



Guest Editor: Prof. Yong-Fu Xiao

## The dilemma of implantable cardioverter-defibrillator therapy in the geriatric population

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### Abstract

Current guidelines for implantable cardioverter-defibrillator (ICD) therapy in heart failure patients were established by multiple device trials; however, very few geriatric patients (patients  $\geq 65$  years old) were included in these studies. This article explores the controversies of ICD implantation in the geriatric population, management of delivered ICD therapy in this age group, and the end of life care in patients with ICD.

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### 1 Introduction

Heart failure (HF) has emerged as the leading epidemic of cardiovascular disease in the 21st century, affecting 23 million people worldwide.<sup>[1]</sup> Mortality from coronary heart disease (CHD) as well as hypertension-related cerebrovascular accidents has declined with improved management of these diseases; however, they remain major contributors towards the development of HF.<sup>[2]</sup> Moreover, HF is a disease of the elderly and with increased survival from acute myocardial infarction, the prevalence of HF has increased annually to include over 5.8 million people in the United States.<sup>[3]</sup>

Due to the high morbidity and mortality from HF, the American College of Cardiology (ACC)/American Heart Association (AHA) established a classification system to increase awareness that heart failure is a continuum. Presently, HF is categorized in four stages: stage A patients have risk factors for heart failure, but normal left ventricular ejection fraction (LVEF) and no heart failure symptoms; stage B patients have developed structural heart disease but no heart failure symptoms; stage C patients have ventricular dysfunction and symptoms of inadequate cardiac output and/or fluid overload; stage D patients have advanced symptoms and severe disability. In the elderly population, the more common stages are C and D. Survival in heart

failure varies with age and symptom severity. In younger patients and in those with minimal symptoms (New York Heart Association (NYHA) class I or II), sudden cardiac death (SCD) is the most common cause of death. While with advanced age and heart failure severity, patients die from progressive heart failure symptoms and bradyarrhythmias.

Current guidelines for HF management were established by multiple pharmacologic and device trials; however, very few geriatric patient (patients  $\geq 65$  years old) were included in these studies. Hence, physicians who manage geriatric heart failure patients frequently encounter clinical situations without evidence-based guidelines. One such clinical scenario is the use of device therapy in the elderly with heart failure—specifically the elderly patient with implantable cardioverter-defibrillator. While (Implantable cardioverter-defibrillator) ICD definitively reduces the incidence of SCD in younger HF patients on optimal medical therapy, it is unclear if the elderly population derives similar benefits since they have different modes of death.

The focus of this paper is to review the current guidelines for ICD implantation and how they translate to elderly patients with HF as well as to discuss management of the elderly patient with appropriate and inappropriate shocks. Lastly, end-of-life care with an ICD will be discussed.

### 2 Age and the ICD implantation dilemma

Current indications for ICD implantation were derived from randomized trials in a well-defined patient population. Specifically, HF patients with ejection fraction (EF) less

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than 35% are at increased risk for SCD. ICD implantation has been shown to prevent SCD and has become the main therapy for SCD prevention. The current ACC/AHA guidelines do not specify an age criterion for selection of candidates for ICD despite the fact that only a minority of patients enrolled in the major device trials were 65 years or older. The only contraindications for device implantation are patients who are NYHA functional class IV and have any disease limiting expected survival of less than one year. Physicians involved in decision-making regarding ICD implantation are driven mostly by inclusion criteria and little attention is paid to exclusion criteria applied in the different trials.

At present, over 40% of all new ICD implants are in patients over age of 70 and 10%–20% of ICD implants are in patients over 80 years of age.<sup>[4]</sup> Presently, the data from randomized clinical trials (RCT) are mixed. In the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) study, the effect of an ICD on total mortality was similar in patients ages < 60, 60–69 or > 70 years.<sup>[5]</sup> In contrast, the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) did not show any significant reduction in total mortality in patients older than 65 years randomized to ICD compared to those in the placebo arm.<sup>[6]</sup> In addition, a pooled analysis of data from secondary prevention randomized clinical trials did not demonstrate any benefit from ICD implantation in patients aged 75 years or older.<sup>[7]</sup> Additional considerations before ICD implantation in the geriatric population with its multitude of concurrent comorbidities are predisposition to higher periprocedural complication rates, including higher mortality and longer duration of hospital stay after device implantation.<sup>[8]</sup> Thus, to date, no clear evidence exists for any beneficial role of the ICD in patients older than 75 years.

Physicians caring for the geriatric cardiac patient are faced with a variety of clinical scenarios: (1) patient receives ICD therapy and has improved survival; (2) patient dies without ICD therapy; (3) patient dies despite ICD therapy, which is considered successful therapy if the death occurs more than a year after ICD implantation or as unsuccessful treatment if ICD therapy preceded death by a few days or weeks; and (4) patient is alive and never required ICD therapy (negative from economical standpoint).<sup>[9,10]</sup> Clearly, from the presented scenarios, the search for the patients that will benefit the most from ICD implantation still continues.

