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Ethical and Legal Views Regarding Deactivation of Cardiac Implantable Electrical Devices in Patients With Hypertrophic Cardiomyopathy

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Abstract

Little is known about patients' views surrounding the ethical and legal aspects of managing pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) near the end of life. Patients with hypertrophic cardiomyopathy (HC) are at heightened risk of sudden cardiac death and are common recipients of such devices. Patients with HC recruited from the membership of the Hypertrophic Cardiomyopathy Association were surveyed about their clinical histories, advance care planning, legal knowledge, and ethical beliefs relating to the withdrawal of PM and ICD therapy. The mean age of the 546 patients was 49.1 years, 47% were women, and 57% had ICDs. Only 46% of the respondents had completed an advance directive, only 51% had a healthcare proxy, and cardiac implantable electrical devices (CIEDs) were commonly not addressed in either (92% and 58%, respectively). Many patients characterized deactivating PMs or ICDs as euthanasia or physician-assisted suicide (29% for PMs and 17% for ICDs), and >50% expressed uncertainty regarding the legality of device deactivation. Patients viewed deactivation of ICDs and PMs as morally different from other life-sustaining therapies such as mechanical ventilation and dialysis, and these views varied substantially according to the CIED type ($p < 0.0001$). The respondents expressed concerns regarding clinical conflicts related to religion, ethical and legal uncertainty, and informed consent. In conclusion, patients who have, or are eligible to receive, CIEDs might require improved advance care planning and education regarding the ethical and legal options for managing CIEDs at the end of life.

Despite the effectiveness of heart rhythm devices in treating dysrhythmias, clinical studies have demonstrated 5% to 20% annual mortality rates for device recipients, meaning that tens of thousands of deaths occur annually among these patients, including many with hypertrophic cardiomyopathy (HC).¹⁻⁴ Caring for patients with life-sustaining devices, including cardiac implantable electric devices (CIEDs), at the end of life raises legal and ethical challenges.⁵ For example, advance care planning might include the deactivation of CIEDs under various circumstances.⁵ Growing data have described the views of physicians

regarding aspects of CIED deactivation⁶⁻⁸; however, less has been published about patients' views, beliefs, and preferences regarding the deactivation of CIEDs.⁹ Patients might have ethical objections to deactivation or might not know the legal options available to them. Previous studies have described a reluctance to engage in discussions regarding the withdrawal of these therapies, which might be related to attitudes, knowledge, and misunderstandings surrounding end-of-life care generally.^{9,10} The degree to which patients with CIEDs have fulfilled advance directives that specifically address their devices has not been reported. To shed more light on patients' perspective on this increasingly important area of healthcare delivery, we surveyed a cohort of patients to identify their ethical beliefs and legal knowledge relating to end-of-life care and the withdrawal of PM and Implantable cardioverter-defibrillator (ICD) therapy.

Methods

All members of the Hypertrophic Cardiomyopathy Association were contacted by electronic mail for study participation. HC is a common inherited condition that can lead to CIED placement to reduce the risk of sudden cardiac death.^{11,12} The Hypertrophic Cardiomyopathy Association is a nonprofit education and advocacy organization that includes patients with HC, their families, clinicians, and other interested parties in its membership of approximately 5,000 persons (approximately 80% to 90% with HC) drawn from across the United States. The electronic mail contained an anonymous link to the survey instrument (no honorarium offered), which could be completed only by the participants with HC. The Beth Israel Deaconess Medical Center institutional review board approved the research.

The survey questions were developed with input from collaborators with ethics and legal expertise. The questions and definitions were pilot tested by a sample of volunteer subjects for comprehension before administration to the study population. This led to some minor adjustments for clarity.

The instrument was divided into 5 sections. First, we obtained basic demographic information, including age, gender, religious preferences, and education. Next, we asked respondents to describe relevant clinical characteristics, including a history of CIED implantation, CIED-related events such as shocks or complications, and medical events in the past year or ever, including hospitalizations, intensive care unit admissions, cardiopulmonary resuscitation, or administration of other life-sustaining device therapies, such as dialysis or mechanical ventilation.

Third, we asked respondents to describe the status of their advance care planning, including whether those with CIEDs had held formal discussions about the status of their PM/ICD with their physicians.

The fourth section assessed the respondents' legal knowledge and ethical views regarding aspects of withdrawal of care at the end of life. The respondents were provided with a set of standard definitions^{5,13,14} and queried about the legal status of euthanasia or physician-assisted suicide and how those terms applied to CIED deactivation. The definitions were as follows. *Euthanasia* is an act that intentionally causes the death of a patient who is very sick or suffering. An example of this would be a physician who administers a high dose of a medicine with the intention of causing cardiac arrest in a patient who is suffering greatly from a severe illness with no hope of recovery. *Physician-assisted suicide* is when a physician helps a patient take his or her own life, such as by intentionally providing a lethal dose of a pain medication with the knowledge that the patient might commit suicide. *Palliative care* is medical treatment that focuses primarily on the relief of symptoms and

suffering for patients with serious illnesses rather than “curing” those illnesses. *Pacemaker deactivation* means turning off a permanent PM, which will no longer recognize and treat slow heart rates. *ICD deactivation* means reprogramming a defibrillator (ICD) so that it will no longer recognize and treat dangerously fast heart rhythms. Patients are considered *pacemaker dependent* if they have no stable heart rhythm of their own and, therefore, require their PMs for every heartbeat.

