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The Prevalence and Contents of Advance Directives in Patients With Pacemakers

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Abstract

Background—Little is known about the use of advance directives (ADs) in patients who have implantable cardiac pacemakers (PMs).

Methods—We conducted a retrospective review of the medical records of residents of Olmsted County, Minnesota, who underwent implantation of a cardiac PM at Mayo Clinic (Rochester, Minnesota) during 2006 and 2007 and determined the prevalence and contents of ADs in these patients.

Results—During the study period, 205 residents of Olmsted County (men, 53%) underwent PM implantation (mean age [SD] at implantation, 77 [15] years). Overall, 120 patients (59%) had ADs. Of these, 63 ADs (53%) were executed more than 12 months before and 33 (28%) were executed after PM implantation. Many patients specifically mentioned life-prolonging treatments in their ADs: cardiopulmonary resuscitation, 76 (63%); mechanical ventilation, 56 (47%); and hemodialysis, 31 (26%). Pain control was mentioned in 79 ADs (66%) and comfort measures were mentioned in 42 ADs (35%). Furthermore, the AD of many patients contained a general statement about end-of-life care (eg, no "heroic measures"). However, only 1 AD (1%) specifically addressed the end-of-life management of the PM.

Conclusions—More than half of the patients with PMs in our study had executed an AD, but only 1 patient specifically mentioned her PM in her AD. These results suggest that patients with PMs should be encouraged to execute ADs and, specifically address end-of-life device

Dario Pasalic: data analysis/interpretation, critical revision of article, approval of article, statistics, data collection.

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Authors' Contributions

Tanya H. Tajouri: data analysis/interpretation, drafting article, critical revision of article, approval of article, statistics, data collection. Abigale L. Ottenberg: data analysis/interpretation, drafting article, critical revision of article, approval of article, statistics, data collection.

Paul S. Mueller: concept/design, data analysis/interpretation, drafting article, critical revision of article, approval of article, statistics, data collection.

Keywords

management.

advance directives; end-of-life care; ethics; pacemakers

Introduction

In recent decades, the indications for pacemaker (PM) therapies have expanded. Nonetheless, symptomatic sinus node disease and atrioventricular block continue to be the most common indications for PM therapies (1). These indications often affect elderly persons, and as a result, several hundred thousand PMs are implanted into US patients annually (2). Currently, millions of people in the United States have PMs (3).

Because of the prevalence of patients with PMs, health care professionals who care for them will inevitably encounter patients who have terminal diseases for which the device no longer provides effective therapy (eg, end-stage heart failure) or is nonbeneficial (eg, cancer). Out of concern that the PM will interfere with a natural death, some of these patients or their surrogate decision makers may request PM deactivation—reprogramming the PM so that it does not deliver pacing therapies. Although it is ethically and legally permissible to carry out requests to withdraw PM support (4), the decision to do so can be difficult when a patient is decisionally incapable and the patient's end-of-life values and preferences, especially about PM management, are unknown.

An advance directive (AD) is a document in which a decisionally capable patient writes his or her values and preferences for health care in the event that he or she loses capacity for making decisions (5). Some ADs allow a patient not only to document health care values and preferences, but also to appoint a surrogate decision maker. Hence, an AD might be helpful in guiding the treatment of patients with a PM who are dying and decisionally incapable. However, little is known about the prevalence and contents of the ADs for patients with a PM. In this retrospective study, we identified residents of Olmsted County, Minnesota, who underwent PM implantation at Mayo Clinic in Rochester, Minnesota, during a 2-year period and ascertained how many of these patients had ADs and whether their ADs addressed end-of-life PM management.

