Cardiovascular Perspective

Informed Consent in Cardiac Resynchronization Therapy

What Should Be Said?

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Cardiac resynchronization therapy (CRT) for the treatment of heart failure (HF) raises complex problems for informed consent. CRT with and without defibrillator backup has been demonstrated in clinical trials to improve symptoms from HF and decrease mortality. A CRT pacemaker (CRT-P) may improve symptoms and reduce mortality in selected patients, even without offering the specific protection from malignant arrhythmias afforded by a CRT defibrillator (CRT-D). Further, CRT-P may prevent disease progression even in earlier stages of HF.Implantable cardioverter-defibrillators (ICDs) alone are effective in preventing sudden cardiac death (SCD) in selected patients. Although most patients eligible for CRT-P will similarly meet guidelines for an ICD, the decision to include ICD backup with a CRT implant may not be straightforward.

The decision for CRT-P or CRT-D implantation includes not only the medical facts, but also the important considerations based on values and principles. Patients and physicians may wrestle with fundamental questions about quality and quantity of life and struggle to come together toward a truly informed consent process. There are no formal guidelines or standards that argue for specific content to be included in the informed consent process for CRT.

This article examines 4 categories of questions regarding CRT based on an understanding of autonomy and shared decision-making as elements of informed consent: (1) control over the manner of death, (2) quality versus quantity of life, (3) therapeutic flexibility, and (4) clinical uncertainty. This article may help to guide clinicians and patients by clarifying the clinical and moral considerations and the principles behind particular treatment decisions.

Autonomy and Shared Decision-Making

Autonomy refers to an understanding and knowledge of available options and the ability to choose between them through rational deliberation. Respect for patient autonomy is the foundation of modern bioethics and, in particular, the widely held consensus on the importance of informed consent. Autonomy as a concept describes the processes of self-definition and self-determination through which individuals develop a system of values and beliefs and make decisions that best accord with these views. It is a component of personhood itself and fundamental to the ethical basis of respect for individuals.

A closely related principle is that of shared decision-making, a model of the patient-physician relationship in which the clinician’s expertise helps to guide the patient toward a treatment course that best accords with the patient’s established values and beliefs. For decisions to be truly shared, both patients and physicians embrace their respective roles as autonomous parties and come to a reasonable conclusion together. Shared decision-making closely aligns with the doctrine of informed consent; both place a high priority on the explicit delineation of medical facts (risks, expected benefits, etc) as well as on the aspects of the decision-making process informed by values.

Decisions on invasive or life-altering therapies necessarily require more input from patients or their surrogates, and it is here where shared decision-making becomes crucial. CRT typically is not regarded as an end-of-life therapy, yet the population it serves retains a substantial mortality rate despite maximal treatment. These patients live along a spectrum of illness encompassing otherwise healthy individuals to dramatically sicker patients whose comorbidities might give them excellent reasons to decline specific interventions, such as dialysis or cardiopulmonary resuscitation. At the same time, the involvement of multiple physicians (internist, general cardiologist, HF specialist, electrophysiologist) further challenges the ideal of shared decision-making by diffusing knowledge and responsibility among different providers. Therefore, patient autonomy and shared decision-making, key elements of informed consent, may be particularly difficult to integrate into choices regarding CRT.

SCD Versus Progressive HF Death

CRT offers patients the opportunity to affect the probabilities of dying in a particular way. Although CRT-P alone may decrease SCD in selected patients, this therapy largely targets symptoms of HF such as congestion and functional limitation. CRT-D, in contrast, provides specific protection against SCD. Therefore, patients who elect for CRT-P alone

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have, in effect, have chosen not to reduce their chances of SCD as far as they might.

In choosing between these devices, there is little controversy at the extremes: CRT-D makes sense for otherwise healthy, relatively young patients who meet criteria for implantation, and CRT-P may be more appropriate for those too debilitated to be expected to benefit because of a shortened life expectancy. But the majority of patients with HF fall between these extremes; annual mortality ranges from <10% in New York Heart Association (NYHA) class I to as high as 75% for NYHA class IV. Importantly, although overall mortality increases with disease severity, the fraction of those deaths that are sudden decreases as progressive pump failure becomes more common (Figure 1). Thus, although a patient in NYHA class IV is more likely to experience SCD than a patient in NYHA class I, that same patient in NYHA class IV is more likely to experience progressive pump failure than SCD.

