Arrhythmia Management Devices

Managing With Pacemakers and Implantable Cardioverter Defibrillators

Rachel Lampert, MD

Implantable cardioverter defibrillators (ICDs) save lives in patients at risk for sudden death attributable to ventricular arrhythmias, pacemakers (PMs) have been improving symptoms in patients with bradyarrhythmias for decades, and, more recently, cardiac resynchronization devices have improved mortality, morbidity, and quality of life for patients with heart failure. However, these devices can also be life-changing for the patients receiving them. The need for long-term follow-up, concerns regarding malfunction, and lifestyle restrictions all affect patients with any implanted device. For patients with ICDs, receiving shocks, both appropriate and inappropriate, can impact quality of life (QOL). Lead or device malfunction can result in unnecessary shocks, and recalls can cause anxiety. Shocks at the end of life can be particularly devastating. However, with careful attention by the healthcare team, both shocks and their impact can be reduced. In addition to shocks, restrictions imposed by the ICD can also impact QOL. The possibility of syncopal arrhythmias and loss of control attributable to shocks, as well, has led to concerns regarding the safety of driving and of sports participation for some individuals, a further burden.

Remote monitoring increases the ease of follow-up for patients and physicians and may improve timeliness of management. However, a consequence of remote follow-up has been a decrease in the amount of time electrophysiologists may spend face-to-face with patients, emphasizing the importance of communication between electrophysiologist and primary cardiologist. This article will review ways in which the patients receiving them. The need for long-term follow-up, concerns regarding malfunction, and lifestyle restrictions all affect patients with any implanted device. For patients with ICDs, receiving shocks, both appropriate and inappropriate, can impact quality of life (QOL). Lead or device malfunction can result in unnecessary shocks, and recalls can cause anxiety. Shocks at the end of life can be particularly devastating. However, with careful attention by the healthcare team, both shocks and their impact can be reduced. In addition to shocks, restrictions imposed by the ICD can also impact QOL. The possibility of syncopal arrhythmias and loss of control attributable to shocks, as well, has led to concerns regarding the safety of driving and of sports participation for some individuals, a further burden.

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Psychosocial Impact of the ICD

Studies of overall QOL for patients with ICDs have shown mixed results. Some studies have found no significant differences in overall QOL between ICD patients and other cardiac patients. In the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial, baseline QOL measured by SF-36 in ICD patients was similar to that of elderly patients with recent myocardial infarction or severe heart failure, but less than for ambulatory patients with heart failure, implying a moderately severe impairment in QOL. These studies may be limited, however, by the use of general measures that do not capture the specific impact of the ICD. Studies that have evaluated both general and ICD-specific measures suggest that, although general QOL is similar to the age-matched population, ICD patients express ICD-specific concerns.

Determinations of factors that impact QOL for ICD patients are under ongoing investigation. Most studies suggest that frequent shocks negatively impact QOL. Shocks have been described by patients as “a blow to the body, a punch in the chest, being hit by a truck, kicked by a mule, or putting a finger in a light socket.” In the Canadian Implantable Defibrillator (CID) trial, although those patients who received either no shocks or 1 to 4 shocks had significant improvement in QOL over time, those with 5 or more shocks did not improve. Similarly, in the AVID trial, the occurrence of even 1 shock was associated with a reduction in mental well-being and physical function, even after controlling for multiple clinical factors such as heart failure, index arrhythmia, and ejection fraction. Further, there was greater reduction in QOL as the number of shocks increased.

Other factors, such as preexisting personality types and coping styles also impact QOL after ICD. For example, type D or distressed personality, ie, individuals with a combination of negative affect and social inhibition, have more difficulties, as do individuals prone to somatization and depression and anxiety. Not surprisingly, individuals who start with high expectations and with optimism have better QOL. Low social support is also a predictor of poor QOL for patients with ICDs, in particular, the absence of a spouse. In studies that evaluated the effects of both shocks and psychosocial factors, some have found that psychosocial factors, such as underlying personality traits, play a larger role than shocks in determining QOL for ICD patients. Thus, it is likely that shocks interact with psychosocial factors such as personality traits and social support in influencing QOL for patients with ICDs.