Methods

The Mayo Clinic Institutional Review Board approved this study. The Division of Cardiovascular Diseases at Mayo Clinic in Minnesota prospectively maintains a list of all patients who undergo implantation of cardiovascular electronic implantable devices, including PMs, at our institution. From this list, adult residents of Olmsted County who underwent implantation of a cardiac PM at our institution during 2006 and 2007 were identified. These years were selected to allow up to 4 years for the patients to execute an AD after PM implantation. In 2010, a retrospective review of the medical records of the included patients was conducted. Demographic and clinical data were abstracted from the patients' medical records by a trained nurse abstractor. The nurse abstractor also identified patients whose ADs were incorporated into their medical records. (At each new outpatient visit and all hospitalizations at Mayo Clinic, patients are asked whether they have ADs and, if so, to submit their ADs for incorporation into their electronic medical records; if not, they are offered AD forms and assistance to complete the ADs.) If more than 1 AD was incorporated into a given patient's smedical record, the most recently executed AD—the legally active AD —was used for this study. Data from each AD were abstracted (eg, type of AD, surrogate,

comments regarding life-prolonging treatments). In accordance with Minnesota law (6), we excluded patients who did not authorize the use of their medical records for research purposes. Incarcerated patients were excluded. Because this study was a retrospective analysis of medical records, no patients were contacted.

Statistical Analysis

The statistical methods used in this study were similar to those used in a study involving patients with implantable cardioverter-defibrillators (ICDs) and conducted by our research team (7). Descriptive statistics were used to summarize the study patients' demographic, clinical, and death data. Overall group data were summarized, and data were also stratified into 2 subgroups according to the presence or absence of an AD in the medical record. Subgroup data were also summarized. To test for an association with having an AD in the medical record, the subgroups were compared using 2-sample *t* test for continuous variables and the Fisher exact test or the χ^2 test for categorical variables. JMP statistical software version 8 (SAS Institute Inc) was used to perform all analyses. A *P* value <.05 was deemed statistically significant.

Results

During 2006 and 2007, a total of 205 residents of Olmsted County underwent implantation of a cardiac PM at our institution. Indications for PM implantation were atrioventricular block (109 patients [53%]), sinus node dysfunction (76 patients [37%]), carotid sinus hypersensitivity (8 patients [4%]), diffuse conduction disease (8 patients [4%]), and syncope of unknown cause (4 patients [2%]). Seventy-two patients (35%) were PM dependent.

Demographic data are summarized in Table 1. The mean (SD) age of patients at the time of PM implantation was 77 (15) years. About half (53%) were men. Overall, 120 patients (59%) had ADs. Patients who had ADs were significantly older at PM implantation than patients who did not have ADs (82 vs 70 years; P<.001). A greater percentage of patients who had ADs were white than patients who did not have ADs (99% vs 91%; P=.003). Patients with ADs did not differ from patients without ADs concerning sex, relationship status, education, or religion or smoking or alcohol use (data not shown).

Clinical data are summarized in Table 2. Half of the study patients had coronary artery disease. Compared with patients who did not have ADs, those who had ADs were more likely to have a history of transient ischemic attack (15% vs 4%; P=.008), stroke (23% vs 11%; P<.02), hypertension (86% vs 74%; P=.04), cancer (58% vs 32%; P<.001), and dementia (23% vs 4%; P<.001). Of note, compared with patients who did not have ADs, those who had ADs were not more likely to be PM dependent or to have undergone their first device implantation.

Death data are summarized in Table 3. As of January 2010, 35 patients (17%) had died. Although more patients with ADs had died than patients without ADs, this difference was not significant (20% vs 13%; P=.19). No patient underwent PM deactivation before death.

Of the 120 patients who had ADs, 63 patients (53%) executed their ADs 12 months or more before PM implantation; 9 (8%) executed their ADs between 6 and 12 months before PM implantation; 9 (8%) executed their ADs 6 months or less before PM implantation; 6 (5%) executed their ADs the day of PM implantation; and 33 (28%) executed their ADs after PM implantation. Many patients identified surrogate decision makers in their ADs. Forty patients (33%) named their spouse, 38 (32%) named a child, 2 (2%) named a friend, and 23 (19%) named a person whose relationship to the patient was indeterminate. Seventeen patients (14%) did not identify a surrogate decision maker. Many patients also identified

alternate surrogates. Forty-eight (40%) patients named a child, 3 (3%) named a friend, and 31 (26%) named a person whose relationship to the patient was indeterminate. Thirty-eight patients (32%) did not identify an alternate surrogate.

