Implantable Cardioverter-Defibrillator Shocks

Epidemiology, Outcomes, and Therapeutic Approaches

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Importance: Implantable cardioverter-defibrillators (ICDs) have revolutionized the approach to the prevention of sudden cardiac death and are commonly used in a wide range of high-risk patients, including the large population of patients with severe left ventricular systolic dysfunction. The benefit of these devices derives from their therapies, including both antitachycardia pacing and high-energy shocks. However, although these therapies may be life saving, devices can also deliver inappropriate shocks.

Objective: To review ICD therapies (shocks and antitachycardia pacing), their effects on health outcomes, and current methods to reduce these therapies.

Evidence Review: We reviewed clinical evidence on ICD shocks and reference lists of retrieved articles. We also examined literature about the methods of reducing ICD therapy.

Findings: Both appropriate and inappropriate ICD shocks are common and are associated with an adverse effect on health outcomes, quality of life, and mortality. Several methods are available to reduce the risk of inappropriate ICD therapies.

Conclusions and Relevance: Implantable cardioverter-defibrillators reduce the risk of sudden cardiac death and prolong life in selected populations; however, many patients will receive an ICD shock, either appropriate or inappropriate. It is imperative that patients be counseled regarding this risk and adverse outcomes associated with shocks. Reduction of ICD shock should be individualized to ensure that patients receiving these devices experience the maximal benefits of therapy while minimizing the adverse consequences.


A 56-YEAR-OLD MAN WITH AN ischemic cardiomyopathy and a left ventricular ejection fraction of 30% presents for routine follow-up. He recently had an implantable cardioverter-defibrillator (ICD) placed for primary prevention of sudden cardiac death (SCD); he has no history of ventricular arrhythmias. During the interview, the patient describes an ICD shock that occurred while he was exercising at the gym. He relates that this has occurred a few other times in the past. He is tired of worrying that his device is about to shock him and wants to resume a “normal life.” An interrogation of his ICD identifies that these shocks have been triggered by sinus tachycardia; there has been no evidence of ventricular tachycardia (VT). As his cardiologist, primary care physician, or other health care professional, what do you do next?

Implantable cardioverter-defibrillators have revolutionized the treatment of individuals at high risk for SCD. Since the first ICD was implanted in 1980, the indications for this intervention have expanded both because of the evolution of device technology and in the clinical science supporting the use of ICDs. After the publication of landmark randomized clinical trials and adoption in multiple professional guidelines, ICDs are frequently used for the primary prevention of SCD in patients with left ventricular systolic dysfunction (LVSD). From January 1, 2006, through December 31, 2009, 486,025 ICD implants were documented in the ICD Registry of the National Cardiovascular Data Registry, which is estimated to account for 90% of all ICDs implanted in the United States during this period. As the number of patients receiving ICDs increases rapidly, the potential consequences associated with inappropriate ICD shocks have received greater attention. This article reviews ICD therapies (shocks and antitachycardia pacing [ATP]), their effects on health outcomes, and current...
methods at attempting to reduce these therapies.

**EPIDEMIOLOGY AND MECHANISMS OF ICD SHOCK**

Sudden cardiac death is often due to ventricular arrhythmias, which are particularly common in patients with LVSD. Implantable cardioverter-defibrillators are used to recognize and promptly treat these malignant ventricular arrhythmias, often implementing high-energy shocks for defibrillation. The event the patient experiences is a sudden intracardiac shock akin to external defibrillation. Patients have described an ICD shock as “an earthquake,” “being hit by a truck,” or “being kicked by a mule.”

Given the traumatic nature of ICD shocks, it would be ideal if the ICD could always successfully distinguish ventricular arrhythmias from non–life-threatening rhythms and administer shocks only for VT or VF. Implantable cardioverter-defibrillators are configured with zones demarcated by particular heart rate settings above which the device is programmed to deliver some type of therapy. The so-called VF zone is typically programmed to identify arrhythmias with faster rates, for example, more than 180 to 200/min, or a cycle length of 300 to 330 milliseconds.

