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Features and Outcomes of Patients Who Underwent Cardiac Device Deactivation

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Abstract

IMPORTANCE—Little is known about patients who undergo cardiovascular implantable electronic device deactivation.

OBJECTIVE—To describe features and outcomes of patients who underwent cardiovascular implantable electronic device deactivation.

DESIGN, SETTING, AND PARTICIPANTS—Retrospective review of medical records of 150 patients at a tertiary academic medical center (Mayo Clinic, Rochester, Minnesota).

EXPOSURE—Cardiovascular implantable electronic device deactivation.

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MAIN OUTCOMES AND MEASURES—Demographic and clinical data and information regarding advance directives, ethics consultations, palliative medicine consultations, and cardiovascular implantable electronic device deactivations.

RESULTS—Of the 150 patients (median age, 79 years; 67% were male), 149 (99%) had poor or terminal prognoses. Overall, 118 patients (79%) underwent deactivation of tachycardia therapies only, and 32 (21%) underwent deactivation of bradycardia therapies with or without tachycardia therapies (6 patients [4%] were pacemaker-dependent). Half of the deactivation requests (51%) were made by surrogates. A majority of deactivations (55%) were carried out by nurses. Although 85 patients (57%) had advance directives, only 1 mentioned the device in the directive. Ethics consultations occurred in 3 patients (2%) and palliative medicine consultations in 64 (43%). The proportions of patients who died within 1 month of device deactivation were similar for those who underwent deactivation of tachycardia therapies only and those who underwent deactivation of bradycardia therapies with or without tachycardia therapies (85% vs 94%; $P = .37$).

CONCLUSIONS AND RELEVANCE—Most requests for cardiovascular implantable electronic device deactivation were for implantable cardioverter-defibrillator–delivered tachycardia therapies only. Many of these requests were made by surrogates. Advance directives executed by patients with these devices rarely addressed device management. Regardless of device therapy, most patients died shortly after device deactivation. Hence, a device deactivation decision may reflect the seriousness of a given patient's underlying illness. Patients with devices should engage in advance care planning to ensure that future care is consistent with their preferences.

Because of an aging society and increasing indications, hundreds of thousands of US patients currently have cardiovascular implantable electronic devices (CIEDs) such as implantable cardioverter-defibrillators (ICDs) and pacemakers (PMs).¹⁻⁴ However, these patients may have subsequent cardiac or noncardiac illnesses for which their devices are no longer beneficial or are perceived as impediments to natural death (eg, shocks from ICDs, perceived prolongation of the dying process because of ongoing pacing). Consequently, some of these patients or their surrogate decision makers request device deactivation (ie, reprogramming the device so that it no longer delivers therapies). A recent Heart Rhythm Society (HRS) consensus statement affirmed the ethical and legal permissibility of CIED deactivation in seriously ill patients who no longer desire CIED therapies.⁵

Prior research has shown that most clinicians who care for dying patients with CIEDs regard device deactivation as allowing natural death rather than actively hastening death. Furthermore, most of these clinicians have themselves deactivated ICDs and PMs.⁶⁻¹¹ Some, however, object to deactivating bradycardia therapies (which can be delivered by both ICDs and PMs) in “PM-dependent” patients (ie, those with “inadequate or even absent intrinsic rhythm”¹²) because doing so might precipitate symptoms of heart failure or rapid death.^{5,13-15}

Nevertheless, little is known about the patients or their surrogates who request CIED deactivations, the individuals who deactivate the devices after such requests, patient outcomes after device deactivation, and the involvement of ethics and palliative medicine consultants. In this study, we describe the features and outcomes of 150 consecutive patients who underwent CIED deactivations at our institution. In addition, the presence or absence of

advance directives (ADs) in patients' medical records and the use of ethics and palliative medicine consultations in these patients are described.