Physicians and patients are challenged to describe or imagine the experience of SCD or progressive death. There are sudden deaths that happen swiftly; others are painful, terrifying experiences for both the patients and their families. Sudden does not always mean instantaneous. Conversely, some pump failure deaths will be dramatic and swift, whereas others will be drawn out for days, weeks, or even months with variable control of symptoms. The perspective of the patient’s family further complicates matters. Depending on the way in which a patient dies (and the success of care at the end of life, however it occurs), the family will experience varying opportunities to say goodbye and to witness a loved one’s passing peacefully or with suffering. All of this merits inclusion in the discussion for patients to truly understand the consequences of choosing between advanced electric therapies.

Patients and clinicians together must weigh the patients’ preferences alongside the best estimate of the expected response to therapy. Patients considering CRT have the potential to exert significant control over the way in which they are most likely to die. A deliberate process of shared decision-making supports this powerful expression of autonomy and guides decisions regarding CRT toward the patient’s values and beliefs.

Quality Versus Quantity of Life

A related feature of CRT decision-making involves point-in-time decisions about quality of life and predictions about the way it will be affected by the chosen intervention. Patients with HF can and will express strong preferences about their own quality of life. For example, consider a 75-year-old man with NYHA class III HF and an ejection fraction of 25% who is referred for CRT implantation. In choosing to have any device implanted, the patient asserts that the risks of the procedure are outweighed by the benefits he expects to gain. For those who respond, CRT can improve symptoms and functional status significantly, with or without decreased rates of SCD. CRT-P may delay disease progression to more advanced congestive HF and, potentially, even improve enough to recharacterize the patient’s disease as NYHA class II or even, rarely, class I HF.

How does the choice between CRT-P and CRT-D factor into this assessment? Defibrillator backup clearly prolongs life in addition to benefits that may be provided by the CRT-P in well-selected patients. But adding an ICD can have both positive and negative effects on quality of life. There may be benefits from the added security against malignant arrhythmias, satisfaction from choosing the maximal therapy, and hope for a longer future in which to continue planning one’s life. Conversely, some patients may experience fear of impending or repeated shocks, and others may have similar fears of impending tachyarrhythmia and sudden death.

Adding ICD backup carries the obligation for future decision-making regarding continuation of this therapy, a responsibility that itself adds an unpredictable burden to one’s quality of life.

Thus, CRT-P and CRT-D each affect quality and quantity of life in different and subtle ways that all will affect the best choice for individual patients. Choosing CRT-P alone in essence favors quality rather than quantity of life, whereas CRT-D places more of an emphasis on longevity.

Therapeutic Flexibility

In CRT, shared decision-making faces additional challenges thanks to the flexibility of the devices themselves. Programmability to modulate biventricular pacing and backup defibrillation is a powerful feature that for many patients can lead
to increasingly difficult decisions about ongoing care. Increasingly, clinicians are recognizing the importance of including information about ethical and legal options for device deactivation as part of the informed consent process.23–25 A patient with CRT-D has the right to request deactivation of the ICD therapies of his or her device. Although the ICD functions may be easily deactivated, this raises additional complexities with an uncertain impact on patients’ quality of life.26,27 Thus, including a nuanced discussion of the option for device deactivation may make some patients more comfortable with accepting CRT-D. Importantly, though, others may find the therapeutic flexibility to be an additional burden and will favor CRT-P. Either reasoning may be sound for individual patients and should be carefully considered as part of the CRT implant decision.

Clinical Uncertainty
Predicting the effectiveness of CRT engenders a number of difficulties in deciding how best to use it. Consider a patient with NYHA class IV HF who elects to have a CRT-P implanted to help alleviate her severe symptoms but deems her overall quality of life to be poor enough (or fears of ICD shock strong enough) to decline defibrillator backup. After several months, however, she responds very well to CRT and considers herself to have a much better quality of life. As she improves clinically, her all-cause mortality may be reduced, yet he is optimistic enough about CRT to suppose that his life will improve past the threshold needed for him to favor a longer life, and therefore, he chooses CRT-D upfront. Is this a reasonable approach given the uncertainty in outcomes? Would the patient really turn off the defibrillator if he did not improve? When? How would this patient be counseled before device (of either type) implantation? These scenarios demonstrate the underlying complexity of HF and CRT and the challenge of helping patients to frame decisions in a way that best supports their values, goals, and beliefs.