The incidence of anxiety and depression is higher in the ICD population than in other cardiac populations. A recent systematic review of 45 studies that assessed >5000 patients reported that between 11% and 28% of patients had a depressive disorder, and 11% to 26% had an anxiety disorder. Posttraumatic stress disorder is also increased in patients with ICDs, with a recent single-center study of 308 ICD recipients describing a rate of 35% for significant anxiety or posttraumatic stress disorder after implant. In this study, psychopathology decreased.
at 1 year overall, but not in patients who had received shocks from the ICD. As with QOL, it is likely that many factors, such as baseline psychological traits and social support, interact with shock to impact whether patients develop anxiety, depression, or posttraumatic stress disorder.15

**Interventions to Improve Psychosocial Outcomes**

General recommendations to improve psychological outcomes in patients with ICDs have recently been outlined.7 Patients given complete information before implantation, including the negative possibilities of inappropriate shocks and lead malfunction, may have better adjustment after implant. Education should be an ongoing endeavor. Next, providers who care for ICD patients should assess for signs of distress. One suggested method to screen for depression is the use of the Patient Health Questionnaire, which starts with 2 simple questions that can be used verbally at each visit in a very short period of time: “over the last two weeks,” has the patient been bothered by any of the following problems: “(1) little interest or pleasure in doing things, and (2) feeling down, depressed, or hopeless,” and then progresses to the full 9-question instrument if the answer to 1 of these 2 questions is positive.7 Referral to appropriate mental health professionals should be implemented for patients with evidence of psychological distress. The Florida Patient Acceptance Survey18 and Florida Shock Anxiety Scale,19 also validated in an electronic version,20 measure ICD-specific concerns. Whether the broad use of these instruments to identify patients who might benefit from referral will improve psychological outcomes is an important avenue of future research.

The importance of psychoeducational interventions, 15 reported to date, to improve QOL and mood disturbances in ICD patients has been recently reviewed.7 Most have included in-person or telephone interventions with the use of cognitive behavioral therapy frameworks, which have shown improvements in anxiety, depression, and posttraumatic stress disorder, although sample sizes have been small. The largest study to date of a stress reduction therapy is ongoing, using a cognitive-behavioral model of stress that emphasizes the interactive relationship of cognition, emotion, physiology, and behavior (Reducing Vulnerability to ICD Shock Treated Arrhythmia [RISTA]).21 Whether interventions should be offered to all ICD patients, or are of most benefit in subgroups demonstrating distress at baseline, is an important avenue of future research.

**Immediate and Long-Term Approach to the Patient With Shocks**

In studies, from 7.5% of primary prevention patients22 to 48% of those with a history of ventricular arrhythmia23 received a shock for any reason in a year. In a contemporary real-world ICD population, appropriate shocks occur in ≈6% per year of ICD patients, and inappropriate shocks occur in ≈8% per year.24 Communication between physician and patient at the time of implantation regarding a plan of action on receipt of a shock will reduce patient anxiety and often unnecessary resource use, as well. Immediate and long-term management of ICD shocks is diagrammed in the Figure. If a single shock is received, and the patient is without other symptoms such as dyspnea or chest pain, a remote transmission should be made and the patient instructed to call the electrophysiology clinic. If the shock is delivered for recurrent occasional ventricular tachycardia/ventricular fibrillation that is not amenable to antitachycardia pacing, and there are no other symptoms, no further action may be needed. Inappropriate shocks for supraventricular arrhythmias, lead malfunction, or other reasons require treatment of the cause. The patient receiving >1 shock, or a shock with associated symptoms, should be evaluated and treated more urgently, and it may be appropriate to call the electrophysiology clinic and emergency services simultaneously.

Because of the impact of shocks on QOL, decreasing shocks over the long term is a key factor in managing ICD patients. The first step is evaluation for reversible precipitants. Pharmacological or device-based therapy for decompensated heart failure, or treatment of metabolic abnormalities or ischemia, if indicated, may be the appropriate first step.