Methods

This study was approved by the Mayo Clinic Institutional Review Board. No patients received a stipend for participating in this study. We retrospectively reviewed medical records of patients with CIEDs referred to the Division of Cardiovascular Diseases Heart Rhythm Service at our institution (Mayo Clinic [Rochester, Minnesota]) for device deactivation from November 1, 2008, through September 1, 2012. In general, such referrals are made by health care teams after receiving a request for CIED deactivation by patients or their surrogates. The CIED deactivations are carried out by nurses or physicians from our Heart Rhythm Service for hospitalized patients and by industry-employed allied professionals (IEAPs) for patients outside the hospital (eg, hospice settings). Nonhospital deactivations are reported to our Heart Rhythm Service.

We applied no age criteria and excluded patients who did not authorize use of their medical records for research purposes, in accordance with Minnesota law.¹⁶ We also excluded incarcerated patients. Demographic and clinical data were abstracted from the medical records. Because this was a retrospective review of medical records, no patients were contacted. At our institution, and for the purposes of this study, PM dependency was defined as the absence of an intrinsic heart rhythm of 30 beats per minute during back-up pacing and after switching off the CIED's pacing function. Race data were abstracted from the medical records. (At our institution, patients are asked to self-identify their race at the time of registration.) We assessed this factor because end-of-life decision making can differ according to race.¹⁷

Data were summarized with descriptive statistics. Data included patient demographics, device type, use of ethics or palliative care consultation, and outcome after CIED deactivation. In addition, if a patient's AD (eg, living will, durable health care power of attorney) was available, the document was analyzed for content.

The decision to deactivate bradycardia therapies in a patient with an ICD is similar to the decision to deactivate bradycardia therapies in a patient with a PM. Thus, patients with ICDs who underwent deactivation of bradycardia therapies (usually also with deactivation of tachycardia therapies) and patients with PMs who underwent deactivation of bradycardia therapies were combined into 1 group for comparison with patients with ICDs who underwent deactivation of tachycardia therapies only. Subgroups were compared using the χ^2 test or the Fisher exact test for categorical variables or the Kruskal-Wallis test for continuous variables. Kaplan-Meier methods were used to estimate and compare survival rates between subgroups. All analyses were performed using JMP statistical software version 9 (SAS Institute Inc). $P < .05$ was considered statistically significant.

Results

During the study period, 159 requests were made for CIED deactivation. Requests were not carried out in 9 patients. In 2 patients, requests were not carried out because of clinician

refusal. Both patients had PMs and were PM dependent. In one case, the clinician requested that an ethics consultation be done before deactivating the PM. The patient died before the consultation could take place. In the second case, the patient died before an alternate electrophysiologist could be involved in the patient's care. The remaining device deactivation requests were not carried out because of change in plan of care (1 patient), the request was retracted (1 patient), and patient death before deactivation could be carried out (5 patients). The remaining 150 patients underwent CIED deactivation, and their medical records comprised the data set for this study.

Patient characteristics are shown in Table 1. Overall, 101 patients (67%) were male. The median age at the time of deactivation was 79 years (range, 31-95 years). A total of 149 patients (99%) had poor or terminal prognoses. (The 1 patient with a good prognosis had Ebstein anomaly and an ICD and requested deactivation of tachycardia therapies only to avoid shocks.) At the time of data analysis, 146 patients (97%) had died. Causes of death included cardiovascular disease (71 patients), neurologic disease (19), malignant neoplasm (18), multiorgan system failure (13), respiratory disease (10), and other causes (15). Regarding CIED type, 135 patients had ICDs (90%), and 15 had PMs (10%).

Of the 135 patients in the study with ICDs, 118 patients (87%) underwent deactivation of tachycardia therapies only, and 17 (13%) underwent deactivation of bradycardia therapies with or without tachycardia therapies. Of the 17 patients with ICDs who underwent deactivation of tachycardia and bradycardia therapies, 3 patients (18%) were PM dependent. Of the 15 patients in the study with PMs, 3 (20%) were PM dependent. Overall, of the 150 patients in the study who underwent CIED deactivations, 118 patients (79%) underwent deactivation of tachycardia therapies only and 32 (21%) underwent deactivation of bradycardia therapies with or without tachycardia therapies. Only 6 patients (4%) were PM dependent. Ten patients (7%) who underwent CIED deactivation also had ventricular assist devices. Of these, 8 underwent ventricular assist device deactivation at the same time as CIED deactivation.

