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The Use of Advance Directives Among Patients With Implantable Cardioverter Defibrillators

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Abstract

Background—We aimed to determine the prevalence of advance directives (ADs) among patients with implantable cardioverter defibrillators (ICDs) and of ADs that addressed ICD management at the end of life.

Methods—The medical records of all patients who underwent ICD implantation during 2007 at a single institution were reviewed retrospectively to determine the number of patients with an AD and the number of ADs mentioning the ICD specifically (ie, ICD management at end of life).

Results—During 2007, 420 patients (males, 71%) underwent ICD implantation at our institution (mean age [range] at implantation, 63 [1–90] years). Primary prevention was the most common indication for device therapy (254 patients [61%]). Overall, 127 patients (30%) had an AD, with 83 ADs (65%) completed more than 12 months before ICD implantation and 10 (8%) completed after it. Several life-sustaining treatments were mentioned in the ADs: tube feeding, 46 (37%); cardiopulmonary resuscitation, 25 (20%); mechanical ventilation, 22 (17%); and hemodialysis, 9 (7%). Pain control was mentioned in 58 ADs (46%) and comfort measures in 38 (30%). However, only 2 ADs (2%) mentioned the ICD or its deactivation at end of life.

Conclusions—About one-third of patients with ICDs had an AD, but only a couple ADs mentioned the ICD. These results suggest that clinicians should not only encourage patients with ICDs to complete an AD, but also encourage them to address ICD management specifically. Not addressing ICD management in an AD may result in ethical dilemmas during end-of-life care.

Keywords

advance directives; end-of-life care; ethics; implantable defibrillators

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Author Contributions

All authors are responsible for concept and design of the project, as well as data analysis and interpretation. T.H.T. and A.L.O. drafted the manuscript, which was critically reviewed by D.L.H. and P.S.M. All authors have approved the submission of the present paper.

Introduction

Indications for implantable cardioverter defibrillators (ICDs) have increased substantially in recent decades and range from primary prevention of sudden cardiac death in asymptomatic patients with both ischemic and nonischemic left ventricular dysfunction to secondary prevention in survivors of cardiac arrest (1). As a result, hundreds of thousands of persons in the United States have these devices (2).

Nevertheless, patients with ICDs may have terminal noncardiac disease or progressive heart disease for which the ICD is no longer an effective therapy. As a result, it is likely that clinicians will care for increasing numbers of dying patients who have an ICD. Fearing that the ICD will unnecessarily prolong, or deliver uncomfortable shocks during, the dying process, some of these patients or their surrogate decision makers may request ICD deactivation (ie, reprogramming the device so that it no longer delivers therapies). Such decisions may be especially difficult when a patient is not capable of making a decision, has not prepared an advance directive (AD), or has an AD that does not address ICD management at end of life. In the present study, we determined the number of patients with an ICD who had an AD, in the form of either living will, durable power of attorney for healthcare, or health care proxy, and whether the AD addressed ICD management, thereby citing preferences for deactivation of the ICD at end of life.

Methods

This study was approved by the Mayo Clinic Institutional Review Board in accordance with federal regulations. Patients were identified who underwent ICD implantation at Mayo Clinic in Rochester, Minnesota, during 2007. The year 2007 was chosen to give several years' time for patients to complete an AD. There were no minimum or maximum age criteria used in the study, and incarcerated patients, or those without a research authorization, were not included. A retrospective chart review was performed and demographic data were abstracted from each patient's medical record; no patients were contacted. The patients who had an AD were identified. Data about the characteristics of each AD and its contents also were abstracted.

Statistical Analysis

Data pertaining to patient demographic characteristics, clinical characteristics, and death were summarized with descriptive statistics. Patients were summarized as an overall group and as 2 subgroups in accordance with the presence or absence of an AD. To test for an association with having an AD, the subgroups were compared using the χ^2 test or the Fisher exact test, as appropriate, for categorical variables or the 2-sample t test for continuous variables. All analyses were performed using JMP statistical software version 8 (SAS Institute Inc, Cary, North Carolina). A P value less than .05 was considered statistically significant.

Results

During 2007, 420 patients underwent ICD implantation at our institution. The demographic characteristics of these patients are shown in Table 1. The mean (SD) age of patients at ICD implantation was 63 (17) years. A majority of the patients (71%) were male, and most patients (92%) were white. About half of the patients (49%) lived outside of Minnesota.

