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Advance Health Planning and Treatment Preferences among Recipients of Implantable Cardioverter Defibrillators: An Exploratory Study

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BACKGROUND

Implantable cardioverter defibrillators (ICD) are devices designed to detect and treat lethal cardiac arrhythmias through electrical leads embedded into heart muscle. Cardiac electrophysiologists typically insert ICDs and these devices are placed using only local anesthesia. The use of ICDs is rapidly increasing in response to recent medical research that has demonstrated improved survival for patients with several common, but serious, cardiac conditions.[1] Despite this treatment, recipients of ICDs often have progressive noncardiac diseases in addition to their cardiovascular maladies, and mortality rates among these patients remain significant.[2] Some ill and debilitated ICD recipients may come to no longer value the additional survival provided by the ICD, and some patients may even determine that their ICD is a barrier to a timely death.[3] Near the end of life, a repeatedly discharging defibrillator may cause significant discomfort and thwart symptom palliation.[4] Moreover, sudden onset of ventricular tachycardia, the cardiac arrhythmia that ICDs are designed to treat, is a relatively painless manner of dying. The procedure for deactivating an ICD is simple and painless and involves placing a magnetic device over the area of the chest corresponding to the implanted defibrillator.[5]

Although physicians caring for patients with ICDs are likely to encounter situations in which deactivation of an ICD may be considered, the medical literature has been slow to address the ethical implications of this recently developed technology.[6] Professional organizations such as the American College of Cardiology and the American Heart Association offer guidelines for implanting ICDs, but not for deactivating already implanted defibrillators.[7] Furthermore, few physicians discuss disabling ICDs with recipients who are dy-

ing.[8] Little is known of patients' preferences for disabling their ICD. However, based on studies of patients' preferences for the use of other life-sustaining interventions, it is likely that many patients have concerns about limiting the use of ICDs under some circumstances.[9] Unfortunately, patients have little assistance in developing and documenting these preferences. Standard living will documents, used by only a minority of patients, do not yet anticipate decisions involving these devices.[10] Nevertheless, patients receiving ICDs should prepare for decision-making incapacity and consider using treatment directives to guide their surrogates regarding ICD use.[11]

There is little empirical study of ICD recipients' treatment preferences or of their use of advance directives. This exploratory study was designed to assess (1) whether recipients of ICDs have considered or developed preferences for non-use of the ICD at the time of its implantation and after living with the device, and (2) the prevalence of advance directives among ICD recipients and whether these advance directives address ICD use.

METHODS

The study was conducted in an out-patient cardiac electrophysiology (EP) office of a tertiary care hospital and was approved by its institutional review board. Subjects were limited to capacitated adults who had received an ICD one or more months prior to entry into the study. Persons with acute cardiologic conditions requiring urgent management or hospitalization were excluded.

A clinical staff member of the cardiology office secured permission from each prospective subject to receive information about the study. The researcher then provided prospective subjects with a verbal and written description of the study. Voluntary participation represented informed consent. Subjects completed a self-administered survey expressly developed for this study. The survey included open- and closed-end questions assessing subjects' understanding of the medical indications for the device, their health-related expectations for the device, their advance health planning both generally and with respect to the ICD, including any preferences for disabling the ICD. We refined and coded participants' subjective responses into categories.

TABLE1 Acronyms and definitions

EP	electrophysiology
ICD	implantable cardioverter defibrillator
n	number of subjects in a group
N	number of subjects in the study
NS	not significant
p	probability value
SD	standard deviation: one of several indices of variability that are used to characterize the dispersion among the measures in a given population
t-test	a test to determine whether the mean for a given group exceeds a certain standard; used in comparing the means of two different groups

RESULTS

Over a five-week period, all of the 59 eligible patients presenting to the EP office for medical follow-up of their ICD were approached regarding participation in the study, and 57 (97 percent) were enrolled and completed the study. Table 2 describes this population. These mostly White, largely Roman Catholic, and well-educated subjects had their devices implanted from one to 91 months prior to the study (mean 25 months, median 30 months). Subjects' self-assessed health status was poor for 5 percent, fair for 32 percent, good for 39 percent, and excellent for 21 percent; 55 subjects had good functional status, as evidenced by their ability to ambulate independently; two subjects were wheelchair-bound.

Subjects were asked to describe, to the best of their knowledge, the medical indication(s) for their ICD (see table 3). The 57 subjects offered 72 reasons, the vast majority of which were pertinent cardiac conditions or symptoms; two subjects indicated "physician recommendation" as the sole reason for receiving the device. We asked the subjects to describe the way in which they expected the ICD to affect their lives (see table 4). These responses centered on greater survival and increased quality of life.