The respondents were then asked whether they believed deactivation of a CIED was morally equivalent to turning off or stopping chest compressions, mechanical ventilation, dialysis, or feeding tubes. The respondents were then asked to classify whether the deactivation of an ICD or a PM in a PM-dependent patient should be considered euthanasia, physician-assisted suicide, or palliative care.

Finally, we presented hypothetical variables, such as the lack of a discussion of device deactivation during the informed consent process, and asked the respondents to rate on a 0- to 10-point Likert scale their level of concern regarding the influence of this potential complexity on decision-making. Scores of 8 were prespecified by the investigators to indicate a substantial expression of concern. The respondents were also asked whether they had directly observed a physician refuse to deactivate a device.

The statistical calculations were performed using Statistical Analysis Systems statistical software, version 9.2 (SAS Institute, Cary, North Carolina). Student's *t* tests and chi-square tests were used to compare the continuous and discrete outcomes, respectively. *p* Values <0.05 were considered statistically significant.

Results

Of the 1,009 HCA members who viewed the survey, 676 provided responses, of whom 546 were patients with HC. The demographic features of these respondents are listed in Table 1. The mean age was 49.7 years, and 47% of the patients were women. Most patients self-identified as white and had completed education beyond high school (*n* = 413, 76%).

ICDs were currently present in 311 patients (57%), 229 (42%) had never had a device, and 6 (1%) had previously had an ICD but did not currently have a device. Device-related events were relatively common among those who had received ICDs, including shocks (*n* = 94, 30%), recalls (*n* = 77, 25%), lead problems (*n* = 46, 15%), and generator problems (*n* = 21, 7%). Many had experienced life-threatening events or serious illnesses. A few patients (*n* = 36, 7%) had experienced sudden cardiac death, and 27 (5%) had received cardiopulmonary resuscitation. Intensive care unit hospitalizations had been experienced by 152 patients (28%), and 76 (14%) had previously required support with mechanical ventilation.

Only 255 of the respondents (46%) had completed an advance directive. Of the 198 patients with ICDs who completed an advance directive, only 15 (8%) of these had specifically mentioned their CIEDs. Similarly, only 278 of patients (51%) had a designated healthcare proxy. Of the 218 with CIEDs who had a healthcare proxy, only 91 (42%) had discussed their views regarding their CIEDs specifically with the designated persons. Those patients >50 years old were approximately twice as likely to have an advance directive (61% vs 30%, *p* <0.0001) or healthcare proxy (67% vs 33%, *p* <0.0001), although no more likely to have included a discussion of their CIEDs in either case. Patients with education beyond high school were also more likely to have completed an advanced directive (51% vs 33%, *p* = 0.0014) or to have a healthcare proxy (55% vs 39%, *p* = 0.007). No significant differences were seen in either advance directive or healthcare proxy designation according to gender or the presence of an ICD.

Widespread uncertainty was found regarding the legal status of CIED deactivation and end-of-life care generally. For PMs, 45 (8%) responded that, in general, it was not legal to withdraw therapy when a patient with decision-making capacity makes such a request; 183 (34%) responded that it was legal; and 316 (58%) were not sure. For ICDs, 33 (6%) responded that it was not, in general, legal to withdraw therapy at a patient's request; 201 (37%) responded that it was legal; and 305 (57%) were not sure. Many respondents were uncertain (n = 235, 43%) whether the degree of PM-dependence influenced the legality of PM deactivation (it does not). Similarly, >50% were uncertain whether a terminal illness must be present for either PM (n = 294, 54%) or ICD (n = 280, 52%) deactivation to be legal (it does not). Age, gender, the presence of a device, and education did not significantly influence these results.

Fewer than half (n = 227, 42%) correctly identified that euthanasia is illegal everywhere in the United States. A total of 159 patients (29%) thought that physician-assisted suicide was illegal everywhere in the United States, and only 134 (25%) correctly identified it as being legal in at least one state (it is legal in Montana, Washington state, and Oregon). Level of education did not markedly influence these results.

A substantial proportion of respondents characterized PM deactivation in a PM-dependent patient as physician-assisted suicide (n = 136, 25%) or euthanasia (n = 22, 4%); many (n = 224, 42%) were not certain. Respondents less frequently characterized ICD deactivation as euthanasia (n = 15, 3%) or physician-assisted suicide (n = 77, 14%), although nearly half (n = 244, 45%) were uncertain. Patients viewed the moral similarity of CIED withdrawal to cessation of other therapies differently for ICDs, PMs, and PMs in dependent patients (Figure 1). More than half of the patients viewed ICD deactivation as morally different from stopping cardiopulmonary resuscitation, mechanical ventilation, renal dialysis, or feeding tubes. PM deactivation in a PM-dependent patient was viewed as morally different from cardiopulmonary resuscitation (n = 160, 31%), mechanical ventilation (n = 122, 24%), and renal dialysis (n = 147, 29%). For non-PM-dependent respondents, however, >75% viewed PM deactivation as morally different from the other 3 examples of care withdrawal. For all 4 therapies, the difference in response according to CIED type was statistically significant (Figure 1; $p < 0.0001$ for each comparison).