The types of ADs executed by the study patients and the life-prolonging treatments specifically mentioned in their ADs are listed in Table 4. A majority (75%) of patients executed a "combined" AD—an AD with features of a power of attorney for health care and living will (5). Many patients mentioned life-sustaining treatments in their ADs, including cardiopulmonary resuscitation (63%), mechanical ventilation (47%), and hemodialysis (26%). Pain control was mentioned in two-thirds of the ADs and comfort measures in about one-third. Only 1 patient (1%) explicitly mentioned her PM in her AD. This patient, who was PM dependent, had a combined AD. In her AD, she specifically wrote "comfort care" as an end-of-life goal. She expressed that she did "not want to be hooked to machine to keep me alive by my pacemaker" [*sic*]. The patient also wrote that she wanted "to be kept comfortable, no artificial life support [and] allow for natural death."

Although only 1 patient mentioned her PM in her AD, many patients had general statements regarding their end-of-life values and preferences in their ADs. Examples of these statements are listed in the Box.

Box

Examples of General Statements Regarding End-of-Life Management in Advanced Directives of Patients With Pacemakers

- If I have been declared terminally ill, I do not want chemo, radiation, heart-lung machine, dialysis, or respirator to prolong life. I only want to be made as comfortable as possible until the natural end of life: ie pain pills, sleeping pills, back rubs, etc."
 I particularly do not want the following in any terminal circumstance: electric or mechanical resuscitation of my heart, nasal-gastric tube feeding when I am no longer able to swallow,
- resuscitation of my heart, nasal-gastric tube feeding when I am no longer able to swallow, uncomfortable diagnostic tests, mechanical respiration when my brain can no longer sustain my own breathing, blood or plasma transfusions."
- If there is no reasonable hope for my recovery, I direct that I be allowed to die naturally; no longterm mechanical ventilation...any treatment that will not help me recover and will only prolong the dying process, including tubes in the [trachea], stomach, colon..."
- ...do not tube feed if in a coma or persistent vegetative state, let me die naturally. I am not afraid of death; I do not want to be a burden to my family."
- I do not want any treatment if it will not help me recover and will only prolong the dying process... I do not want tube feeding or CPR or long-term mechanical respiration that is not necessary to provide comfort or relief from pain...I do not want any artificially administered sustenance, tube feeding in particular."
- I do not want extraordinary measures or other artificially life-sustaining procedures, such as
 mechanical respirators, intravenous feeding, and transfusions of blood; heart stimulation; and
 similar-like procedures if I have an incurable or terminal injury or illness from which there is no
 reasonable expectation of recovery. Similarly, if I am in a coma from which there is little or no
 chance of regaining consciousness, I do not want such procedures. I want no surgery, invasive
 measures, or tube feeding for a terminal condition."
- I wish not to be put on a ventilator if it is known that my condition is terminal ... no ventilator, no CPR, no blood transfusions."

Abbreviation: CPR, cardiopulmonary resuscitation.

Discussion

All patients with PMs eventually have terminal cardiac or noncardiac illnesses for which their devices are no longer effective or are nonbeneficial. Some dying patients with PMs, or their surrogate decision makers, may come to regard the devices as impediments to a natural

and peaceful death and, therefore, request PM deactivation. It is ethically and legally permissible for health care professionals to fulfill these requests, assuming patients—and, more likely, surrogate decision makers—are informed of the consequences of, and alternatives to, doing so (4). Nevertheless, decisions to carry out such requests may be challenging for decisionally incapable patients who do not have ADs or have ADs that do not mention the device or its management at the end of life.

We determined the prevalence of ADs among Olmsted County residents who underwent PM implantation during a 2-year period and the contents of their ADs—to our knowledge, the largest study of its kind. A majority (59%) of the patients had executed ADs. Yet, only 1 patient specifically mentioned her PM in her AD. These results are similar to the results of studies involving patients with other implantable cardiac devices—namely, ICDs and left ventricular assist devices—which showed that although 30% to 60% of these patients have ADs, only a few mention their device and its management at the end of life (7–9). Overall, cardiac device–specific advance care planning, which includes executing an A+D and documenting end-of-life values and preferences regarding device management at the end of life, appears uncommon among patients who undergo implantation of these devices.