Overall, 127 patients (30%) had an AD and 293 (70%) did not. Patients who had an AD were significantly older at ICD implantation than patients who did not have an AD (69 vs 60 years; $P<.001$). In addition, a higher proportion of patients with an AD were white than of

patients without an AD (97% vs 90%; $P<.02$). A higher proportion of patients with an AD lived in Olmsted County, Minnesota, than patients without an AD (14% vs 5%; $P=.004$). Patients who had an AD did not differ from patients who did not have AD regarding sex, marital status, smoking, alcohol use, education, and religion (Table 1).

Table 2 summarizes the significant clinical characteristics of the patients. A majority of patients had congestive heart failure (67%) and coronary artery disease (61%). Patients who had an AD were likely to have renal insufficiency (40% vs 26%; $P=.005$), chronic obstructive pulmonary disease ($P<.02$), cancer ($P=.02$), and dementia ($P=.03$) compared with patients who did not have an AD.

The indication for ICD implantation was primary prevention in 300 patients (72%) and secondary prevention in 119 patients (28%). Among patients who had an AD, the indication for ICD implantation was primary prevention in 97 patients (77%) and secondary prevention in 29 patients (23%), whereas among patients who did not have an AD, the indication for ICD implantation was primary prevention in 203 patients (69%) and secondary prevention in 90 patients (31%). These differences were not statistically significant ($P=.11$).

As of January 2010, 44 of the patients (11%) had died (Table 3). As noted in the medical record, the ICD was deactivated prior to death for 7 of these patients (16%). Patients with an AD were no more likely than those without an AD to have had their devices deactivated.

Of the 126 patients who had an AD, 83 ADs (65%) were completed more than 12 months before ICD implantation; 44 (35%), within 12 months before implantation; 39 (31%), within 6 months before implantation; and 10 (8%), after implantation. In addition, 110 patients (87%) designated surrogate decision makers in their AD; the most common surrogate was the spouse (Table 4).

Life-sustaining treatments (and directions related to them) were specifically mentioned in the ADs as follows: tube feeding, 46 ADs (37%); CPR, 25 (20%); mechanical ventilation, 22 (17%); and hemodialysis, 9 (7%). Pain control was mentioned in 58 ADs (46%) and comfort measures in 38 (30%) (Table 5). However, only 2 ADs (2%) mentioned the ICD or ICD deactivation at the patient's end of life; both of these ADs addressed other life-sustaining treatments, such as tube feeding, cardiopulmonary resuscitation, and mechanical ventilation. Of the 7 patients or surrogates who requested ICD deactivation, 2 patients had an available AD that was helpful in making the decision to withdraw ICD support. Illustrative examples of general statements are shown in the Box.

Box

Examples of Statements in the Advance Directives of Patients With Implantable Cardioverter Defibrillators Who Requested Deactivation at End of Life

My goals for health care:

"I do not wish to suffer pain. IF there is no reasonable hope of recovery, I wish to be kept comfortable without application of medical procedures or medications that prolong dying. I would like medical procedures or medications if they will significantly improve my quality of life during the dying process."

My fears about health care:

"Pain and suffering during the dying process and/or prolonged, drawn-out death."

My beliefs about when life would no longer be worth living:

“I wish to control my own destiny as long as I am not incapacitated. If I am terminally ill and have no reasonable hope of recovery or if I am permanently incapacitated and have no reasonable expectation of gaining capacity, I do not wish to have artificial mechanisms which artificially prolong my life.”

My thoughts about how my medical condition might affect my family:

“If you have to terminate life supports, think of this as preserving my dignity and not ending my life.”

I have these views about health care in these situations:

“If I had a reasonable chance of recovery, and were temporarily unable to decide or speak for myself, I would want: Medical care necessary to help recover. However, if I have no reasonable expectation that I will have a satisfactory quality of life in future as I have defined quality of life in my overall statement, I do not wish to be kept alive through artificial means.”

If I were dying and unable to decide or speak for myself, I would want:

“Medical procedures, medication, food and water that would keep me comfortable and alleviate pain. However, I do not wish to be kept alive through artificial means and I do not wish to be resuscitated if my heart stops.”