If no reversible precipitants are found, a number of modalities are available to decrease shocks, including programming changes, pharmacological suppression of arrhythmias, ablative therapy, and psychological approaches. Reviewing the ICD’s programming in the context of the rate and morphology...
of the shocked arrhythmia, and recently published data\textsuperscript{25} on optimal programming, as well, discussed in detail elsewhere in this series, is the first step in decreasing shocks. Many studies\textsuperscript{26} have demonstrated that pharmacological interventions such as sotalol\textsuperscript{27} and amiodarone\textsuperscript{27} can decrease shocks, although, owing to the potential adverse effects and the low overall shock rate, they are generally initiated following receipt of appropriate or inappropriate shocks. In general, the choice of an initial agent is individualized based on patient characteristics such as renal function (abnormal renal function precluding sotalol) or the desire to avoid the long-term toxicities of amiodarone in a younger patient. More recently, ranolazine has decreased shocks for refractory ventricular arrhythmias in a small series,\textsuperscript{28} although further research is needed. Azimilide also decreases ICD shocks,\textsuperscript{29} although it is not currently available in the United States. Another option for the patient receiving shocks is radiofrequency ablation of the ventricular tachycardia circuit. In the Substrate Mapping and Ablation in Sinus Rhythm to Halt Ventricular Tachycardia (SMASH-VT) trial,\textsuperscript{30} which randomly assigned 128 ICD patients with a history of ventricular arrhythmia and myocardial infarction to ablation or usual care, arrhythmia recurrence was significantly decreased from 33\% to 12\% with ablation.

Following shocks, in particular, a first shock or multiple shocks, patients should be assessed for psychological distress. Psychological treatment can decrease distress, as above, and further, psychoeducational interventions have shown promise in decreasing arrhythmias. One small study (N=70) found a positive effect of cognitive therapy on ICD-treated ventricular arrhythmias at 3 months.\textsuperscript{31} The larger ongoing RISTA study described above\textsuperscript{31} is powered to investigate the effects of a stress management intervention on receipt of appropriate ICD therapy as a primary end point.

Reducing Shocks at Patients’ End of Life

To improve QOL for patients at the end of their lives and to provide direction for clinicians, the Heart Rhythm Society published recommendations regarding the deactivation of both defibrillators and PMs.\textsuperscript{32} Twenty percent of ICD patients receive shocks in the last weeks, days, or hours of their lives, decreasing their QOL, and that of their families, as well.\textsuperscript{33}

The ethical and legal underpinnings of the discontinuation of life-sustaining therapies such as hemodialysis, ventilators, feeding tubes, and cardiac rhythm devices, are well described. The primary ethical principle supporting the withdrawal of life-sustaining therapies is respect for autonomy. US courts have consistently ruled that adult patients have a constitutional right to refuse any treatment, including life-sustaining treatments, and that there is no legal difference between withdrawing an ongoing treatment and not starting it in the first place.\textsuperscript{32,34,35} These rights extend to patients who lack decision-making capacity, through previously expressed statements (eg, advance directive) and surrogate decision makers.\textsuperscript{34}

Although most physicians are comfortable with the deactivation of an ICD, some describe less comfort with PM deactivation, particularly in PM-dependent patients.\textsuperscript{36,37} However, ethically and legally, the right of patients to deactivate a PM is no different than their right to remove any unwanted life-sustaining therapy. The law applies to the person, and informed consent or refusal of therapies is a right of the patient—it is not specific to any 1 medical intervention.\textsuperscript{34,35,38}

Some have questioned whether deactivation of PMs, particularly in dependent patients, is akin to assisted suicide or euthanasia.\textsuperscript{39} However, as described by the Supreme Court,\textsuperscript{39} there are 2 key differences between withdrawal of unwanted therapies and assisted suicide. First is clinician intent—withdrawal of an unwanted therapy, versus hastening death\textsuperscript{40,41}—and second is the cause of death. In assisted suicide or euthanasia, death is caused by the intervention provided, prescribed, or administered by the clinician. In contrast, when a patient dies after a treatment is refused or withdrawn, the cause of death is the underlying disease.