To avoid ethical dilemmas and to respect a dying patient's wishes for end-of-life care, the Heart Rhythm Society recommends that patients who undergo cardiac device implantation engage in advance care planning, including executing ADs (4). The European Heart Rhythm Association has made similar recommendations (10). Such planning should occur early and often, before and after device implantation, and when patients' clinical circumstances have changed. Patients should address device management in their ADs and share their ADs with their potential surrogate decision makers and their clinicians. Doing so promotes respect for the patients' values and preferences and may prevent ethical conflicts if such patients lose decision-making capacity. Of note, electrophysiologists are not the only health care professionals who can engage patients with PMs in advance care planning. Other physicians and especially primary care physicians, nurses, social workers, and other professionals can engage patients in this process.

Although only 1 patient in our study specifically addressed PM management in her AD, many patients addressed other life-sustaining treatments, such as mechanical ventilation and hemodialysis. In addition, many addressed end-of-life issues, such as comfort measures and pain control. These results are similar to those of prior studies involving patients with ICDs (7) or left ventricular assist devices (9) and heart failure (11). These observations suggest that patients with PMs have thought about end-of-life issues and, if prompted, might address PM management in their ADs as they do other life-sustaining technologies. Nonetheless, in the absence of specific statements in ADs, clinicians might deduce decisionally incapable patients' values and preferences for end-of-life care from broad or general statements in ADs, such as withdrawing life-sustaining treatments if the patient is approaching death and there is little hope for recovery (see Box). However, evidence suggests that health care professionals prefer statements in patients' ADs that are treatment specific, especially in conjunction with prior discussions with the patients (12). These discussions and the execution of an AD optimally should occur before PM implantation. Nonetheless, although a majority of patients with ADs in our study executed their ADs before device implantation, nearly a third (28%) executed their ADs after device implantations. These findings emphasize the importance of reviewing a patient's AD not only at the time of device implantation, but also afterward and especially whenever a patient's clinical circumstances change.

The patients in our study with ADs were significantly older and were more likely to have chronic diseases (eg, prior stroke, dementia, cancer) than patients without ADs. Several

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factors might account for these findings. Despite the possible life-threatening reasons for having PMs, older patients may feel more compelled to execute ADs than younger patients. Similarly, patients who have PMs and have comorbid disease may feel more compelled to execute ADs than patients who have PMs and are otherwise healthy. Furthermore, health care professionals may be more inclined to recommend that their older and sicker patients execute ADs. Of note, patients who had ADs were not more likely to be PM dependent than patients who did not have ADs. Nonetheless, many patients who are being evaluated for PM implantation or already have a PM have cardiac conditions that should prompt advance care planning. Such patients should document their values and preferences for end-of-life care in their ADs, including preferences for device management and the names of surrogate decision makers. Patients should also communicate their values and preferences to their loved ones and health care professionals (4).

Of the 35 patients in our study who had died, none underwent PM deactivation. However, during 2008 to 2012, of 150 patients who underwent deactivation of their cardiovascular electronic implantable devices at our institution, 118 patients (79%) underwent deactivation of tachycardia therapies only and 6 patients (4%) who were PM dependent underwent deactivation of bradycardia therapies. All 6 of these latter patients were seriously or terminally ill, 5 lacked decision-making capacity, and none had executed ADs (13). Rather than viewing withdrawal of PM therapies as allowing a natural death (eg, due to the underlying heart disease [14]), some authors have expressed concern about whether withdrawing bradycardia therapies in PM-dependent patients is unethical (ie, whether such withdrawal is a form of assisted death) (15). Nonetheless, about three-quarters of clinicians who care for patients with implantable cardiac devices report having deactivated PMs and only one-tenth of them regard deactivating PMs as euthanasia (16). Furthermore, in our experience, patients or surrogate decision makers may view the PM as prolonging the dying process. To help guide clinicians in these situations, the Heart Rhythm Society sponsored the release of an expert consensus statement on the ethical and legal permissibility of withdrawing cardiovascular implantable electronic device therapies (including PM therapies) in patients who are nearing death or requesting withdrawal of such therapies (4). The statement also provides practical management tips regarding these patients, such as the role of palliative care clinicians. Clinicians who care for patients with a cardiovascular implantable electronic device should be familiar with this statement.