In an attempt to find a risk scoring model several noninvasive and invasive electrophysiological tests have been evaluated, including signal-averaged ECG, heart rate

variability, and T-wave alternant testing but the risk-stratification results from these tests have not been very encouraging. Using the MADIT-II database, a convincing risk scoring model to predict mortality was developed. It includes five independent predictors determined at the time of ICD implantation: atrial fibrillation, NYHA > II, QRS > 120 ms, age > 70 and blood urea nitrogen (BUN) > 9 mmol/L. Patients with an intermediate score benefited the most from ICD implantation. Though these findings are encouraging, we need to do better. Unfortunately, aside from LVEF determination, no other convincing stratification method of identifying patients at high risk for SCD exists. All these clinical situations should be discussed with the patient prior to implantation in order for the ideal informed consent to occur.

### 3 Management of the patient that received ICD therapy

A major aspect of ICD therapy not adequately discussed in ICD studies is quality of life after ICD implantation. Followup of the major ICD trials (MADIT-II, DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Evaluation), and SCD-HeFT) regarding frequency of ICD therapy revealed that appropriate shock for life-threatening arrhythmia was delivered in approximately 35% of heart failure patients in the first one to three years after implantation. In comparison, the incidence of inappropriate shock in the HF ICD population was as high as 27%.<sup>[9]</sup> While frequently the intuitive response to ICD shocks is a sense of relief that SCD has been aborted, a more thoughtful approach to these patients must be developed since both appropriate and inappropriate shock are associated with increased mortality.

#### 3.1 Appropriate shock therapy in HF ICD patients

An appropriate shock is one that is delivered for a potentially life-threatening ventricular arrhythmia, such as ventricular tachycardia, ventricular fibrillation or torsades de pointes. Patients who experience their first ICD shock, appropriately, become anxious, particularly regarding their ability to perform activities of daily living. This anxiety can degenerate into a panic disorder or agoraphobia. Physicians involved in the care of the patient with an ICD should be aware of this psychological aspect. The cause of ICD shock should be explained to the patient. Reassurance and psychological support are extremely important. On occasion, use of anxiolytic agents may be necessary.

A single ICD shock does not necessarily warrant an emergency room visit unless it is associated with dyspnea,

syncope, angina or persistent palpitations. Patients should be reassured and referred to their electrophysiologist within a week for device interrogation. In patients with clinical symptoms described above, a cause for the arrhythmic event should be sought such as active coronary disease, worsening heart failure, electrolyte imbalance or recent change in medications. Frequent isolated ICD shocks are managed by optimization of antitachycardia pacing, administration of antiarrhythmic medication or both. Antitachycardia or overdrive pacing is when the ICD paces the ventricle at a rate slightly faster than the rate of ventricular tachycardia resulting in termination of tachycardia. Antitachycardia pacing can effectively terminate up to 81% of episodes of spontaneous ventricular tachycardia and is highly effective at preventing the need for appropriate shock therapy, therefore, reducing patient distress as well as battery drain.<sup>[11]</sup>

Though antiarrhythmic therapy for prevention of SCD is inferior to ICD treatment, it is often initiated in patients with ICDs to reduce the frequency of appropriate shocks. This is achieved through the following mechanisms: reducing the tendency for sustained ventricular tachycardia; decreasing the rate of ventricular tachycardia by making such episodes more susceptible to antitachycardic pacing; suppressing atrial arrhythmias, which in turn could trigger ventricular arrhythmias. Several antiarrhythmic medications have been studied for this purpose, including sotalol, amiodarone, and azimilide (not available in USA). In the multicenter, international pharmacological therapy in cardioverter defibrillator patients (OPTIC) study, 412 patients with ICD were randomized to receive beta-blocker alone, amiodarone plus beta-blocker, or sotalol. At the 1-year follow-up, the shock rate was 10.3% in the amiodarone plus beta-blocker group vs. 38.5% in the beta-blocker alone group and 24.3% in the sotalol group.<sup>[12]</sup> Pulmonary toxicity was more common in patients assigned to amiodarone. When considering antiarrhythmic therapy in ICD patients, one has to be aware of the possibility of increasing the defibrillation threshold. While unlikely in the case of sotalol, amiodarone has this potential. Another consideration prior to use of antiarrhythmic medication is that the medication can be proarrhythmic. Sotalol, in particular, is associated with torsades de pointes. Based on these data, the reasonable approach is to initially use beta-blockade in all ICD patients. In patients with recurrent ICD shocks and heart failure amiodarone should be first-line therapy. Sotalol is contraindicated in patients with uncontrolled heart failure and left ventricular dysfunction. Other antiarrhythmics should be used as second-line therapy in patients unresponsive to amiodarone.