Clinicians may have personal values and beliefs that lead them to prefer not to participate in device deactivation.\textsuperscript{36,42} As described in the American Medical Association code of Medical Ethics, clinicians should not be compelled to perform procedures they view as inconsistent with their personal values, but, instead, they should involve a second clinician who is willing to comanage the patient by performing the desired procedure.\textsuperscript{43}

Timely and effective communication among patients, families, and healthcare providers is essential to prevent unwanted shocks at the end of life, yet few patients or families discuss the option of device deactivation with their physicians before the days preceding death, even among patients with do-not-resuscitate orders, or during terminal situations. Many do not know that device deactivation is an available option.\textsuperscript{31,34,44} Patients and families desire conversations about end-of-life care.\textsuperscript{36,44} Effective communication includes determining the patients’ goals of care, helping patients to weigh the benefits and burdens of device therapy as their clinical situation changes, clarifying the consequences of deactivation, and discussing potential alternative treatments. Following the model of shared decision making, the physician should work together with patients and families to ensure that patients understand, in the context of their illness, the benefits and burdens of the device and the potential outcomes that may occur as a result of its continued use or discontinuation,\textsuperscript{45} such as death or a change in symptoms. Patients can then assess how the benefits and burdens of continued device therapy fit with their ongoing healthcare goals. These conversations should continue over the course of their illness, because patient preferences for outcomes and the level of burden acceptable to a patient may change as illness progresses.\textsuperscript{46} In a formal advanced directive, a patient can identify values, preferences, and goals regarding future health care and a surrogate decision maker in the event the patient loses decision-making capacity.\textsuperscript{41}

Although the logistical aspects of device deactivation will vary with the setting, some basic principles apply (Table 1). Following confirmation of the decision-making capacity of the patient or identification of the appropriate surrogate, the attending physician should document in the chart the patient’s wishes, that discussion concerning consequences has taken place, and what therapies are to be discontinued. Arrangements should be made for palliative care interventions and family support as appropriate. Deactivation should be performed whenever possible by individuals with electrophysiological expertise such as physicians or device-clinic
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the evaluation of transmissions, the determination of actionable findings, and contacting of patients. Establishing lines of communication between device clinics, heart failure clinics, and primary cardiologists is paramount to the realization of the potential benefits of remote monitoring.

In many clinical conditions, such as diabetes mellitus and congestive heart failure, outcomes and QOL are improved when patients have access to their clinical data and play a role in managing their own symptoms. Whether access to data from remote monitoring systems, for example, access to data on volume status, could improve outcomes and QOL for device patients is an important area of further research.

**Lead and Device Malfunction and Recalls: Impact on QOL**

Since 1990, >60 device or lead advisories have been announced, affecting >1 million device patients. Lead or device malfunction and recalls lead to morbidity, mortality, and the need for invasive procedures, as described in detail in other reviews in this series. Furthermore, recalls, and perhaps the surrounding negative press, impact device patients’ QOL. Both PM and ICD patients may fear loss of device function, whereas ICD patients additionally may be faced with inappropriate shocks. One recent study suggested no change in standard measures of depression, anxiety, and device-specific concern in patients with leads under advisory compared with controls, but significant psychological morbidity in patients with actual lead fracture, mostly related to inappropriate shocks. A meta-analysis by Pedersen et al examined 6 studies of the impact of device advisories on patient-centered outcomes, including distress, device acceptance, and QOL. The 2 prospective studies in this meta-analysis showed that device advisory may lead to increased anxiety and decreased confidence in the device. In case control studies, patients with devices under a class I advisory reported poorer QOL than those with a device under a class II advisory. Whether prophylactic replacement of leads under advisory impacts patients’ QOL has not been investigated.

Two documents from the Heart Rhythm Society have addressed the management of device and lead recalls. Both of these documents emphasized the importance of communication, not just between industry and physicians, but between industry and patients, resulting in the implementation of direct patient communication about important device and lead performance issues. Both stressed that “physicians and patients need timely, accurate, and understandable information regarding device performance.” Physician–patient communication needs to start at implant, because physicians set expectations for longevity and the potential for malfunction. In the event of an advisory, direct contact with patients is encouraged, as the decision to monitor or replace the device or lead is considered. Physicians must provide informative counseling regarding the individualized risks of both prophylactic explant and watchful monitoring. These are based on the characteristics of the patient, including PM dependence, history of ventricular arrhythmia, and comorbidities, and the characteristics of the malfunction, including the possibilities for mitigation through programming, and the likelihood of warning signals; in addition, these must take into account patient preference.