Although the reported frequency of ICD shocks varies, a consistent finding is that substantial proportions of patients receive shocks after ICD implantation. In patients receiving ICDs in the secondary prevention Antiarrhythmics versus Implantable Defibrillators (AVID) trial, the proportion of patients with an arrhythmic event, defined as SCD, sustained ventricular arrhythmia, or ICD therapy, was 35% at 3 months, 53% at 1 year, and 68% at 2 years.

Approximately 45% of patients had a shock within the first year. In a meta-analysis of 7 major ICD trials, appropriate ICD therapy (including both ATP and shock) occurred in up to 64% and inappropriate therapies occurred in up to 24% during 20 to 45 months of follow-up (Figure 1). Among the 194,000 patients included in a large, observational, prospective study, appropriate and inappropriate shock rates at 5 years were 23% and 17%, respectively.

Compared with earlier studies, roughly half of 422 patients (52%) analyzed in a prospective cohort experienced appropriate ICD therapy at a median follow-up of 3.6 years, suggesting that the incidence of appropriate ICD therapy may have declined in recent years. Expanding indications for use of ICD implantation (primary prevention) have resulted in a selection of patients who are less likely to experience malignant ventricular arrhythmias than the secondary prevention population. In addition, compared with these earlier trials, the implementation of specific strategies may reduce the rates of avoidable and inappropriate ICD shocks. Thus, the actual risk of inappropriate shocks in contemporary practice may be lower than those documented in the clinical efficacy trials of ICDs.
appropriate shock. Technical causes of inappropriate ICD shock include faulty components, oversensing of electrical noise, lead fracture, electromagnetic interference, oversensing of diaphragm myopotentials, oversensing of T waves, and double counting of QRS complexes. Recently, there have been widely publicized Food and Drug Administration Class 1 Product Advisories (recalls) of ICD leads, specifically the Medtronic Sprint Fidelis and the St Jude Medical Riata leads. These recalls resulted from evidence of high rates of lead failure, in some cases manifest as inappropriate ICD shocks. In a study of long-term performance of ICD leads in the Veterans Affairs system, the failure rates of both the Medtronic Sprint Fidelis and St Jude Medical Riata leads were substantially greater than conventional benchmarks. In addition, of the St Jude Medical Riata leads that failed, almost 30% resulted in one or more inappropriate shock. Particularly among patients with leads and/or pulse generators known to have higher than expected rates of failure, hardware failure should be considered in the differential diagnosis of ICD shocks.

Ventricular pacing may increase the risk of VT or VF through various mechanisms, including mechanical ventricular irritability at the site of the lead implantation and increased the risk of inducing scar-based reentrant ventricular arrhythmias among patients with myocardial fibrosis. In MADIT II, higher rates of right ventricular pacing were associated with higher rates of appropriate therapies for VT or VF and new or worsened heart failure. Finally, right ventricular pacing among ICD recipients is associated with increased mortality, possibly due to induction of left ventricular dyssynchrony and worsening heart failure.

Certain patients are at higher risk for any ICD shock. In a community-based study, appropriate ICD therapy was more likely in patients receiving ICD therapy for secondary prevention, who were older, or who had lower left ventricular ejection fraction. Post hoc analyses from the randomized clinical trials have also identified risk factors for inappropriate ICD shocks. In a study of MADIT II, patients with AF, tobacco use, and diastolic hypertension had a higher risk of inappropriate shocks; in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), inappropriate shocks were more frequent in patients with nonischemic heart failure compared with those with ischemic heart disease. Inappropriate ICD shocks are presumably more common in patients with AF because of rapid ventricular response rates that meet the heart rate threshold to trigger shocks. The mechanisms of the association between the other factors and ICD shocks are unclear.

**HEALTH OUTCOMES AFTER ICD SHOCK**

There is little controversy that ICD therapy can prolong life in appropriately selected patients with LVSD because of the ability to abort arrhythmic SCD with defibrillation. However, several studies have found that the life-prolonging benefit of an ICD shock comes with a cost and is associated with adverse outcomes.