Subjects were asked about their preferences for ICD deactivation: both currently held preferences and

preferences they may have had at the time the device was implanted. Of the 57 subjects, 53 did not recall formulating preferences for disabling their ICD at the time the device was implanted. Of the four subjects that had done so, two had wanted the device disabled only for improvements in their cardiac condition that caused the ICD to be no longer needed.

TABLE 2 Demographics (*N* = 57)

Age		
Characteristic	Mean	Median
Years (range = 40 - 86)	70	72
***n* and % of Subjects by Characteristic**		
Characteristic	*n*	%
Gender		
Female	10	17
Male	47	82
Ethnicity		
Non-Hispanic White	52	91
African-American	3	5
Hispanic	2	4
Religion		
Roman Catholic	38	67
Protestant	9	16
Jewish	9	16
No preference	1	2
Education		
Less than high school graduate	12	21
High school graduate	30	53
College graduate	15	26

TABLE 3 Subject-Described Reason for ICD Placement

Reason	%
Cardiac condition (nonspecific)	44
Arrhythmia	44
Nonspecific symptoms	14
Syncope	11
Physician recommendation	9
Congestive heart failure	5

Percentages add to >100% because the 57 subjects offered 72 reasons.

When asked about currently held preferences for ICD use, 36 subjects had not developed preferences. However, 21 (38 percent) subjects described situations or conditions for which they would want the ICD deactivated (see table 5); 10 of these 21 subjects wished to have the device deactivated for impaired quality of life, and three subjects did not want the ICD used in the event of terminal illness.

An advance directive document was completed by 35 (61 percent) of the subjects. Of these documents, 60 percent were living wills, 31 percent were healthcare proxy documents, and 9 percent were combined proxy-living will directives. Of the 35 advance directives, six (18 percent) were completed after the ICD was placed, and these documents were equally divided between living wills and proxy documents. No advance directive (executed either before or after the ICD was placed) addressed the use of an ICD.

Analysis of Variance (ANOVA) performed on the data revealed no relationship between subjects' anticipated ICD-related health benefits and their age, level of education, or self-reported health status. Paired *T*-tests revealed no relationship between self-reported health status and current preferences to dis-

TABLE 4 Subjects' Expectations of ICD-Derived Benefit

Expectation	%
Increased survival	45
Improved quality of life	42
Arrhythmia control	23
No particular effect or expectations*	11

* None of these subjects offered secondary expectations.

TABLE 5 Reasons for Disabling ICD in 21 Respondents

Reason	%
Impaired quality of life	48
Physician recommendation	19
Terminal illness	14
No benefit	10
Availability of better treatment/technology	10

able the ICD. A relationship between education level and completion of an advance directive approached significance ($p = 0.056$) on the *T*-test procedure.

As mentioned, none of the advance directives addressed the use of an ICD, yet 15 (44 percent) of 34 subjects who had completed an advance directive, when asked by the researchers, indicated preferences for disabling the ICD. In contrast, only six (27 percent) of 22 of the subjects who had no advance directive considered disablement. Of the six subjects who completed an advance directive after ICD insertion, four (80 percent) communicated their preferences regarding disablement of their ICD to the researchers, compared to only 11 (39 percent) of 28 subjects whose directive was written prior to ICD insertion (NS, $p = 0.152$). It is interesting that none of the five subjects whose reason for having an ICD was "physician recommendation" would consider disabling the device. However, this finding was not statistically significant ($p = 0.145$). None of the six subjects who had an ICD implanted for syncope had a preference for disabling the device, compared to 42 percent of subjects whose ICD was placed for other indications (NS, $p = .074$). That approximately two-thirds of women (67 percent), compared to one-third of the men (32 percent), indicated a preference to disable the ICD (trend towards significance at $p = .066$).

DISCUSSION

Approximately 4 million Americans currently meet medical criteria for the implantation of an ICD, and it is expected that at least 300,000 will join them each year.[12] Undoubtedly, the prevalence of ICDs among hospitalized patients, and the likelihood that physicians, patients, and families will confront ethical dilemmas involving ICDs will increase. Among our study population, a significant minority (38 percent) indicated a preference for limiting the use of the ICD under some specified circumstance. Yet none communicated this preference, despite the apparent sophistication of this group as evidenced by a high level of education, a high prevalence of advance directives, and a good grasp of the medical indications for the ICD. It is surprising that the subjects who had completed an advance directive after they received an ICD neglected to mention use of their ICD in their formal health planning. Another study similarly reports no association between having completed an advance directive and discussing end-of-life preferences for ICD deactivation among dying patients who had ICDs.[13] Similar inattention to advance planning is evident among users of chronic hemodialysis.[14] Perhaps these findings parallel the public's reticence to consider and plan for disability and death. Perhaps patients are simply unaware of the discomfort an ICD may impose, through repeated electrical shocks, on the process of dying, and are similarly unaware of the advantages of health planning. Perhaps patients and their physicians mirror each other's inattention to the implications of having an ICD in states of poor quality of life or approaching end of life. Certainly, there is little guidance regarding the ethical implications of ICDs available to physicians who are, of course, best situated to advise these patients.