Specialized algorithms that monitor for lead failure and reduce lead-related inappropriate shocks in conjunction with remote monitoring may decrease morbidity and QOL impact for patients with systems under advisory. For example, following an advisory issued regarding the Medtronic Fidelis lead, Medtronic developed downloadable software in which a lead integrity alert, triggering both audible and a remote-system alert and a change in detection criteria, as well, is triggered by either a change in impedance or detection of oversensing recognized as rapid impulses whose cycle length is too short to be consistent with physiological signals. Among patients who later developed lead fractures, those with the lead integrity alert downloaded had a 46% reduction in inappropriate shocks (lead integrity alert 38% versus control 70%). Prospective although smaller studies have also demonstrated that lead integrity alerts decrease shocks.

**Drug–Device Interactions: Importance of Physician–Physician Communication**

Drugs can impact device patients through changes in defibrillation, arrhythmia characteristics, sensing, pacing, defibrillation, and interactions with programming, and it is therefore imperative that ICD-following cardiologists be kept appraised of changes in patients’ medical regimens. Data on the impact of antiarrhythmic drugs, used for atrial and ventricular arrhythmias, as well, on the defibrillation threshold are variable, but 1 randomized study has suggested that amiodarone may increase, whereas sotalol and β-blockers decrease, the defibrillation threshold. However, these changes were of small magnitude in most, suggesting that follow-up testing is probably not necessary. These and other antiarrhythmic drugs can also slow the rate of ventricular tachycardia, potentially below the rate cutoff currently programmed, or can be proarrhythmic. Class Ia and Ic antiarrhythmic agents, as well as β-blockers and calcium blockers, can potentially increase pacing thresholds. Further, many heart failure drugs can cause hyperkalemia, which can lead to T-wave oversensing and inappropriate shocks. Finally, β-blockers may slow atrioventricular conduction with resultant increases in right ventricular pacing, which can worsen heart failure owing to the loss of ventricular synchrony. Because patients may have antiarrhythmic medications managed by several physicians, cardiologists and patients should inform the electrophysiologist’s office of these and other changes in medical regimen to avoid these adverse interactions.

**Restrictions: Driving**

It is possible that sudden incapacitation attributable to syncopal arrhythmia or shock while driving could put others at risk. In modern life, driving plays an integral role in emotional and economic health, and restriction from driving significantly impacts QOL. For ICD patients, restriction from driving results in perceptions of a loss of independence, emotional and economic health, and restriction from driving outcomes and QOL are improved when patients have access to their clinical data and play a role in managing their own symptoms. Whether access to data from remote monitoring systems, for example, access to data on volume status, could improve outcomes and QOL for device patients is an important area of further research.

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in athletics becomes an issue of QOL. As described above, many studies suggest that ICD shocks can decrease QOL.96 However, restriction from sports may have a similar impact. For example, although collegiate athletes in general report higher QOL than nonathlete students, on psychological and physical measures, as well, QOL for athletes sidelined even with a minor injury goes down, not only in comparison with students actively playing, but also in comparison with more sedentary individuals.97

There has been concern as to whether the ICD can terminate ventricular arrhythmias occurring during exercise. Exercise increases potassium,98 decreases pH,99 increases catecholamines,100 and can induce ischemia, any of which could potentially increase the defibrillation threshold.95,101–103 However, only 2 cases of shock failure during exercise, both on a treadmill, have been reported; one of which had a known Ethmozine-induced increase in defibrillation threshold104 and the other following very heavy alcohol ingestion.105

A third potential risk of sports participation in ICD patients is the possibility of injury attributable to syncope from an arrhythmia or fall related to the shock itself. Finally, sports participation could lead to damage to the ICD system because of direct trauma or repetitive arm motion.