Requests for CIED deactivations were made by 74 patients (49%) and 76 surrogate decision makers (51%). Requesters differed significantly according to the therapies deactivated: for tachycardia therapies only, 54% of requests were from patients, whereas for bradycardia therapies, 31% of requests were from patients ($P = .02$).

Deactivations were carried out by nurses in 82 patients (55%), by physicians in 46 (31%), and by IEAPs (ie, field sales representatives) in 22 (15%). Notably, IEAPs are not allowed to deactivate CIEDs at our institution (but are allowed to do so in nearby nursing homes, etc). In addition, during the study period, CIED manufacturers did not allow their IEAPs to deactivate PMs in PM-dependent patients. At our institution, a policy was implemented in which only physicians were allowed to carry out PM deactivations in PM-dependent patients. As a result, for 5 of the 6 PM-dependent patients, physicians carried out the deactivations. (It is unclear why 1 PM was deactivated by a nonphysician in a PM-dependent patient, although the physician's involvement is clear from the medical record review.)

Eighty-five patients (57%) had ADs in their medical records; of these, 41 (48%) executed ADs before CIED implantation. Only 1 patient, however, specifically mentioned a CIED in the AD; he was a 79-year-old man with ischemic cardiomyopathy who had an ICD for ventricular tachycardia. The patient's AD (based on wording from Nebraska's statute relating to use of life-sustaining treatment¹⁸) indicated "If I should lapse into a persistent vegetative state or have an incurable and irreversible condition that without the administration of life-sustaining treatment, will, in the opinion of my attending physician, cause my death within a relatively short time, and I am no longer able to make decisions regarding my medical treatment, I direct my attending physician...to withhold or withdraw life-sustaining treatment, including the implantable cardiac defibrillator..." He executed his AD 4 months after receiving his ICD. About 10 years later, when the patient developed end-stage heart failure, he requested CIED deactivation. He underwent deactivation of tachycardia therapies only and died 2 days later.

Ethics consultations were provided only for 3 patients (2%). One consultation addressed intrafamily conflict surrounding a decisionally capable 57-year-old woman with an ICD, who requested withdrawal of all life-prolonging treatments (including ICD deactivation). The second consultation involved a 58-year-old woman with an ICD and a ventricular assist device who vacillated over whether to continue or withdraw life-prolonging treatments (eg, CIED and ventricular assist device therapies) and whether to initiate others (eg, feeding tube). The third consultation involved a decisionally incapable 76-year-old man with an ICD and a ventricular assist device whose surrogate was not clearly acting in accordance with the patient's values and preferences.

Palliative medicine consultations were provided for 64 patients (43%). Of these, CIED management was specifically addressed by the palliative medicine consultation in 44 patients (69%). The occurrence of palliative medicine consultations did not differ between patients who underwent deactivation of tachycardia therapies only vs those who underwent deactivation of bradycardia therapies with or without tachycardia therapies. Likewise, the occurrence of palliative medicine consultation did not differ between patients who did or did not have ADs. Patients who executed ADs before CIED implantation, however, were significantly less likely to undergo palliative medicine consultation than patients who executed ADs after CIED implantation (24% vs 64%; $P < .001$). Palliative medicine consultations occurred significantly more frequently in patients who requested CIED deactivation requests themselves (ie, had decision-making capacity) than patients whose surrogated decision makers made the requests (54% vs 32%; $P = .008$).

At the time of data analysis, 146 patients (97%) had died after CIED device deactivation. The outcomes of these patients are shown in Table 2. The median survival of patients who underwent deactivation of tachycardia therapies only was significantly longer than the survival of patients after deactivation of bradycardia therapies with or without tachycardia therapies (3 vs 0 days; $P < .001$). The proportions of patients in each group who died within 1 month following deactivation, however, were similar (85% vs 94%; $P = .37$). All 4 patients (3%) who were alive after CIED deactivation had ICDs and underwent deactivation of tachycardia therapies only. These surviving patients were confirmed alive after ICD deactivation (3, 288, 414, and 461 days, respectively).

