EDITORIAL COMMENT
Who Needs a Defibrillator?
The Beat Goes On*
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In this issue of the Journal, Elhendy et al. (1) and Singh et al. (2) wrestle with the problem of how to predict which patients who qualify for implantation of an automatic implantable cardioverter-defibrillator (ICD) will actually benefit from the device. These studies reflect a renewed interest in risk stratification to improve the specificity of the selection process, to improve the cost-effectiveness of ICD therapy, and to reduce the number needed to treat (NNT) to save one life.

Over the last decade, there has been a dramatic rise in the number of ICDs in use. This has been driven by a combination of results from a successive series of randomized clinical trials and by easier implantation techniques. In addition, a great expansion has occurred in the indications for primary prevention (prophylactic) ICD use. At the same time, many restrictions have been discarded, including failure to respond to antiarrhythmic drugs, presence of non-sustained ventricular tachycardia (VT), and (usually) VT inducibility at electrophysiologic studies (EPS). Thus, ever larger numbers of patients at risk of an arrhythmic event can be offered the protection that is provided by an ICD. At the same time, however, the percentage of patients with an ICD who receive appropriate therapy has decreased, for example, from 50% to 55% in Multicenter Automatic with an ICD who receive appropriate therapy has decreased, the Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) study, Medicare imposed another series of restrictions (7,8), some of which were based on an attempt to collate the results of several trials so as to make the guidelines more consistent. Other restrictions, such as a requirement for a registry or participation in an approved protocol for any primary prevention implant, represent a new level of supervision and de facto restriction. At the same time, Medicare called for additional investigation into screening tests or risk stratifiers that could help to assure that a higher percentage of patients receiving defibrillators would actually benefit from them (8). Physicians and trial designers should carefully ponder the desirability of this shift of inclusion/exclusion criteria from trial designers to insurers. These concerns have already prompted a number of commentaries (9,10).

Elhendy et al. (1) found that evidence of ischemia based on a stress-echocardiographic test was an independent predictor of death. Other independent predictors were spontaneous or induced sustained VT at the time of the original ICD placement. This was a consecutive series of patients with a history of coronary artery disease (CAD) and prior ICD implantation. As with Elhendy et al. (1), in the larger MUSTT study of over 2,200 patients, inducibility of VT was statistically predictive of subsequent events (4,11). However, sensitivity and specificity were low enough so that EPS currently has less effect on the decision to implant.

The importance of ischemia can be inferred from previous studies. One of the few ICD trials that failed to show advantage for the device was the Coronary Artery Bypass Graft-ICD Patch (CABG-Patch) trial (12). In this study, all patients received best possible surgical revascularization and were randomized to receive an ICD or not. The fully revascularized patients had no added benefit from the ICD. In the MUSTT trial, patients implanted within several days following surgical revascularization also had no benefit from the ICD (13). Taken together with the Elhendy et al. (1) report, the implication is clear: patients with CAD have a progressive process and should be tested periodically for new ischemia; and such ischemia should be corrected if possible. Still, it remains uncertain whether continued absence of evidence of ischemia or correction of newly identified ischemia would obviate the advantages of ICD implantation.

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Singh et al. (2) found that a hospital admission for heart failure during follow up was a strong predictor of reaching the end points of VT or ventricular fibrillation (VF), or the combined end point of VT, VF, or death. This is another reminder of the dynamic and progressive nature of heart disease in many patients. The findings are consistent with earlier reports that ICD patients who receive their implant for arrhythmia rather than heart failure indications tended to have more events including mortality during follow up if ejection fractions were lower (14,15). In contrast, patients implanted primarily for heart failure indications (e.g., SCD-HeFT) benefited less from the ICD if they were in New York Heart Association functional class III versus class II (5). This again marks worsening heart failure as a good predictor of a bad outcome. It has long been known that simply receiving an ICD shock has been associated with a poorer prognosis (16).

In summary, both papers by Elhendy et al. (1) and Singh et al. (2) in this issue of the Journal remind us that patients have disease that progresses at an unpredictable rate, and that some patients are lucky enough to have warning signs (spontaneous or through testing) that can help avert a cataclysmic event. For the physician the challenge is to learn to recognize and use these warning signs, and to develop better predictive tests. For insurers and for society, the challenge is how to pay for it all (17–20). For citizens at large, the challenge is to reach a consensus on just how to balance and to prioritize these competing forces. “All well and good, but not for my patient (or loved one)” is an attitude challenge we all must face.

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REFERENCES