A recent prospective study, the ICD Sports Safety Registry,106 identified those individuals with an ICD who have made the decision to participate in sports, and followed them prospectively for up to four years. There were 372 athletes, age 10-60 years, participating in dangerous (N=44) or organized sports (N=328), including sixty highly competitive athletes (varsity/junior varsity/traveling team). Close to half had a pre-ICD history of ventricular arrhythmia. Running, basketball, and soccer were the most common sports. Over a median two and half years follow-up, shocks, both appropriate and inappropriate, were not rare. Shocks occurred at similar rates during competition or practice, occurring in 10% of participants, as during other physical activity, occurring in 8%, although were statistically less common at rest, occurring in 6%. However, there were no occurrences of either primary endpoint: 1) death or resuscitated arrest, or 2) arrhythmia- or shock-related injury, during sports. Ventricular arrhythmias requiring multiple shocks occurred in 8 episodes in 7 patients, 2% of the study population, all of whom had either catecholaminergic polymorphic ventricular tachycardia, idiopathic ventricular fibrillation, or coronary artery disease. Freedom from lead malfunction was 97% at 5 years (from implant) and 90% at 10 years, similar to previously-reported malfunction rates in unselected populations.66

These data do not indicate that any sport is safe for any patient under any conditions. How best to to evaluate individual risk is an important avenue of future research. Stress testing can evaluate for propensity of frequent exercise-induced arrhythmia, as well as catecholaminergic polymorphic ventricular tachycardia or ischemia as clinically relevant. For patients with arrhythmogenic right ventricular dysplasia, some early data suggests that exercise may exacerbate the underlying structural abnormalities.107,108 Whether exercise impacts the progression of hypertrophic cardiomyopathy is unknown.

Many factors may decrease the potential risks of shocks participation in patients who wish to continue. One factor
known to decrease exercise-related sudden cardiac death is habitual exercise. In the Physician’s Health Study, although sudden cardiac death increased during exercise, habitual vigorous exercise reduced the risk of sudden cardiac death during exercise 7-fold.11 Another factor that decreases lethal arrhythmias,108 and ischemia, as well,109 during exercise in patients who have coronary disease is compliance with target heart rate, defined as <85% of maximal heart rate on treadmill testing. Teaching patients to monitor and recognize a target heart rate will also decrease shocks attributable to sinus tachycardia. β-Blockers may be needed to treat the underlying condition, and to avoid shocks for sinus tachycardia, as well. Programming should include available rhythm discriminators and standard optimization as discussed in other reviews in this series. Whether the subcutaneous system will decrease the likelihood of lead malfunction, owing to the removal of the repetitive stress of the lead against the clavicle, or increase this likelihood, because the leads are now outside the thorax and vulnerable to damage from contact, is unknown.

Common sense suggestions for other at-risk cardiac populations have included the avoidance of excessive activity or extreme weather conditions (skiing all day or in a snowstorm) or extreme sports such as hang-gliding.110 These should apply to ICD patients as well. Further, given the high risk of syncope while swimming in open water, some physicians recommend that ICD patients should wear a life vest when swimming in open water.

The benefits of exercise are well-described, improving survival in healthy individuals111 and in patients with known coronary disease, as well.112 Inactive individuals are at increased risk of development of coronary artery disease,113 cardiac arrest,114 and death.111 Although some studies have shown frequent brisk walking to be as beneficial as more vigorous exercise,112 most show a graded effect of exertion.111,113 Thus, vigorous exertion and perhaps even sports should perhaps be encouraged for selected ICD patients.

For patients with a PM, the recommendation is avoidance of sports with danger of bodily collision; however, sports in which that danger is less may be practiced.91 However, recommendations from physicians vary widely, with a survey of the Pediatric and Congenital Electrophysiology Society (PACES),115 finding that, for a patient with an adequate escape rhythm, 18% of practitioners approved all sports. Level of contact, level of competition, and adequacy of escape rhythm had the largest influence on recommendations.

Conclusion
Although ICDs and PMs are life-saving, the impact of these therapies on many aspects of QOL can be substantial. More data are needed on how best to prevent appropriate and inappropriate shocks throughout the lifespan, on how best to mitigate the impact of recalls, and on defining activities that pose a true safety risk for device patients. To maximize patients’ autonomy, whenever possible, we must allow the patient to manage his or her device, rather than allowing the device to manage the patient.

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