidence are expressed in the ACC/AHA/ESC format as follows:

Classification of Recommendations

- **Class I:** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
- **Class II:** Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment.
 - Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
 - **Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.
- Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

Level of Evidence

- Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
- Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
- Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

The schema for classification of recommendations and level of evidence is summarized in Table 2, which also illustrates how the grading system provides an estimate of the size of treatment effect and an estimate of the certainty of the treatment effect.

Recommendations with respect to therapy have considered the following:

- 1. The therapy to be offered (implantable cardioverterdefibrillator [ICD], antiarrhythmic drugs, surgery, and miscellaneous other treatments)
- 2. The point at which therapy is offered (primary prevention for those who are at risk but have not yet had a life-threatening ventricular arrhythmia or sudden cardiac "death" episode, or secondary for those patients who have already experienced such arrhythmias or events)
- 3. The purpose of therapy (life preservation or symptom reduction/improved quality of life)
- 4. The etiology of the arrhythmia substrate (coronary heart disease [CHD], cardiomyopathy, or other conditions)
- 5. The functional status of the patient (New York Heart Association [NYHA] functional class)
- 6. The state of left ventricular (LV) function (LV ejection fraction [LVEF])
- 7. The specific arrhythmia concerned (e.g., sustained monomorphic VT, polymorphic VT, and ventricular fibrillation [VF])

Not all therapeutic combinations are clinically relevant, and many have no evidence base and probably will not have one in the future because of the lack of clinical relevance or the relative rarity of the particular grouping. In many instances, the probable value of therapy may be reasonably inferred by the response of similar patients to specific therapies.

1.2. Prophylactic Implantable Cardioverter-Defibrillator Recommendations Across Published Guidelines

The ACC/AHA/NASPE 2002 Guidelines Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices (1), the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (2), the ESC 2001 and 2003 Guidelines on Prevention of Sudden Cardiac Death (3,4), the ESC 2005 Guidelines for the Diagnosis and Treatment of Chronic Heart Failure (5a), and the ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult (6) include a large number of recommendations on ICD therapy that merit attention.

Recommendations for prophylactic ICD implantation based on ejection fractions (EFs) have been inconsistent because clinical investigators have chosen different EFs for enrollment in trials of therapy, average values of the EF in such trials have been substantially lower than the cutoff value for enrollment, and subgroup analyses of clinical trial populations based on EF have not been consistent in their New implantable recorders are capable of monitoring the rhythm and can record on patient activation or automatically for prespecified criteria. Although these devices require surgical implantation, they have been shown to be extremely useful in diagnosing serious tachyarrhythmias and bradyarrhythmias in patients with life-threatening symptoms such as syncope (120,146).

5.2.4. Electrocardiographic Techniques and Measurements

Recommendations

Class IIa

It is reasonable to use TWA to improve the diagnosis and risk stratification of patients with ventricular arrhythmias or who are at risk for developing lifethreatening ventricular arrhythmias. *(Level of Evidence: A)*

Class IIb

ECG techniques such as signal-averaged ECG (SAECG), heart rate variability (HRV), baroflex sensitivity, and heart rate turbulence may be useful to improve the diagnosis and risk stratification of patients with ventricular arrhythmias or who are at risk of developing life-threatening ventricular arrhythmias. *(Level of Evidence: B)*

ICD trials, especially Multicenter Automatic Defibrillator Implantation Trial (MADIT) II, have highlighted the need to develop novel tools in order to identify patients at highest risk of ventricular arrhythmias and SCD. Numerous modalities exist at present for assessing this risk but only 2 are currently approved by the U.S. Food and Drug Administration (FDA): SAECG and TWA. However, HRV and baroflex sensitivity also show considerable promise. SAECG improves the signal-to-noise ratio of a surface ECG, permitting the identification of low-amplitude (microvolt level) signals at the end of the QRS complex referred to as "late potentials." Late potentials indicate regions of abnormal myocardium demonstrating slow conduction, a substrate abnormality that may allow for reentrant ventricular arrhythmias, and they are believed to serve as a marker for the presence of an EP substrate for reentrant ventricular tachyarrhythmias. The presence of an abnormal SAECG was shown to increase the risk of arrhythmic events by 6- to 8-fold in a post-MI setting (147). However, the restoration of patency to the infarct-related coronary artery with fibrinolysis or angioplasty and the widespread use of surgical revascularization have modified the arrhythmogenic substrate, leading to a noticeable reduction in the predictive power of this tool. SAECG in isolation, therefore, is no longer useful for the identification of post-MI patients at risk of ventricular arrhythmias. However, a high negative predictive value of 89% to 99% rendered the SAECG a

useful tool with which to exclude a wide-complex tachycardia as a cause of unexplained syncope (148,149).

TWA, which is a fluctuation in the amplitude or morphology of the T wave that alternates every other beat assessed during exercise testing or atrial pacing, has been shown to be an effective tool for identifying high-risk patients post-MI (150) and in the presence of ischemic or nonischemic cardiomyopathy. This association appears to be independent of EF and equally strong in patients with ischemic and nonischemic cardiomyopathy. TWA appears to have a very high negative predictive accuracy (151-153). TWA may also be used to identify risk of arrhythmic mortality in patients with LV dysfunction due to prior MI (154). In a small study of patients with MADIT II characteristics (post-MI with EF less than or equal to 30%), a microvolt TWA test was found to be better than QRS duration at identifying a high-risk group and also a low-risk group unlikely to benefit from ICD therapy (155).

HRV, which is a beat-to-beat variation in cardiac cycle length resulting from autonomic influence on the sinus node of patients in sinus rhythm, has been shown to independently predict the risk of SCD and total mortality in patients post-MI (156) both with and without impaired LV function (157-159). Observational studies also suggest its usefulness in the presence of nonischemic cardiomyopathy, but this has to be confirmed with large clinical trials. There are many different forms of heart rate analysis, some of which, such as heart rate turbulence, may be more productive than others. Reduced baroflex sensitivity, a quantitative assessment of the ability of the autonomic nervous system to react to acute stimulation involving primarily vagal reflexes, compared with a continuous assessment of basal sympathovagal information provided by HRV, has also proved successful in assessing the risk of SCD both alone (increased inducibility of arrhythmic events including VT during EP testing) (160,161) and when used in combination with HRV (increased risk of cardiac mortality post-MI) (157) and TWA (increased risk of arrhythmic events if both parameters are abnormal in a cohort of patients with ICDs) (162). Additional prospective studies are needed to further clarify the role of these ECG parameters in assessing risk in differing clinical settings.

5.2.5. Left Ventricular Function and Imaging

Recommendations

Class I

- 1. Echocardiography is recommended in patients with ventricular arrhythmias who are suspected of having structural heart disease. *(Level of Evidence: B)*
- 2. Echocardiography is recommended for the subset of patients at high risk for the development of serious ventricular arrhythmias or SCD, such as those with dilated, hypertrophic, or RV cardiomyopathies, AMI survivors, or relatives of patients with inherited disorders associated with SCD. (Level of Evidence: B)

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