EDITORIAL

Enhancing Patient Care by Estimation and Discussion of Risk for ICD Shock

SAMUEL F. SEARS, PH.D.,*,† AMANDA WHITED, PH.D.,*,† and KENT J. VOLOSIN, M.D.‡

From the *Department of Psychology, East Carolina University, Greenville, North Carolina; †Department of Cardiovascular Sciences, East Carolina Heart Institute, East Carolina University, Greenville, North Carolina; and ‡Shore Medical Center, Somers Point, New Jersey

Introduction

Modern clinical trials have demonstrated that implantable cardioverter defibrillators (ICDs) have been broadly successful in terminating potentially life-threatening arrhythmias in at-risk patients. This success fostered greater attention to the potential negative aspects of the therapy, with particular focus on ICD shocks. Substantial research examining the psychological and quality-of-life effects of shock has followed and been debated,[1–3] and have generally shown that the effects of shock are equivocal in relation to generic quality-of-life outcomes, but more detectable when examined in the acute setting (short-term, 30-day window) and using disease-specific measures (e.g., shock anxiety vs general anxiety).

Current clinical practice has generally taken a "one size fits all" approach for communicating a patient's risk for ICD shock. Going beyond reassurance to a more empirically based conversation about individual patients' risk for shock is now possible with recent clinical trial data. This conceptualization prompts a more clinically meaningful effort to address patient anxiety routinely encountered in cardiology clinics. The purpose of this paper is to integrate recent clinical trial data with psychological and behavioral research to provide a discussion base for a clinical forecast to patients about the nature and probability of ICD shock.

Shock Probabilities from Clinical Trials

When ICDs were first developed, the only therapy delivered was an unsynchronized shock. However, over time it became clear that many, if not most, ICD shocks could be avoided by use of advanced programming tools. For example, compared to the SCDHeFT trial where 20% of patients received inappropriate shocks in the first 5 years, modern device programming can bring this number to as low as 3–5% at 5 years.[4,5] The use of antitachycardia pacing (ATP) alone reduces shocks for fast VT by 75%.[6] Moreover, ATP can terminate episodes of ventricular and supraventricular tachycardia (SVT), which is essentially painless and may go unnoticed by patients, often avoiding the need for shock. Additionally, the use of longer detection times allows episodes of nonsustained VT to terminate spontaneously, thus avoiding therapy.[7–9] There are, however, many device-specific features (e.g., ATP during charging, noise rejection algorithms, T-wave oversensing features, and SVT criteria) that can also have an impact on shock rate. Which device is chosen, whether these features are present, and the physicians' preference in programming influences inappropriate shock rate. The EMPIRIC trial demonstrated the impact of physician-chosen programming versus an empiric programming option.[10] Physicians were not effective in beating the EMPIRIC inappropriate shock rate. Collectively, the state-of-the-art programming and technology available in modern ICDs have significantly reduced the risk for ICD shock. Newer features to avoid shocking for lead fractures or T-wave oversensing have further reduced inappropriate shocks.[4]

Nonetheless, multiple mechanisms contribute to ICD shock. Some of these factors cannot be changed, such as individual patient characteristics and genetics, but many other factors can be modified to reduce patients' risk for shock, such as optimal device programming and medication compliance (Table I). Furthermore, remote monitoring has also demonstrated robust effects on shock reduction, increased survival, earlier clinical decision making, enhanced follow-up, and quality of life.[11–16]

Progress in ICD Patient Management: Patient-Reported Outcomes

The primary psychological benefit of an ICD is increased perception of safety from the threat of potentially life-threatening arrhythmias. Despite optimal effort from patients and assurance

Address for reprints: Samuel F. Sears, Ph.D., Department of Psychology, East Carolina University, 104 Rawl Bldg, Greenville, NC 27858. Fax: 252-328-6283; e-mail: searss@ecu.edu

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Table I.