Modifying advance directives to address ICD-related decision making may have little clinical impact, since advance directives generally have not been proven to be of great value to patients and clinicians.[15] This may reflect the need to reconceptualize advance health planning, rather than to discard it.[16] Regardless, some patients, surrogates, and physicians may find having clearly documented preferences for ICD use to be valuable. Provisions for commenting on ICDs can be easily incorporated into standardized living will, do-not-resuscitate forms, as well as into the informed consent process that precedes ICD placement. Patients whose directives indicate a preference to discontinue life-sustaining interventions should strongly consider a statement for deactivating the ICD in anticipation of inevitable fatal arrhythmias. Patients who wish to appoint an agent for healthcare should, of course, inform these proxies of their preferences for ICD use. Clinicians should routinely discuss the use of ICDs with patients when hospice services begin.

It is prudent for cardiac electrophysiologists and other cardiologists to ask these patients to consider parameters for ICD use at the time the device is implanted, or, if the patient is too ill, at some regular time intervals thereafter. Many patients prefer to discuss health planning when in the office, rather than during an illness requiring hospitalization.[17] These discussions, as well as discussions about limiting other treatments, are best embedded within conversations of broad health goals and general preferences for treatment. The

care of patients may be improved by understanding their care goals for the ICD. For example, a patient with a recurrent primary brain tumor is expected to live less than four months. The tumor has impaired her decision-making capacity. During these last months, the ICD may be viewed as obstructing a timely, arrhythmic death and enabling her to live only to die of the malignancy, or, alternatively, as supporting her remaining life, however it may be valued. Another patient, persistently vegetative, may have his life prolonged indefinitely by a functioning ICD. In each of these examples, the identification of the patient's treatment goals and preferences for ICD use could assist health professionals in providing the patient with optimally appropriate care.

Despite entering nearly all potential subjects into the study, this data is limited by the lack of diversity in subjects' gender, ethnicity, and religion. Although the ages of the participants were fairly well clustered around 70 years, the duration of ICD use ranged from one month to over seven years. Since subjects' initial preferences regarding ICD use were based on recollection rather than obtained contemporaneously, the large range of time since ICD placement may have affected these results. Certainly, a more accurate method for identifying the evolution of preferences would be an assessment of preferences contemporaneous with ICD insertion and again at a point in the future.

The number of subjects enrolled into the study limited the statistical power of our results. However, this exploratory investigation identifies themes worthy of further research. Although a majority of subjects (61 percent) had advance directives, none of these addressed ICD use. Additionally, most ICD recipients had not considered or developed preferences for limiting ICD use. These two findings suggest a greater role for informational counseling and health planning around the time of ICD placement. Our finding that 38 percent of subjects indicated some preference for ICD deactivation suggests that we can better serve our ICD recipients by actively assisting them in developing, communicating, and documenting these preferences.

Additional study is needed to determine whether patients want this assistance, whether they want these preferences documented, and whether they want their family members bound by these preferences in surrogate decisions. Further study is needed to better identify and specify conditions under which patients want these devices deactivated. An interesting finding to be confirmed and studied in future research is the fact that most of the ICD recipients who had completed an advance directive after receiving the device had formulated preferences for deactivation, yet none had communicated these preferences.

We note, incidentally, that women and members of minority groups appeared to be under-represented in our sample. This finding has been reported in other research on ICDs.[18] The question of whether ICDs represent yet another of several cardiac technologies associated with gender- or ethnicity-related disparity is one that should be investigated.

CONCLUSIONS

ICDs are another life-sustaining technology whose widespread use precedes careful thought about planning for treatment withdrawal. While our preliminary data should be confirmed by additional study, our investigation raises concerns that preferences of ICD recipients for limiting ICD use remain unidentified. Furthermore, typical treatment directives do not facilitate the recording of patients' preferences for ICD use. Physicians and other health professionals should assist recipients of ICDs in developing and communicating preferences for ICD deactivation.