Another situation frequently encountered in elderly patients with ICDs is so-called electrical storm, which is defined as 3 or more episodes of sustained ventricular tachycardia within a 24-hour period. When managing a patient with electrical storm, it is important to rule out reversible causes such as electrolyte imbalance, myocardial ischemia, and medication overdose. As part of antiarrhythmic therapy, amiodarone is considered first-line therapy. Sympathetic blockade is critical in this situation and can be achieved with oral or intravenous beta-blockers. Sedation is another critical step in controlling the electrical storm, especially with propofol which may have antiarrhythmic properties. Also, patients are electively intubated. Class I antiarrhythmics can be considered but are less effective than amiodarone or beta-blockers. Electrical storm requires emergent electrophysiological evaluation and consideration for catheter ablation. The European Heart Rhythm Association/Heart Rhythm Society guidelines support the use of catheter ablation in symptomatic sustained ventricular tachycardia that persists despite antiarrhythmic drugs as well as control of incessant ventricular tachycardia storm without a reversible cause.<sup>[13]</sup>

Appropriate shocks can give a false sense of relief that SCD was prevented. However, they detrimentally affect quality of life and are associated with poor prognosis and with worsening heart failure. The physician taking care of a patient experiencing ICD shocks must be aware of this impact.

### 3.2 Inappropriate shock therapy in HF ICD patients

Causes for inappropriate shock are multiple and include: supraventricular arrhythmias, multiple premature ventricular contractions, oversensing of the T wave, and mechanical problems such as lead fracture, insulation break, and lead dislodgement. Heart failure patients who receive inappropriate ICD shocks are usually younger and more likely to have atrial fibrillation. Since the most common arrhythmia in heart failure is atrial fibrillation, intuitively it is the most common cause of inappropriate shocks as well. This mostly occurs because the ICD detects ventricular tachycardia or fibrillation based on a prespecified range of ventricular rate called ventricular fibrillation/ventricular tachycardia zone. A supraventricular tachycardia with rapid ventricular response can fall in the range of this detection zone and trigger an inappropriate shock.

At present, ICDs have a variety of sophisticated algorithms to discriminate ventricular tachycardia from supraventricular tachycardia in order to decrease the occurrence of inappropriate shocks. For example, by introducing the sudden-onset algorithm to detect a sudden

increase in ventricular rate, the ICD can differentiate ventricular tachycardia from sinus tachycardia, which has a more gradual onset. Another discriminating parameter that can be programmed into the ICD is the monitoring of the stability of the ventricular rate (R-R interval) during tachycardia. In atrial fibrillation with rapid ventricular response the R-R intervals vary whereas in ventricular tachycardia the interval is regular and stable. This can be sensed by the ICD lead and thus the atrial fibrillation with rapid ventricular response can be differentiated from ventricular tachycardia. Dual chamber ICDs (with a lead in right atrium and a lead in the right ventricle) have the advantage of atrial sensing, thereby facilitating the discrimination of ventricular tachycardia from supraventricular tachycardia. Pharmacologic therapy can be used to reduce inappropriate shocks caused by supraventricular tachycardias. In the OPTIC study, the inappropriate shocks for supraventricular tachycardia were reduced in the amiodarone and beta-blocker arm,<sup>[12]</sup> however, beta-blocker therapy alone has not been shown to reduce inappropriate shocks in heart failure patients. This could be due to inadequate control of atrial fibrillation with fast ventricular response.<sup>[14]</sup>

Mechanical causes of inappropriate ICD shocks can be identified on a chest X-ray (lead fracture, dislodgement) or by interrogation of the device. To terminate inappropriate shocks, a magnet can be placed on the device.

Cardiologists and geriatricians should be aware of the high incidence of inappropriate shocks in the elderly population. It is imperative that adequate drug therapy is prescribed and that the ICD is programmed correctly to avoid inappropriate shocks, since patients that receive inappropriate shocks have increased mortality when compared to patients that did not receive any shocks.