If I were permanently unconscious and unable to decide or speak for myself, I would want:

“Reasonable care, including food and water, but do not resuscitate me if something happens to me.”

This is how I feel about pain relief if it would alter my alertness or could shorten my life:

“I still would like pain relief even if it does shorten my life or reduce alertness if I am terminally ill. If I am not terminally ill, I wish to have pain relief even if it affects my alertness, but I wish to have only as much pain relief as is necessary for me to tolerate the pain if pain relief will significantly shorten my life.”

My goals for my health care:

“If no chance of recovery, do nothing.”

My fears about my health care:

“No prolong life in nursing home.”

My beliefs about when life would no longer be worth living:

“If I can’t make my own decisions.”

If I were dying and unable to decide or speak for myself, I would want:

“To die.”

If I were permanently unconscious and unable to decide or speak for myself, I would want:

“To die.”

If I were completely dependent on others for my care and unable to decide or speak for myself, I would want:

“To die.”

Discussion

Patients with an ICD may have noncardiac terminal illnesses or progressive heart disease for which the ICD is no longer an effective therapy. A dying patient who has an ICD may view the device as a barrier to a natural death and wish to avoid uncomfortable shocks during the dying process. Thus, the patient may request device deactivation (3). In general, it is ethical and legal for clinicians to carry out such requests in informed patients (4).

Such decisions, however, may be difficult for patients who lack decision-making capacity, do not have an AD, or have an AD that does not mention ICD management and results in ethical dilemmas (eg, uncertainty following a request for ICD deactivation) and undesired outcomes (eg, uncomfortable and unwanted ICD shocks during the dying process). Patients being considered for ICD implantation and those who already have an ICD should engage in advance care planning in which they identify their values, goals, and preferences about health care, identify prospective surrogate decision makers, communicate such decisions to their loved ones, as well as their physicians, and document the outcomes of this process in an AD (5).

Our study, which to our knowledge is the largest series of its kind, describes the prevalence of ADs among patients with an ICD and whether the ADs address ICD management, including at the end of life. Only 30% of patients in our study had an AD, and of those who had one, only 2 of the AD documents mentioned the ICD. These findings are consistent with those of previous studies, which showed that although 30% to 60% of patients with ICDs and pacemakers have an AD, very few of their ADs address device management or preferences for device deactivation at end of life (6,7).

We found that patients with an ICD who had an AD were older and more likely to have chronic diseases, such as renal insufficiency, chronic obstructive pulmonary disease, cancer, and dementia, than patients who did not have an AD. These findings could be due to a number of factors. Despite having an ICD (and the medical implications for having such a device), younger patients may feel less compelled to execute an AD than older patients. In contrast, patients with an ICD who have comorbid chronic diseases may feel more compelled to execute an AD (and their clinicians may be more likely to advise them to do so) than healthier patients. Nevertheless, whether the indication for ICD implantation is primary prevention or secondary prevention, patients who are being considered for or who have an ICD are at risk for, or already have, potentially life-threatening cardiac conditions. Such patients should be encouraged to engage in advance care planning and document their end-of-life values, goals, and preferences in an AD.

Of note, although only 2 of our patients specifically mentioned devices in their ADs, many patients had general statements regarding life- sustaining treatments. In addition, many patients mentioned in their AD life- sustaining treatments other than devices, including tube feeding for 46 patients (37%), cardiopulmonary resuscitation for 25 (20%), mechanical ventilation for 22 (17%), and hemodialysis for 9 (7%). In addition, pain control was mentioned in 58 ADs (46%) and other palliative care measures in 38 (30%).

These findings are important for several reasons. The findings indicate that many patients who have executed ADs have also thought about life-sustaining treatments and specifically mention these treatments in their ADs. In addition, clinicians may be able to infer end-of-life values, goals, and preferences of patients who lack decision-making capacity from general

statements in their AD, such as requesting that life-sustaining treatments be withheld or withdrawn if the patient is dying and has no chance of recovery, is terminally ill, or is permanently unconscious. Nevertheless, clinicians prefer treatment-specific statements in a patient's AD, especially if coupled with prior discussions with the patient (8). A patient's AD should be reviewed periodically and revised when appropriate. Ideally, these discussions and the completion of an AD should take place before ICD implantation and should be ongoing after implantation. In our study, most of the patients with an AD had completed it before ICD implantation. Ideally, the AD would have been updated on or around the time of implantation.