The respondents expressed important concerns regarding the potential for clinical conflicts in CIED deactivation related to religion, ethical and legal uncertainty, and informed consent (Figure 2). Although the patients identified physician refusal to deactivate a CIED as potentially concerning, only 13 respondents (2.5%) reported having directly observed such a circumstance.

Discussion

The results from the present survey of patients with, or potentially eligible for, CIEDs adds to the current understanding of patients' perspectives on the ethical and legal aspects of device deactivation. We identified important gaps in advanced care planning and shortcomings in patients' legal knowledge regarding an increasingly common life-sustaining device, and identified central ethical objections and other points of conflict regarding withdrawal of therapy.

Despite having been diagnosed with a condition with an increased risk of dangerous arrhythmias, only approximately half of patients had completed advance directives or selected a healthcare proxy. When these components of advanced care planning were completed, CIEDs were rarely included in either. Even this highly-educated cohort expressed substantial uncertainty and confusion about the legal status of CIED deactivation,

and more than half could not identify whether variables such as the presence of a terminal illness were required for a device to be deactivated. In the United States, neither PM-dependence nor a patient's prognosis influence the legality of device deactivation.^{5,14,15} Most patients viewed CIED deactivation as morally distinct from cessation of other therapies such as mechanical ventilation, a finding perhaps related to the frequent characterization of CIED deactivation as either euthanasia or physician-assisted suicide, and the important concerns identified regarding delivery of care at the end of life.

These findings support recent statements from the Heart Rhythm Society⁵ and the European Heart Rhythm Society,¹⁶ both which have called for better advance care planning and improved patient education. It is hoped that more proactive communication will allow the millions of patients with CIEDs to express their wishes more clearly regarding their treatment during times of illness. Also, the care of patients with CIEDs is often shared by several specialists, with no single physician clearly responsible for the combination of education and planning clearly lacking in our patient sample. Addressing these shortcomings, therefore, will require a critical assessment of this model of care and its ability to successfully meet the needs of patients with complex devices. In our sample, patients aged >50 years and those with education beyond high school were twice as likely to have engaged in advance care planning, suggesting that younger patients at risk of sudden cardiac death and those without higher education should be targeted specifically by outreach efforts.

Additionally, understanding in more depth the reasons for the perceived moral differences between life-sustaining therapies might facilitate open communication between patients and providers. The differences between the Heart Rhythm Society and European Heart Rhythm Association consensus statements highlight this challenge—the European Heart Rhythm Association document notes but does not refuse the distinctions between CIEDs and other life-sustaining therapies, and gives much less attention to PM deactivation than ICD deactivation. Additionally, both documents (the European Heart Rhythm Association statement in particular) focus largely on terminally ill patients, although many patients (such as those with HC) might very reasonably decide to turn off an ICD even without a terminal illness. Regardless, our results have confirmed that patients might not be aware of, or in agreement with, the ethical and legal options outlined by these guidelines.

Our study had several limitations. The subjects included were drawn from one of many populations who might receive CIEDs; thus, the applicability of our data to other demographic groups or patients with congestive heart failure, infarct-related cardiomyopathy, or other genetic syndromes is not known. The HC population is younger than the broader population living with CIEDs and, thus might be less likely to consider advance directives. However, our population represents a self-selected and socially active group who might be expected to have a greater awareness of the issues raised in our survey; we expect that the knowledge would be even less robust in the broader community of CIED-eligible patients. Despite the anonymous nature of the survey, a potential existed for a socially desirable response bias, with patients reporting a greater degrees of advance care planning than was actually the case. However, this would have tended to strengthen our observation that such planning is uncommon and inadequately inclusive of CIEDs specifically.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

The percentage of patients who viewed withdrawal of PM in a PM-dependent patient (red-hatched bars), ICD therapy (blue-solid bars), or PM in a non-PM-dependent patient (green-dotted bars) or therapy to be morally different compared to withdrawal of each additional therapy is shown. For example, nearly 80% of patients believed deactivation of a PM in a nondependent patient was morally different from ceasing cardiopulmonary resuscitation or withdrawing mechanical ventilation.

Figure 2.
The percentages of patients who rated their level of concern as 8 on a 0 to 10 scale regarding the influence of each variable on deactivation of a CIED shown.

Table 1

Patient characteristics (n = 546)

Variable	Value
Demographics	
Men	287 (53%)
Mean age $\pm$ SD (years)	49.7 $\pm$ 13.2
White	505 (92.5%)
Education beyond high school	413 (76%)
Clinical history	
Implantable cardioverter-defibrillator	311 (57%)
Shocks	94 (30%)
Sudden death	27 (5%)
Intensive care unit admission	152 (28%)
Mechanical ventilation	76 (14%)