Clinical Markers for Stratifying Risk Probabilities for ICD Patients

Low Risk
1. Primary prevention indication for implant —less appropriate shocks
2. No history of atrial fibrillation or supraventricular tachycardia
3. Good compliance with medications
4. Shock reduction programming
5 Long QT syndrome with a single gene mutation
6. Brugada syndrome—primary prevention
7. Compliance with remote monitoring
Medium Risk
1. Advisory lead
2. Secondary prevention—more appropriate shocks
3. Hypertrophic cardiomyopathy
4. History of appropriate therapy
5. Not remote monitored
High Risk
1. Recurrent Afib or SVT
2. Recurrent VT—sustained or nonsustained
3. Fractured lead
4. Poor medication compliance
5. Advanced heart failure
6. Electrolyte abnormalities—dialysis patients
7. Inadequate device programming
8. Long QT syndrome with multiple mutations
9. History of VT storm
10. Currently smoking

ICD = implantable cardioverter-defibrillator; SVT = supraventricular tachycardia; VT = ventricular tachycardia.

from providers, the desired effect on patients' perception of cardiac safety and security is not always achieved. Although providers explicitly enhance patient security via ICD implantation, they may lack the time or clinic resources to explicitly communicate the psychological benefits associated with the device. Further, many patients recognize that multiple threats persist including both the progression of the underlying disease substrate and the potential intervention of ICD shocks. Thus, the ICD patient manages a host of threats, and shock only represents one such threat. Every psychological issue faced by ICD patients cannot be addressed in routine cardiac care, but attention to psychological factors that are amenable to brief interventions in a cardiac clinic is indicated.

Patient acceptance of an ICD can be defined as understanding and psychologically accommodating the advantages and disadvantages of having an ICD.[17] Device acceptance has been associated with greater quality-of-life scores in ICD patients.[18] Shock anxiety, or fear of both the precipitants and consequences of an ICD shock, represents another ICD-specific outcome that is amenable to routine cardiac care.[19] Recent research has demonstrated that approximately 15% of ICD patients, with and without shock history, experience clinically significant levels of shock anxiety, and 44% endorse items to a degree that indicates a level of shock anxiety that warrants clinical concern and further assessment.[20] Unaddressed shock anxiety may ultimately generalize to a clinically significant anxiety disorder or avoidance of activities due to perceived ability or desire to avoid ICD shock.

More generic psychiatric issues are established in the ICD patient population as well. Generalized anxiety as a psychological morbidity presents itself in 13–38% of ICD recipients.[1] Posttraumatic stress disorder (PTSD) symptoms have also been established in as many as 20% of a primarily secondary prevention group of ICD patients, and PTSD symptoms were associated with 3.2 times greater risk of mortality at 5-year follow-up.[21] Significant depressive symptoms affect between 18% and 41% of ICD patients.[1] Risk for poor psychosocial adjustment is particularly high among ICD patients less than 50 years of age, with previous psychological difficulties, with multiple comorbidities, and following exposure to five or more shocks.[16] Collectively, the patient experience of ICD therapy and psychosocial functioning presents challenges to the clinician in cardiac electrophysiology.

The Psychology of ICD Shock Risk

Avoiding the experience of shock remains a goal for all ICD patients. Patients with ICDs are aware that they are at risk for shock. What they *do not* know is their individual level of risk. For patients, understanding risk is both a cognitive and an emotional process. Although it may seem that providing information on specific shock risk to patients could produce anxiety, reducing uncertainty about risk by quantifying and describing that risk can make living with ICD more predictable.

Risk is processed and understood in three parts. First, individuals begin to grasp the *concept of loss*. For ICD patients, loss often comes in the form of perceived loss of health or freedom due to perceived restrictions in longevity or quality of life. The second component of risk is the *significance of the loss*, or perceived severity of the loss. ICD patients may fear the severity of the pain of shock itself, as well as the disruption it might have on themselves and their loved ones. Third, individuals also must comprehend the

Table II.