Studies in several settings suggest that health-related quality of life is influenced adversely in patients who experience ICD shocks, regardless of whether they are appropriate or inappropriate. In the SCD-HeFT trial—a primary prevention randomized controlled trial—patients who received shocks within 1 month of a scheduled assessment (n = 49) had substantially lower health-related quality of life than those who had not received shocks in the previous month. In the secondary prevention setting in the AVID trial, patients who had experi-
Implantable cardioverter-defibrillator shocks are also associated with psychological disorders. Anxiety is particularly common, with 24% to 87% of patients with an ICD experiencing worsened symptoms and diagnosis of anxiety disorders. Patients who experienced more shocks were significantly more anxious and depressed than the group not experiencing shocks. Among 95 ICD recipients, those who experienced more than 5 shocks developed significantly higher anxiety than other ICD recipients. Godemann et al evaluated 90 patients with ICDs using a standardized interview that focused on the diagnosis of anxiety disorders. Panic disorder and/or agoraphobia were identified in 16.7% of the patients, which was markedly higher than the general population. Patients who had an ICD shock had a 21% prevalence of these diagnoses vs a 6.9% prevalence in those patients without an ICD shock. Patients with an ICD are under substantial risk of psychological distress; the number of ICD shocks contributes to these disorders. We do not know of any study that addresses psychological distress confined to patients with inappropriate shock only. There is increasing evidence that ICD shocks are associated with increased risk of heart failure hospitalization, a particularly concerning finding given the high baseline rates of hospitalization in patients with LVSD. In a subgroup analysis of MADIT II, the risk of a heart failure event at 1 year was 26% and 31% after first treatment for VT and VF, respectively, compared with 19% for those without ICD therapy.

Finally, clinical trials have identified an association between ICD shock and mortality. MADIT II found that appropriate ICD therapy identifies more than a 3-fold increase in mortality risk. In the SCD-HeFT trial, both appropriate and inappropriate ICD shocks were significant predictors of death, increasing risk of death by 5- and 2-fold, respectively. Of 2135 ICD patients analyzed by Sweeney et al, shock for ventricular arrhythmias was associated with a 20% increase in mortality, whereas no change was noted in mortality among those with ATP-treated arrhythmias. The most common cause of death among patients with ICD shock was progressive heart failure.

Although there is little dispute regarding the association of ICD shock and adverse outcome, the meaning of this relationship is unclear. A potential explanation for these apparent associations is that ICD shocks might cause adverse outcomes by inducing myocardial injury; however, it is perhaps more likely the case that patients who are sicker and who have poorer functional status more often experience ventricular arrhythmias. This finding is illustrated in the prospective cohort who demonstrated that patients with inappropriate ICD shock due to technical failure (noise and oversensing) were not at increased risk of mortality, supporting the claim that ICD shocks are a marker rather than a mediator of adverse outcomes.

METHODS TO REDUCE INCIDENCE OF ICD SHOCK

ICD Programming

Antitachycardia pacing for VT is a safe and effective alternative to shocks for terminating many ventricular arrhythmias. With ATP, the ICD delivers a burst of ventricular-paced beats at a rate faster than the underlying arrhythmia. This approach will often terminate reentrant arrhythmias, even monomorphic VTs as fast as 240/min, obviating the need for shocks in many cases. To date, large-scale trials have found that ATP may effectively terminate more than 90% of spontaneous VT. The advantages of ATP over shock include less patient discomfort, less battery drain, and possibly lower risks of adverse health outcomes. Therefore, ATP is preferred as the initial therapy for many monomorphic VTs unless otherwise contraindicated.