The present study has several limitations. First, the study population was limited to residents of a single county in Minnesota treated at a tertiary medical center and, hence, may not be generalizable to patients elsewhere. Second, it is possible that some patients in our study had executed ADs but did not submit them for inclusion in their medical records. However, we believe the number of such patients is low, given our institution is the only PM-implanting center in southeastern Minnesota and the only center that provides follow-up care for these patients. Also, our systematic approach to asking all patients at new outpatient visits and hospitalizations whether they have executed ADs minimizes the number of patients who have ADs that have not been incorporated into their medical records. Third, the study was retrospective and did not involve contact with patients, surrogate decision makers, or loved ones who might have added relevant data to the study. An important strength of our study is that its findings likely represent the experiences of nearly the entire population of Olmsted County that received PMs during 2006 and 2007, because Mayo Clinic is the only PM-implanting center in southeastern Minnesota.

Future research should focus on means of enhancing advance care planning in patients receiving life-prolonging technologies such as PMs. Research should also identify methods for identifying patients' health care–related preferences, avoiding unwanted therapies (including those delivered by devices), and palliating symptoms in dying patients who have

Conclusion

In this study, the largest of its kind, a majority of patients who had PMs had executed ADs. However, only 1 patient mentioned her PM in her AD. Health care professionals who care for patients with PMs should encourage these patients to execute ADs and to specifically mention their preferences for PM management at the end of life in their ADs. Lack of clarity regarding patients' preferences for end-of-life care, including device management, may result in ethical dilemmas, such as what to do in following requests for PM deactivation in decisionally incapable patients with PMs who are approaching death.

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Abbreviations

AD	advance directive
ICD	implantable cardioverter-defibrillator
PM	pacemaker

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Table 1

Patient Demographic Characteristics

	All D. C (N. 205)	Subgro	oup	
Characteristic ^{<i>a</i>}	All Patients (N=205)	With AD (n=120)	No AD (n=85)	P Value
Age at pacemaker implantation, mean (SD), y	77 (15)	82 (9)	70 (18)	<.001
Men	109 (53)	64 (53)	45 (53)	.96
Race				.003
White	196 (96)	119 (99)	77 (91)	
Other than white	9 (4)	1 (1)	8 (9)	

Abbreviation: AD, advance directive.

 a Values are expressed as number and percentage of patients unless specified otherwise.

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Table 2

Patient Clinical Characteristics

		Subgroup	dno	
Characteristic ^a	All Patients (N=205)	With AD (n=120)	No AD (n=85)	P Value
PM dependent				.55
Yes	72 (35)	40 (56)	32 (44)	
No	133 (65)	80 (60)	53 (40)	
Coronary attery disease				.29
Yes	103 (50)	64 (53)	39 (46)	
No	102 (50)	56 (47)	46 (54)	
Prior myocardial infarction				.16
Yes	43 (21)	28 (23)	15 (18)	
No	160 (78)	92 (77)	68 (80)	
Unknown	2 (1)	0 (0)	2 (2)	
Congestive heart failure				44.
Yes	91 (44)	56 (47)	35 (41)	
No	114 (56)	64 (53)	50 (59)	
Renal insufficiency and/or failure				.72
Yes	68 (33)	41 (34)	27 (32)	
No	137 (67)	79 (66)	58 (68)	
History of hemodialysis				.67
Yes	6 (3)	3 (3)	3 (4)	
No	199 (97)	117 (98)	82 (96)	
COPD				60.
Yes	35 (17)	25 (21)	10 (12)	
No	170 (83)	95 (79)	75 (88)	
TIA				.008
Yes	21 (10)	18 (15)	3 (4)	
No	184 (90)	102 (85)	82 (96)	
Stroke				.03
Yes	36 (18)	27 (23)	9 (11)	
No	169 (82)	93 (78)	76 (89)	