### 3.3 ICD therapy and end-of-life care

In the last days of their lives, 20% of patients will receive ICD shocks. This adds pain, causes suffering, and decreases the quality of life.<sup>[15]</sup> Deactivation of their ICD could improve the quality of life in terminally ill patients by eliminating the pain and emotional distress associated with ICD shocks. While difficult to discuss, the conversation regarding the option for device deactivation in the setting of burdensome therapy should be clearly explained at the time of implantation as part of the informed consent. Since HF is a terminal disease, all patients should be encouraged to have some form of advanced directives regarding their device. Unfortunately, rarely do ICD patients know that deactivation is an option.<sup>[16]</sup> As the disease progresses, an evolution regarding ICD therapy occurs over time. As HF worsens

and the frequency of hospitalizations for decompensated heart failure and/or arrhythmias increases, the conversation regarding the benefits and burdens of the device should be held. The physician should explore the patient's understanding of the device role, and the patient should be allowed to express his/her goals in the setting of worsening heart failure. In cases when the patient chooses a "Do not resuscitate" order, the physician must have a discussion regarding the role of the device since it is also a form of resuscitation. The decision regarding device deactivation is ultimately made by the patient (or legal surrogate), but the dialogue regarding device deactivation should be held with the support of the family. This meeting should occur early enough in the patient's illness, so the entire family is in agreement in terms of goals of medical care to avoid future misunderstandings and conflicts between caregivers and patients. The patient's primary care physician, electrophysiologist and cardiologist with whom the patient has formed long-term relationships, should actively participate in this process. This multidisciplinary approach is essential to support the patient's family.

Special ethical considerations arise once the issue of ICD deactivation is raised. Specifically, who decides to proceed with ICD deactivation? Legally and ethically this decision is made by the patient with decision making capacity or by his/her legal surrogate. The criteria examined in the decision making process are the treatment effectiveness as well as the treatment burdens and benefits. Treatment effectiveness is determined by the health care providers, and reflects the ability of the treatment to alter the natural history of the disease. The benefits and burdens of the therapy can only be determined by the patient. This decision is unique for each patient since it is based on his/her own values and health care-related goals. The physician should not impose his/her own moral values or views upon the patient and the patient's decision takes priority over the clinician's decision. At the same time, patient cannot request treatments that are ineffective and are against reasonable medical practice. The general agreement is that ICD deactivation is ethically permissible, especially if it is done to avoid painful shocks. The same agreement exists to withdraw other treatments, such as hemodialysis, artificial nutrition or mechanical ventilation.<sup>[15]</sup> Some physicians may raise the concern that ICD deactivation is equivalent to assisted suicide or euthanasia. The factors that differentiate between ICD deactivation and assisted suicide or euthanasia are the intent of the physician and the cause of death. First, the intent of the physician in ICD deactivation is not to accelerate the patient's death but rather to remove a therapy that is perceived by the patient as painful and burdensome. In

assisted suicide the physician provides means (e.g., drugs) for the patient that intentionally terminates his/her own life. With euthanasia, the physician intentionally terminates the patient's life (e.g., via lethal injection). Secondly, the cause of death in ICD deactivation is the underlying, terminal disease. Whereas in assisted suicide or euthanasia the cause of death is the intervention provided by the physician.<sup>[17]</sup> Lastly patients (or their surrogates) have the right to refuse or withdraw life-sustaining therapy based on their health-care goals or preferences. Deactivation of ICD in this context is not assisted suicide or euthanasia but is legally and ethically permissible.<sup>[17]</sup>

The practical instruction and steps in ICD deactivation are described extensively in the 2010 Heart Rhythm Society expert consensus statement for the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy.<sup>[17]</sup> Briefly, the following general considerations in ICD deactivation were identified: (1) Documentation of the physician's determination of the patient's decision making capacity or identification of the patient's surrogate. The health care provider should assess whether the patient or the surrogate understands the overall clinical condition and the consequences after withdrawal of ICD therapy. (2) Confirmation that alternative therapies have been offered and discussed (if relevant). (3) The physician order for deactivation should include the specific therapies to be deactivated or reprogrammed. (4) The physician must anticipate the symptoms after ICD deactivation, and should arrange for appropriate palliative care based on individual patient needs. (5) The clinician can choose not to participate in deactivation process if this is contrary to his/her religious or personal beliefs. In this case, the physician is required to arrange the transfer of the patient care to another clinician. (6) The deactivation should be performed (when it is possible) by persons with expertise in the electrophysiological field (physicians, device-clinic nurses or technologists). When they are not available this can be performed by the any health care provider with the help from industry-employed allied professionals.<sup>[18]</sup>

HF is a disease of the elderly and as this population grows, we will need clearer guidelines regarding use of cardiac devices in this group of patients. This paper discussed the importance for determining indications for ICD implantation and subsequent withdrawal of care as these patients reach end of life; however, a separate topic is the discussion of cardiac resynchronization therapy without ICD in an effort to improve quality of life without adding the trauma of potential, inappropriate ICD shocks; neither, did we discuss the potential financial impact of ICD therapy

in this population, usually with multiple comorbidities, who already have a foreshortened lifespan. These questions can only be answered by either RCT or observational studies. Until then, physicians are charged with the task of educating patients with the benefits of ICD and how to manage end of life care.

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