Two large-scale trials have addressed specific programming strategies to reduce the need for ICD shock. First, ATP for VT faster than 200/min, which had been traditionally treated by shock because of safety concerns, reduced the need for shock and improved quality of life with little risk of VT acceleration and syncope and no difference in mortality. Second, the aggressive use of ATP, SVT discrimination, and high-output first shock compared with a historical control cohort of patients who had ICD parameters programmed at the discretion of their physician lowered the risk for any shock during the first year (8.9% vs 16.9%).

Recently, the MADIT–Reduce Inappropriate Therapy trial evaluated whether more stringent ventricular arrhythmia detection algorithms and, once arrhythmias are detected, more aggressive use of ATP would reduce inappropriate therapies. Patients with primary prevention ICDs were randomly assigned to 1 of 3 programming configurations to evaluate rates of inappropriate ICD therapy. At a mean follow-up of 1.4 years, the high-rate therapy (initiation of therapy at >199/min) and delayed ICD therapy (with a 60-second delay at 170 to 199/min, a 12-second delay at 200–249/min, and 2.5-second delay at >249/min) groups compared with conventional device programming significantly reduced the first and total occurrence of both appropriate and inappropriate therapy. More important, the conventional treatment group had a significantly higher cumulative mortality during follow-up compared with both of the new programming strategies.

Other programming features may also reduce the likelihood of ICD shocks. On the basis of the observation that VT tends to be abrupt in onset and somewhat regular (high stability), sinus tachycardia tends to accelerate gradually, and AF is irregularly irregular (low stability), Brugada et al found that programming sudden onset and stability criteria helped discriminate supraventricular arrhythmias and reduced the risk of inappropriate shock. In addition, just as the surface QRS complex during VT generally differs from that during sinus rhythm, discrimination algorithms can be used to identify the differences in the contour of the sensed intracardiac electrograms compared with a template of the electrograms during known sinus rhythm. Although all devices are preprogrammed, it is important for the implanting clinician to review the device settings because these settings may be inappropriate for the individual patient.

Dual-Chamber ICDs

A dual-chamber ICD might theoretically help distinguish SVT from VT by using atrial and ventricular sensing information to discriminate between the 2 arrhythmias. Detecting atrioventricular dissociation can help distinguish VT from SVT not only by using surface electrocardiography but also via the
sensed device electrograms. Conceptually, the idea is that a ventricular rate of 200/min with an atrial rate of 75/min would be consistent with VT; in contrast, a ventricular rate of 110/min with an atrial rate of 350/min suggests SVT (likely AF). However, data supporting dual-chamber devices as a means of improving arrhythmia discrimination are limited; no study reports that dual-chamber device programming is effective at reducing the risk of inappropriate ICD shocks.43-46 In addition, the potential benefits of dual-chamber devices must be weighed against the costs and risks of this therapy. Dual-chamber devices are more expensive and are associated with higher periprocedural complication rates than single-chamber ICDs.47,48

Pharmacologic Therapy

Select antiarrhythmic medications can be used to reduce the frequency of ICD shocks. The mechanisms of benefit include suppressive atrial and ventricular arrhythmias and slowing episodes of VT, which may allow patients to better tolerate VT hemodynamically, thereby allowing for broader use of ATP.

Evidence-based heart failure therapy with β-blockers, angiotensin-converting enzyme inhibitors, and aldosterone receptor antagonists reduce the risk of heart failure hospitalization and mortality (including SCD) among patients with LVSD.50-53 These therapies are underused in eligible patients undergoing ICD implantation, which, in turn, may add to the burden of ICD shocks.54,55 Optimal medical therapy may result in improvement of left ventricular systolic function such that ICD therapy may no longer be warranted. In addition, medical therapy offers improvements in symptoms of heart failure, mortality, and the risk of ventricular arrhythmias, resulting in ICD therapies. Further, β-blockers may reduce ventricular rates in patients with supraventricular arrhythmias, such as AF, which could prevent inappropriate ICD shocks.