Of the 44 patients in our study who had died, 7 underwent ICD deactivation. Patients with an AD were no more likely than those without an AD to have had their device deactivated. Several reasons may account for this finding. First, we were unable to determine end-of-life ICD management for most (30) of the patients who died. Second, the number of patients in our study who died is likely too small to detect a difference. Third, the ADs of the patients who had died may not have had clinical impact. Additional data with details of all deaths would have been helpful to determine whether the lack of an AD actually made a difference in the quality of the patients' deaths.

In 2010, the Heart Rhythm Society released an expert consensus statement on the management of ICDs in patients requesting withdrawal of therapy on nearing the end of life (4). This statement outlines the ethical, legal, and religious principles that underlie the permissibility of withdrawing life-sustaining treatments, including device therapies, from patients who no longer want the treatments. The statement also provides guidance on the care of patients who have devices and are nearing the end of life (eg, logistics of device deactivation, role of palliative medicine specialists). Clinicians who care for patients with implantable cardiac devices should be familiar with this helpful document.

Our study has several limitations. The findings represent the experiences of patients during 1 year at a single institution and therefore may not be generalizable to other years or other institutions. A majority of our patients were white men; therefore, results may not be generalizable to women or other populations. Moreover, because the design of the study was retrospective, it did not involve contact with the patients or their loved ones. Finally, the number of patients in our study may have limited our ability to identify other significant differences between patients who had ADs and those who did not.

This experience has created an impetus for change in our institution's approach to patients who are being considered for ICD implantation. Efforts are under way to create a device-specific AD for patients to complete before device implantation. Future research could include contacting the patients who did not have ADs in order to more clearly identify the personal reasons that may have impacted their decision.

Conclusion

In our study, some patients with an ICD had an AD. Among those patients who did, only a couple cited the device in their ADs. Hence, these results suggest that clinicians should not only encourage patients with ICDs to complete an AD, but also encourage them to specifically address ICD management in their ADs. Not mentioning ICD management in an AD may lead to an ethical dilemma, such as uncertainty in following a request for ICD deactivation in a dying patient who lacks decision-making capacity, and undesired outcomes (eg, uncomfortable, unwanted ICD shocks during dying).

Abbreviations

AD	advance directive
ICD	implantable cardioverter defibrillator

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Table 1Patient Demographic Characteristics^a

Characteristic ^b	All Patients (n=240)	Subgroup		P Value
		AD (n=127)	No AD (n=293)	
Age at ICD implantation, mean (SD), years	63 (17)	69 (11)	61 (19)	<.001 ^c
Race/ethnicity ^e				<.02 ^d
White	386 (92)	123 (97)	264 (90)	
Other than white	33 (8)	4 (3)	29 (10)	
Residence ^f				0.004 ^d
Olmsted County, Minnesota	33 (8)	18 (14)	15 (5)	
Other county in Minnesota	173 (44)	47 (37)	136 (46)	
Outside of Minnesota (including outside of United States)	203 (49)	61 (48)	142 (49)	

Abbreviations: AD, advance directive; ICD, implantable cardioverter defibrillator.

^aPatients who had an AD did not differ from patients who did not have AD regarding sex, marital status, smoking, alcohol use, education, and religion.

^bValues are expressed as number and percentage of patients unless specified otherwise.

^cTwo-sample *t* test.

^d χ^2 test.

^eOne unknown value for race/ethnicity.

^fEleven unknown values for residence.

Table 2Patient Clinical Characteristics^{aa}

Characteristic ^a	All Patients (n=419) ^b	Subgroup		P Value
		AD (n=126)	No AD (n=293)	
Renal insufficiency				.005 ^c
Yes	126 (30)	50 (40)	76 (26)	
No	293 (70)	76 (60)	217 (74)	
COPD				<.02 ^c
Yes	77 (18)	32 (25)	45 (15)	
No	342 (82)	94 (75)	248 (85)	
Cancer				.02 ^c
Yes	90 (21)	36 (29)	54 (18)	
No	329 (79)	90 (71)	239 (82)	
Dementia				.03 ^d
Yes	5 (1)	4 (3)	1 (0.3)	
No	414 (99)	122 (97)	292 (99.7)	

Abbreviations: AD, advance directive; COPD, chronic obstructive pulmonary disease.