Strategies and Rationale for Communicating Effectively with Patients about ICD Shock Risk

Strategy	Rationale	Health Care Provider Communication and Behavior	
Medical information translated to patient-centric utility	Reducing ambiguity will reduce anxiety	Content and concepts	• Review multiple goals of cardiac care with ICD ○ Prevent premature death ○ Prevent shocks ○ Identify and manage controllable and uncontrollable risks of ICD shocks (e.g., uncontrollable: disease type, controllable: adherence to β-blocker medications; no smoking)
		Sample talking points	• "I want you to live confidently with your device. Let's discuss your level of shock risk and go over a plan to manage shock if and when it occurs. We have the tools to prepare you." • "There is a lot you personally can do to reduce your risk of shock and manage your cardiac condition(s). Taking your medications correctly, using remote monitoring, and quitting smoking are just a few places to start. What can we begin to tackle today to get on the right track with your heart health and build some confidence?"
Risk framing	Anxiety is unnecessarily triggered by emphasis of risk versus protection from harm	Content and concepts	• Reduce the chances of shock via medications, programming, and/or follow-up care and monitoring • Focus on percentages of no shock as well as shock (e.g., 95% likelihood of no shock for that year/time period vs 5% chance of shock)
		Sample talking points	• "Although the device is designed to deliver a shock to save your life when needed, there are many things you can do on a daily basis to protect your health and increase shock-free days, weeks, months, or even years." • "We know from studying large groups of patients like yourself that 95% of patients won't even receive a shock within the first year of implantation."
Stimulus substitution	Shock represents safety net activation versus solely disease severity	Content and concepts	• Shift focus away from pain and discomfort of shock • Emphasize meaning of shock as safety net
		Sample talking points	• "Shock is uncomfortable, but it's a temporary experience that signals to you that your device is active and 'at the ready.' It will treat your arrhythmia and save your life if needed." • "When shock occurs, your device is doing its job—it's protecting you." • "Because you have an ICD, you have a safety net. It will step in and correct arrhythmias to protect your life. It allows you to live a secure life."

(Continued)

Table II.

Continued

Strategy	Rationale	Health Care Provider Communication and Behavior	
Remote management	Helps to keep "watch" on your heart and your device around the clock	Content and concepts	• Use of remote management has demonstrated many benefits, including higher survival, quicker identification of adverse events, and lower rates of inappropriate shock.
		Sample talking points	• "Remote monitoring provides us with the quickest and most successful strategy to evaluate the functioning of the device and your heart." • "Remote monitoring allows us to stay connected to your heart's activity in between visits and act immediately and as needed on potential problems. This will benefit you much more than relying only on what we discover during your visits to clinic."
Routine and ongoing in clinic patient education	Patients benefit from repeated presentation of information	Content and concepts	• Fostering knowledge about our treatments (medications and ICD) can help reduce anxiety • The use of open-ended questions can help you determine how much the patient understands about his/her condition, prognosis, treatment, etc.
		Sample talking points	• "The purpose of ICD is to identify and terminate potentially dangerous heart rates. It does that by using either small pulses of energy (antitachycardia pacing) or larger amounts of energy (shock)." • "The beta-blocker you're prescribed helps control your arrhythmia by affecting your blood pressure and heart rate. Taking it will help reduce your chances of your device delivering a shock." • "Today we talked about what to do when you experience shock. Could you tell me how what you'd do in response to shock? I want to make sure we're on the same page so you can feel prepared."

ICD = implantable cardioverter-defibrillator.

Table III.

Planning for Critical Events with Patients and Providing Relevant Coaching

Shock plan	Initiate a standard procedure for patient behavioral response to an ICD shock.[23] Discuss the reality of man-made devices and the continuous quality and safety monitoring process.
Recall plan	Engage with companies in communicating and managing any possible risks to prevent an adverse event.
Hospital plan	Management of cardiac conditions occasionally warrants "tuning up" of the treatment plan. "Hospitalizations are to be avoided but serve a purpose. We will work together to prevent these and minimize these as much as possible."
Activity plan	The resumption of physical activities to some degree is the hallmark achievement of care. "Activities are important to for reengagement and quality of life. What activities do you plan to return to following this event?"
End-of-life plan	"The ICD works to prevent premature death due to a cardiac arrhythmia but it cannot prevent death due to other causes. We would like to prevent unnecessary shocks as you manage other health problems."

uncertainty of loss. For ICD patients, there is uncertainty about whether and when shock will occur. This, in turn, may cause some patients to overestimate their risk for shock, leading to a persistent cycle of fear-induced avoidance and cardiac hypervigilance. Providing tailored risk information could reduce anxiety surrounding their device and ICD shock by minimizing ambiguity and engaging patients in their care.