Finally, although our discussion thus far has focused on CRT-P versus CRT-D decisions, the uncertainty regarding the benefits of CRT by itself may well lead a patient to elect only for an ICD. For example, a patient with NYHA class III congestive HF and a left ventricular ejection fraction of 25% with a right bundle branch block is less likely to benefit from CRT than the same patient with a left bundle branch block.28,29 Comorbidities, such as pulmonary hypertension, also attenuate the benefits of CRT.30 Given the higher risk of complications with CRT compared to ICDs28 and reasonable skepticism about the incremental benefits, a patient might reasonably elect for only SCD prevention without CRT.

What Actually Happens?
We have outlined the elements of an ideal informed consent discussion for CRT-eligible patients. Figure 2 summarizes the key features of this interaction and the ways in which it might influence patients toward one or the other therapy. Unfortunately, very little evidence describes whether these discussions include any of these critical points.27,31,32 Surveys of both patients and physicians have illustrated that informed consent for ICDs as currently practiced does not adequately address the possibility of deactivation.23,27,33 Despite evidence suggesting that more-thorough advance care planning can help patients to avoid shocks at the end of life.34 One series
of structured interviews in secondary-prevention ICD recipients with clinical HF found an achingly deficient informed consent process in which no patients considered themselves informed about alternatives or estimated risks with and without a device.35 Although models have been proposed to assist patients with complex decision-making,36 no specific model has been validated in patients receiving CRT. However, innovative approaches to improving the informed consent process for coronary interventions has demonstrated improved patient satisfaction and decreased anxiety at the pilot level; CRT offers a similar opportunity.37

It is troubling how little we understand about the best way to conduct informed consent for CRT We have proposed specific elements of discussion, but several other variables remain unexplored, such as where and when these conversations should take place, which providers should participate, and how to involve important family members. Although proposals have been made along these lines with respect to cardiac implantable electrical device deactivation,25 in the absence of any evidence-based approach, we recommend that future research focus first on the current nature of informed consent while eliciting patient and provider preferences for aspects of the discussion that require further characterization.

**Future Research**

We have necessarily speculated on the status of CRT discussions and proposed a more rigorous ideal because of the paucity of data describing the specific methods, content, and outcomes of informed consent discussions today. Several areas of research require exploration to fill these gaps, each an opportunity to characterize the state of affairs and provide avenues for improvement.

**Observational Studies**

Cohort studies are needed to describe the setting, content, and participants in CRT informed consent discussions as well as the perspectives of patients, providers, and families on the process as it currently exists and the ways in which it might be improved.35

**Risk Models**

Building on retrospective studies and substudies of clinical trials, a prospective, real-world cohort may help to develop more-precise risk models. These models would help to characterize more precisely the short- and long-term risks of therapy as well as help to better refine the expectations for benefits in selected patients.29,38

**Decision Support**

Providers and patients alike need more education regarding clinical evidence, expected benefits, and ethical and legal boundaries around decision-making for these devices.23,33,39—41 As noted previously, studies of patients undergoing percutaneous coronary intervention may provide a useful roadmap both for descriptive research and for developing tools to improve the process.37 At the same time, more work is needed to clarify the ways in which to integrate different specialists as well as family members into these discussions.

**Costs**

Although there are no specific data to draw on, we suspect that a small but important percentage of patients currently receiving CRT-D as a default option would instead, if better-informed, elect for CRT-P. Because these devices are substantially less expensive and have fewer complications, advancing this field as we propose should include analyses of cost savings realized through a more-thorough process of informed consent.

**Conclusions**

Clinical decision-making for patients and clinicians with respect to CRT includes important medical facts as well as more-nuanced considerations regarding the way in which patients with HF will live and die. Studies continue to argue for CRT implantation in broader HF populations; thus, these discussions will become increasingly common across a wide spectrum of disease states. Optimizing informed consent requires careful attention to these features of CRT. Physicians and patients may address this challenge with an approach to informed consent that emphasizes respect for patient autonomy and an ideal of shared decision-making. Specifically, clinicians and patients may use this framework to facilitate discussion of the manner of eventual death, quality and quantity of life, and the possibility of decisions being changed in the future as the clinical course evolves.

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