^{aa}Patients who had an AD did not differ from patients who did not have AD with regards to personal histories of the following: coronary artery disease, prior myocardial infarction, congestive heart failure, hemodialysis, TIA/stroke, depression, and feeding tube.

^aContinuous values are expressed as mean (SD); categorical values are expressed as number and percentage of patients.

^bClinical characteristic data unavailable for 1 patient.

^c χ^2 test.

^dFisher exact test.

Table 3**Death Among Patients**

Characteristic ^a	All Patients (n=419) ^b	Subgroup		P Value
		AD (n=126)	No AD (n=293)	
Status in 2010				<.10 ^c
Alive	375 (90)	108 (86)	267 (91)	Dead
	44 (11)	18 (14)	26 (9)	
Cause of death (descriptive only)				
Unknown	27 (61)	12 (67)	15 (58)	Heart
disease/failure	5 (11)	0 (0)	5 (19)	Arrest
	4 (9)	1 (6)	3 (12)	Sepsis
	3 (7)	3 (17)	0 (0)	
Cardiomyopathy	1 (2)	0 (0)	1 (4)	
Respiratory failure	2 (5)	2 (11)	0 (0)	Subdural
hematoma	1 (2)	0 (0)	1 (4)	Cerebral
infarct	1 (2)	0 (0)	1 (4)	
Was CPR done before death?				<.12 ^d
Yes	5 (11)	3 (17)	2 (8)	
No	12 (27)	2 (11)	10 (38)	
Unknown	27 (61)	13 (72)	14 (54)	
Was the ICD deactivated before death?				>.99 ^d
Yes	7 (16)	3 (17)	4 (15)	
No	7 (16)	2 (11)	5 (19)	
Unknown	30 (68)	13 (72)	17 (65)	

Abbreviations: AD, advance directive; CPR, cardiopulmonary resuscitation; ICD, implantable cardioverter defibrillator.

^a Continuous values are expressed as mean (SD); categorical values are expressed as number and percentage of patients.

^b Mortality data unavailable for 1 patient.

^c χ^2 test.

^d Fisher exact test.

Table 4

Characteristics of the 126 ADs Among Patients With an ICD

Characteristic	No. of ADs (%) ^a
Person who completed the AD	
Patient	84 (67)
Attorney	4 (3)
Other/Unknown	36 (29) No
Answer	2 (2)
Person who witnessed signature of the AD	
Notary	73 (58)
2 Witnesses	43 (34)
Other/Unknown	4 (3) No
Answer	6 (5)
Health care agent/surrogate	
Spouse	71 (56)
Child	13 (10)
Friend	1 (1)
Other/Unknown	25 (20)
No Answer	16 (13)
Alternate health care agent	
Spouse	0 (0)
Child	38 (30)
Friend	0 (0)
Other/Unknown	49 (39)
No Answer	39 (31)

Abbreviations: AD, advance directive; ICD, implantable cardioverter defibrillator.

^aThe total number of ADs among patients with an ICD was 127; however, the characteristics reviewed (eg, person who completed the AD) were not available in 1 patient's AD, rendering the total count to be less than 127 (n=126).

Table 5

Life-Sustaining Treatments Addressed in the 126 ADs

Characteristic ^a	Finding, No. of ADs (%) ^a		
	Yes	No	No Answer
ICD management	2 (2)	115 (91)	9 (7)
Cardiac resuscitation (CPR/ACLS)	25 (20)	90 (71)	11 (9)
Mechanical ventilation	22 (17)	93 (74)	11 (9)
Dialysis	9 (7)	105 (83)	12 (10)
Tube feeding/artificial nutrition	46 (37)	71 (56)	9 (7)
Organ donation	59 (47)	57 (45)	10 (8)
Anatomical gift	26 (21)	89 (71)	11 (9)
Autopsy	29 (23)	85 (67)	12 (10)
Burial/cremation	49 (39)	67 (53)	10 (8)

Abbreviations: ACLS, advanced cardiac life support; AD, advance directive; CPR, cardiopulmonary resuscitation; ICD, implantable cardioverter defibrillator.

^aThe total number of ADs among patients with an ICD is 127; however, the life-sustaining treatments addressed (eg, ICD management) were not available in 1 patient's AD, rendering the total count to be less than 127 (n=126).