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		Subgroup	dn	
Characteristic ^a	All Fatients (N=205)	With AD (n=120)	No AD (n=85)	P Value
Hypertension			-	.04
Yes	166 (81)	103 (86)	63 (74)	
No	39 (19)	17 (14)	22 (26)	
Hyperlipidemia				.37
Yes	128 (62)	78 (65)	50 (60)	
No	77 (38)	42 (35)	35 (41)	
Diabetes mellitus				.58
Yes	49 (24)	27 (23)	22 (26)	
No	156 (76)	93 (78)	63 (74)	
Cancer				<.001
Yes	96 (47)	69 (58)	27 (32)	
No	109 (53)	51 (43)	58 (68)	
Depression				.34
Yes	68 (33)	43 (36)	25 (29)	
No	137 (67)	77 (64)	60 (71)	
Dementia				<.001
Yes	30 (15)	27 (23)	3 (4)	
No	175 (85)	93 (78)	82 (96)	
Sleep apnea				.93
Yes	50 (24)	29 (24)	21 (25)	
No	155 (76)	91 (76)	64 (75)	
Patient's first device				.15
Yes	143 (70)	(99) 62	64 (75)	
No	62 (30)	41 (34)	21 (25)	
Feeding tube				.48
Yes	7 (3)	5 (4)	2 (2)	
No	198 (97)	115 (96)	83 (98)	

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 $^{a}\mathrm{Values}$ are expressed as number and percentage of patients.

Table 3

Patient Death Characteristics

	All D- 4 (NI 205)	Sub	group	
Characteristic ^{<i>a</i>}	All Patients (N=205)	AD (n=120)	No AD (n=85)	P Value
Status in 2010				.19
Alive	170 (83)	96 (80)	74 (87)	
Dead	35 (17)	24 (20)	11 (13)	
CPR done before death				.03
Yes	1 (3)	0 (0)	1 (9)	
No	32 (91)	24 (100)	8 (73)	
Unknown	2 (6)	0 (0)	2 (18)	
Pacemaker deactivated before death				.02
Yes	0 (0)	0 (0)	0 (0)	
No	25 (71)	20 (83)	5 (45)	
Unknown	10 (29)	4 (17)	6 (55)	

Abbreviations: AD, advance directive; CPR, cardiopulmonary resuscitation.

 a Values are expressed as number and percentage of patients.

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Table 4

Type of AD and Life-Sustaining Treatments Addressed Within the 120 ADs

Characteristic	ADs, No. (%)
Type of AD	
Living will	0 (0)
Power of attorney	15 (13)
Combined (living will and power of attorney)	90 (75)
Miscellaneous	15 (13)
Pacemaker management	
Yes	1 (1)
No	100 (83)
No answer or does not apply	19 (16)
Cardiopulmonary resuscitation	
Yes	76 (63)
No	35 (29)
No answer or does not apply	9 (8)
Mechanical ventilation	
Yes	56 (47)
No	44 (37)
No answer or does not apply	20 (17)
Dialysis	
Yes	31 (26)
No	69 (58)
No answer or does not apply	20 (17)
Autopsy	
Yes	42 (35)
No	65 (54)
No answer or does not apply	13 (11)
Anatomical gift	
Yes	19 (16)
No	83 (69)
No answer or does not apply	18 (15)
Organ donation	
Yes	52 (43)
No	49 (41)
No answer or does not apply	19 (16)
Comfort measures	
Yes	42 (35)
No	58 (48)
No answer or does not apply	20 (17)
Pain control	
Yes	79 (66)

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Characteristic	ADs, No. (%)
No	22 (18)
No answer or does not apply	19 (16)

Abbreviation: AD, advance directive.