Perspectives

Selecting Patients for Discussion of the ICD as Primary Prevention for Sudden Death in Heart Failure

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ABSTRACT

This clinical perspective addresses the practical aspects of the decision to implant an implantable cardioverter-defibrillator (ICD) for primary prevention of sudden death in patients with symptomatic heart failure and reduced left ventricular ejection fraction, based on a distillation of recent trial experience. Potentially eligible patients are selected on the basis of left ventricular ejection fraction <30% to 35% and anticipated survival with good functional capacity beyond 1 year. Communication with these patients focuses on a horizon of 5 years, during which for every 100 patients receiving devices, approximately 30 patients are predicted to die with or without an ICD, while 7 to 8 lives may be saved with the ICD. These estimates are presented in the context of adverse events, including unnecessary shocks, and the possibility that circumstances may arise for which the defibrillator may be inactivated to allow natural death.
Key Words: Heart failure, Sudden death, Defibrillator, Cardiomyopathy.

Implantable cardioverter-defibrillators (ICDs) have saved lives and offered peace of mind to many patients who have already survived life-threatening ventricular tachyarrhythmias. The use of ICD to prevent recurrent events is appropriate in patients for whom recurrence of a fatal arrhythmia would represent an untimely end to an otherwise extended functional life. Its use would, however, generally be inappropriate for patients in whom the arrhythmic event occurs in the setting of rapidly declining organ function anticipated to lead to death within the year. ICDs have also provided welcome reassurance in families who have undergone tragic loss of young people in connection with inherited sudden death syndromes. A unique case is presented by the potential candidate for cardiac transplantation who has had previous life-threatening arrhythmias. The security provided by the ICD against recurrent sudden death allows listing for transplantation to be delayed until the quality of life is also severely limited. Although ICDs are generally contraindicated in Class IV heart failure because of likelihood of death within 1 to 2 years, an ICD to prevent sudden death has often been used during the long waiting period for listed transplant candidates, whose successful resuscitation can be followed by an average survival for 10 or more years after cardiac transplantation. These special populations account for only a small proportion of the devices inserted.

Primary Prevention of Sudden Death

Approximately half of sudden deaths occur in patients without previously known cardiac disease. However, a group of patients at higher risk than the general population are those with decreased left ventricular ejection fraction, arising from previous myocardial infarction, valve disease, or cardiomyopathy of known or idiopathic etiology. Within this group, the patients at highest risk, after addressing those with previous life-threatening events, may be those with inducible ventricular tachycardia, although noninducibility does not predict freedom from sudden death, particularly for patients with nonischemic

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cardiomyopathy.[1] Other more accessible markers for high risk have been suggested, such as nonsustained ventricular tachycardia, positive signal-averaged electrocardiogram, prolonged QRS duration, and abnormal microvolt T-wave alternans, but these are commonly present in patients with symptomatic heart failure and do not reliably discriminate patients who will experience tachyarrhythmic sudden death.

Positive results from the Multicenter Automatic Defibrillator Implantation Trial (MADIT II) of patients with left ventricular ejection fraction (LVEF) ≤30% after myocardial infarction increased the number of patients eligible for ICD late after myocardial infarction even without a previous history of tachyarrhythmias.[2] The improvement in survival was detected by 18 months, and the trial was stopped at an average follow-up of 20 months. The absolute improvement in survival with defibrillator therapy was approximately 6% (mortality rate 19.8% for conventional therapy vs. 14.2% for ICD; hazard ratio 0.69, 95% CI 0.51−0.93). More recently, the recent Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) included Class II and Class III patients of both ischemic and nonischemic etiology, with LVEF ≤35%.[3] Patients receiving ICD had mortality of 29% after 5 years compared with 36% in patients without ICD (hazard ratio 0.77, 95% CI 0.62−0.96). As with the MADIT II trial, the curves did not diverge until after the first year. The 7% absolute difference in survival in SCD-HeFT at 5 years represents the longest demonstrated benefit for primary prevention, comparable to the improvement in actuarial survival at 3 years in MADIT II after myocardial infarction and in DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation), which included only patients with nonischemic cardiomyopathy.[4]

The benefit of these devices in saving lives can be overestimated if equated to the number of successfully delivered therapies for tachyarrhythmias. Many episodes of ventricular tachycardia terminated by device therapies might have terminated spontaneously. This is most evident from the DEFINITE trial, in which the frequency of device therapies for ''life-threatening'' tachyarrhythmias was twice as high as the apparent rate of such events in the control group without devices.[5] Furthermore, prognosis after successful ICD termination of a ventricular arrhythmia is worse than for patients without such events, with a 3-fold increase in mortality in the first year after device therapy for ventricular tachycardia, and an even worse outcome after a shock for ventricular fibrillation.[6]

Most Deaths Are Not Sudden

The ICD does not confer immortality. It is most likely to result in meaningful prolongation of life in patients who are at high risk for lethal arrhythmias but low risk of death from hemodynamic failure or other organ system disease.[7] The proportion of deaths attributed to primary arrhythmias occurring suddenly in the absence of hemodynamic deterioration is highest in patients with mild symptoms, the New York Heart Association Class II group. Although the total number of deaths increases with increasing severity of symptoms, the proportion of deaths occurring suddenly in Class III patients is less than 50%, and is even lower for Class IV patients. For all patients with heart failure, the risk of dying suddenly has diminished during the past 10 years even in the absence of ICD, as the cumulative benefits of early therapy with angiotensin-converting enzyme inhibitors and β-blockers have been realized. In a recent study of the deaths occurring in 1 heart failure program since 2000, the average duration of heart failure was 5 years, 74% had been hospitalized in the preceding 6 months, half of deaths occurred in the hospital or hospice, and only 21% of all deaths were considered unexpected.[8]

With the reduction of premature mortality during mild-moderate disease, an increasing proportion of patients survive to suffer from crippling symptoms of end-stage hemodynamic decompensation. In previous years, these patients usually died before prolonged passage through Class IV. The premature tragedy and the welcome ending are the 2 faces of natural sudden death in heart failure. As the heart failure population ages, the likelihood of death from noncardiac conditions increases. The implantable defibrillator will prevent only a minority of deaths overall. Many patients who realize the risk of sudden death do not appreciate the likelihood of other modes of death.

In many patients, this limited efficacy is compounded by the frightening prospect of multiple defibrillations during death. Fortunately, however, ventricular fibrillation and shocks occur rarely at the end of life except in patients who have had a history of repeated device firings. It is in these patients that inactivation of device defibrillation in the face of imminent death is most crucial for the patient and family. For other patients, inactivation of the device close to the end of life may occasionally prevent unwanted defibrillation, but more often serves primarily as another step along the path of preparation for the end. Hemodynamic death from end-stage heart failure usually occurs with refractory bradyarrhythmias and asystole, sometimes due to hyperkalemia from progressive renal dysfunction, that do not respond to defibrillation or electrical pacing.

Unwanted Effects of ICDs

The most common adverse effect from ICDs is inappropriate shocks. Shocks for non−life-threatening arrhythmias constitute about one third of all ICD shocks in the largest trial,[3] and can be more common than appropriate shocks in patients with nonischemic causes of cardiomyopathy.[5] The majority of inappropriate shocks, particularly those that occur repeatedly, result from atrial fibrillation or flutter, less commonly from sinus tachycardia during exercise or other stress, oversensing, or lead failures. Some patients develop nightmares and flashbacks typical of posttraumatic stress disorder after device shocks.[9] Some have extreme