As patients digest their tailored risk, some level of anxiety may arise due to the risk feeling more tangible or known than it had been previously. Demystifying shock and reducing uncertainty is expected to improve patients' self-efficacy and mobilize them. Empowering patients by providing them with knowledge about their cardiac condition and access to resources will likely help boost their ability to confidently engage in a shock plan and combat ICD-related anxiety. In fact, utilizing risk stratification (see Table I) can help direct providers and patients into different tiers of treatment and facilitate the development of a collaborative, personalized treatment plan.

The communication of risk and reassurance of clinical planning is detailed in Table II. Specifically, a summary of strategies intended to combat distress and anxiety-driven fears in relation to their risk of ICD shock are offered. Patients with higher risk as determined through review of factors in Table I allow providers to be more strategically proactive in allaying their concerns and working to build confidence in their treatment and shock plan. Further, all ICD patients benefit from discussion about critical events in the course of ICD care, such as review of a shock plan or end-of-life issues (detailed in Table III).

Conclusions

Significant progress has been made on the reduction of ICD shocks via enhanced technology. Today, evidence suggests that the probability of an inappropriate shock for a primary or secondary prevention patient is approximately 5% at 5 years. Both the Painfree SST trial and published computer modeling support the hypotheses that these percentages are achievable.[4,5] Appropriate shock rates in patients without high-risk factors can be estimated to be less than 20% at 5 years. Therefore, total shock risk is estimated to be approximately 5% per year. The recent Advance III trial found inappropriate shock to occur at 13.6 per 100 patient years with an extended detection duration, and only 4% of secondary prevention patients were found to suffer an inappropriate shock.[9] Excluding the potential physical morbidity and mortality aspect of ICD shocks, these emerging data can be used clinically to more assertively address patient psychological and behavioral functioning with a clinical forecast of the probability of ICD shock risk.

In reality, however, ICDs are not optimally programmed to minimize appropriate or inappropriate shocks.[23] These investigators found that even with direct feedback regarding shock reduction programming, many outpatients were not getting their devices programmed to provide maximum shock avoidance. Physicians often get "today's" implant programmed correctly, but

reviewing all patients implanted in the last 3–5 years and making appropriate adjustments is an ongoing challenge in most electrophysiology clinics. As battery longevity increases, now is the time to develop outpatient device clinics that proactively use new information from published clinical trials to make appropriate programming choices before the patient experiences shock. Shock reduction involves changing typical follow-up patterns to update shock reduction programming in all appropriate patients, including changing time to detect, ATP parameters, or SVT limits. Remote monitoring data should also be aggressively prescribed, analyzed, and results discussed during clinical encounters. Episodes of nonsustained ventricular tachycardia predict sustained episodes. Episodes of atrial fibrillation with a rapid ventricular response predict shocks. Lead noise predicts shocks. Gradual changes in impedance, even without reaching alert threshold, can still be a marker of lead failure.

There is also a growing awareness and attention to heterogeneity among ICD patients in terms of their individual risk for shock. Data from a number of clinical trials suggest that the traditional "one size fits all" approach for understanding and communicating patients' risk for ICD shock fails to benefit a majority of ICD patients. Thus, the need for personalized shock risk assessment is increasingly recognized. This paper provides an initial framework for facilitating discussions with patients about their individual risk for shock and designing a treatment to further minimize their risk. Engaging patients in this discussion provides a more realistic perception of their probability of experiencing shock, thereby reducing ambiguity and related shock anxiety. Empowering patients with knowledge and realistic expectations of ICD discharge rates is an important clinical strategy that has the potential to increase device acceptance and improve the quality of life of ICD patients and their families.

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