NOTES

1. A.J. Coats, "MADIT II, the Multi-Center Autonomic Defibrillator Implantation Trial II Stopped Early for Mortality Reduction, Has ICD Therapy Earned its Evidence-Based Credentials?" *International Journal of Cardiology* 82, no. 1 (2002): 1-5; M.A. Hlatky, G.D. Sanders, and D.K. Owens, "Cost-Effectiveness of the Implantable Cardioverter Defibrillator," *Cardiac Electrophysiology Review* 7, no. 4 (2003): 479-82; J. Irvine et al., "Quality of Life in the Canadian Implantable Defibrillator Study," *American Heart Journal* 144, no. 2 (2002):

282-9; E. de Marchena et al., "Usefulness of the Automatic Implantable Cardioverter Defibrillator in Improving Survival of Patients with Severely Depressed Left Ventricular Function Associated with Coronary Artery Disease," *American Journal of Cardiology* 67, no. 9 (1991): 812-6; A.D. Mercando et al., "Survival of Patients with the Automatic Implantable Cardioverter Defibrillator," *Pacing and Clinical Electrophysiology* 11 (1988): 2059-63.

2. A.J. Moss et al., "Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction," *New England Journal of Medicine* 346 (2002): 877-83; S. Akshay et al., "Implantable Defib-rillators for the Prevention of Mortality in Patients with Nonischemic Cardiomyopathy: A Meta-Analysis of Randomized Controlled Trials," *Journal of the American Medical Association* 292 (2004): 2874-9; I. Javatilleke et al., "Long-Term Follow-Up of Implantable Cardioverter Defibrillator Therapy for Hypertrophic Cardiomyopathy," *American Journal of Cardiology* 93 (2004): 1192-4.

3. N.E. Goldstein et al., "Management of Implantable Cardioverter Defibrillators in End of Life Care," *Annals of Internal Medicine* 141 (2004): 835-8.

4. V. Nambisan and D. Chao, "Dying and Defibrillation: A Shocking Experience," *Palliative Medicine* 18 (2004): 482-3.

5. S.L. Wilbur and F.E. Marchlinski, "Implantable Cardioverter-Defibrillator Follow-Up: What Everyone Needs to Know," *Cardiology Review* 7, no. 4 (1999): 176-9.

6. P.S. Mueller, C.C. Hook, and D.L. Hayes, "Ethical Analysis of Withdrawal of Pacemaker or Implantable Cardioverter-Defibrillator Support at the End of Life," *Mayo Clinic Proceedings* 78, no. 8 (2003): 959-63.

7. G. Gregoratos et al., "ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: Executive Summary — A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation)," *Circulation* 97(1998): 1325-35; G. Gregoratos et al., "ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices — Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines)," *Journal of the American College of Cardiology* 40 (2002): 1703-19.

8. Goldstein et al., see note 3 above.

9. J.T. Berger and D. Majerovitz, "Stability of Preferences for Treatment among Nursing Home Residents," *Gerontologist* 38, no. 2 (1998): 217-23.

10. M. Danis et al., "A Prospective Study of Advance Directives for Life-Sustaining Care," *New England Journal of Medicine* 324, no. 13 (1991): 882-8; G.S. Fischer et al., "Patient Knowledge and Physician Predictions of Treatment Preferences after Discussion of Advance Directives," *Journal of General Internal Medicine* 13, no. 7 (1998): 447-54.

11. K.E. Covinsky et al., "Communication and Decision-Making in Seriously Ill Patients: Findings of the SUPPORT Project. The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments," *Journal of the American Geriatrics Society* 48, no. 5, suppl. (2000): S187-S93; D.P. Sulmasy, K. Haller, and P.B. Terry, "More Talk, Less Paper: Predicting the Accuracy of Substituted Judgments," *American Journal of Medicine 9*6, no. 5 (1994): 432-8.

12. *http://www.americanheart.org/presenter .jhtml?identifier=3007300,* accessed 9 November 2004.

13. Goldstein et al., see note 3 above.

14. J.L. Holley et al., "Failure of Advance Care Planning to Elicit Patients' Preferences for Withdrawal from Dialysis," *American Journal of Kidney Diseases* 33, no. 4 (1999): 688-93.

15. A Fagerlin and C. Schneider, "Enough: The Failure of the Living Will," *Hastings Center Report* 34, no. 2 (2004): 30-42.

16. J.T. Berger, "Ethical Challenges of Partial Do-Not-Resuscitate (DNR) Orders: Placing DNR Orders in the Context of a Life-Threatening Conditions Care Plan," *Archives of Internal Medicine* 163 (2003): 2270-5.

17. S.C. Johnston, M.P. Pfeifer, and R. McNutt, "The Discussion about Advance Directives. Patient and Physician Opinions Regarding When and How it Should be Conducted," *Archives of Internal Medicine* 155, no. 10 (1995): 1025-30.

18. Goldstein et al., see note 3 above.