Optimal heart failure therapy alone may be inadequate to prevent shocks. In a randomized trial comparing a β-blocker alone, amiodarone and a β-blocker, or sotalol, 40% of patients treated with β-blockers alone had shocks at 1 year, whereas those treated with amiodarone and β-blockers had only a 10% risk.56 Thus, all patients with LVSD should receive optimal heart failure therapy, and in selected patients, additional rhythm control therapy may be warranted.

Antiarrhythmic medications also have limitations. Most are potentially proarrhythmic; sotalol has a considerable (1%-4%) risk of triggering torsades de pointes, especially among patients taking higher doses (>320 mg/d), with elevated serum creatinine levels, with a history of VT or heart failure, and of female sex.56 Amiodarone causes many important and sometimes severe extra-cardiac toxic effects.58,59 The addition of antiarrhythmic medications needs to be individualized, considering the number of shocks, the effect of these shocks on the patient, and risk of adverse effects of the medications.

Catheter Ablation

Catheter-based ablation techniques are also used to treat ventricular arrhythmias. The typical indication for ablation is VT refractory to medical therapy in patients who also receive multiple ICD shocks. The prophylactic use of catheter ablation on the rate of ICD therapy in secondary prevention patients was examined with 128 patients who were randomized to either catheter ablation using a substrate-based approach or no ablation.60 In the ablation group, there was a 65% lower risk of receiving ICD therapy (ATP or shock) and a 73% lower risk of receiving ICD shocks. However, ablation had no significant effect on mortality, and no data were collected on quality of life. Furthermore, ablation was conducted at highly experienced centers, is exceptionally operator dependent, and is not widely available. In addition, although there were no reported adverse effects of ablation, the procedure inherently carries with it multiple potential complications. Given the lack of evidence and clinical trials supporting the widespread use of ablation techniques, it should not be considered clinically indicated as prophylaxis to reduce ICD therapy.

Optimizing Evidence-Based ICD Implantation

Because patients who do not undergo ICD implantation will not receive inappropriate (or appropriate) ATP or shocks, any strategy to minimize inappropriate device therapies should begin with ensuring that the decision to implant an ICD is based on established indications outlined in the relevant clinical guidelines.61,62 Rigorous adherence to current evidence in selecting patients for ICD implantation will ensure that treatment is provided to those for whom the benefits are expected to outweigh the risks of therapy, including the risks of inappropriate ICD shocks. A recent study63 suggests that patient selection for primary prevention ICD therapy could be improved.

CASE SCENARIO REVISITED

The patient in the clinical vignette received multiple inappropriate ICD shocks for sinus tachycardia while exercising. At the time of ICD implantation, the manufacturer’s default programming settings had been used, including a lower-limit VF zone starting at 180/min. To minimize his risk of inappropriate ICD shock, his device was reprogrammed to a higher-threshold heart rate for the VF zone, and his β-blocker dose was increased. He has since been free of inappropriate ICD shocks while maintaining his active exercise regimen.

CONCLUSION

Implantable cardioverter-defibrillators reduce the risk of SCD from ventricular arrhythmias, thus prolonging life in selected high-risk patients. However, it is important that patients understand that many with ICDs receive a shock; indeed, the benefit of the device results from its treatment of malignant ventricular arrhythmias. Unfortunately, shocks may also be delivered inappropriately (ie, for nonlethal rhythms). Furthermore, shocks, both appropriate and inappropriate, may have consequences for health status and other important health outcomes.

After careful selection, once a patient undergoes implantation, the first step in reducing adverse outcomes should be to minimize any ICD shock to the extent possible, acknowledging that the primary purpose of the device is to treat malignant ventricular arrhythmias, often with shocks. All patients should have programming with individual settings based on history and demographics; aggressive use of ATP; and appropriate use and dosing of evidence-based therapies for LVSD, including β-blockers, angiotensin-converting enzyme inhibitors, and aldosterone antagonists when appropriate. Other approaches, including use of dual-chamber ICDs and catheter ablation, are still controversial. The therapeutic approach should be individualized to ensure
that patients receiving ICDs experience the maximal benefits of therapy while minimizing the possible adverse consequences.

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