Discussion

Because hundreds of thousands of people in the United States have CIEDs, clinicians inevitably will encounter seriously ill patients with these devices who request device deactivation. The current study describes the features and outcomes of 150 consecutive patients with CIEDs who underwent device deactivation during a 46-month period at our institution (about 3 deactivations per month).

Nearly all patients in our study (99%) had poor or terminal prognoses. A majority (79%) underwent deactivation of tachycardia therapies only. This finding suggests that most patients or surrogates who request CIED deactivation are those who want to avoid shocks during the dying process. Of the 32 patients (21%) who underwent deactivation of bradycardia therapies, only 6 (4%) were PM dependent. This finding is relevant because concerns have been expressed about whether deactivating bradycardia therapies in PM-dependent patients is unethical (ie, whether it is a form of assisted death).¹⁹ First, our results suggest that this practice is relatively uncommon. Second, clinicians should acknowledge the supporting ethical arguments and the legal permissibility of deactivating bradycardia therapies in seriously ill, PM-dependent patients when the therapies are perceived as interfering with a natural dying process. At the same time, a clinician who conscientiously objects to deactivating CIEDs should not be compelled to do so. Under these circumstances, care of the patient should be transferred to another clinician.^{5,20}

For more than half of the patients in our study (51%), CIED deactivation requests were made by surrogates. Prior research has shown that surrogates commonly are burdened with decisions to withdraw life-prolonging treatments from patients they represent.²¹⁻²³ Furthermore, in our study, surrogates were more likely to be involved with requests to deactivate bradycardia therapies than tachycardia therapies only. This finding was unsurprising because requests to deactivate bradycardia therapies usually involve seriously ill patients without decision-making capacity, whereas decisions to deactivate tachycardia therapies are often made by decisionally capable patients who wish to avoid shocks.

More than half of the patients in our study (57%) had ADs, yet only 1 specifically mentioned a CIED; this finding was consistent with those of prior studies.^{24,25} Notably, prior research has also shown that few patients with CIEDs know that device deactivation is an option²⁶ and that many dying patients with ICDs experience shocks as they approach death.²⁷⁻²⁹ Yet, a recent study showed that most patients with ICDs would want device deactivation in 1 or more clinical scenarios involving serious illness (eg, advanced incurable disease).³⁰ Evidence also suggests that advance care planning and timely discussions of device deactivation reduce the risk for shocks in dying patients with ICDs.^{27,31} We recommend encouraging patients with or being considered for CIEDs to engage in advance care planning and execute ADs that specifically address CIED management to ensure they receive care that is consistent with their preferences.^{5,22} This approach may reduce ethical dilemmas and moral distress among surrogates and care providers.

Less than half of our patients (43%) had a palliative medicine consultation. Device management was specifically addressed in only two-thirds of these consultations (69%).

Patients who made the decision to undergo device deactivation were more likely to involve palliative medicine than patients whose surrogates made the decision. This finding might reflect the shared decision-making process between a clinician and an autonomous patient with decision-making capacity. The HRS recommends palliative care consultation in patients undergoing CIED deactivation to promote shared decision-making practices and proactive management of symptoms.⁵

Only 3 patients in our study had an ethics consultation. This finding is consistent with that of a prior study⁶ and was not surprising, given that the ethical and legal permissibility of CIED deactivation, especially deactivating tachycardia therapies, is largely settled. Furthermore, our institution allows conscientious objection to CIED deactivation, consistent with the HRS consensus statement.⁵

Most deactivations (55%) were carried out by nurses, and a substantial number (15%) were carried out by IEAPs. The HRS has specific recommendations regarding the involvement of IEAPs in device deactivations, including that they must be supervised by medical personnel and that they have the right to refuse to participate in a deactivation.⁵ Although the median survival of patients who underwent deactivation of tachycardia therapies only was longer than the survival of patients after deactivation of bradycardia therapies with or without tachycardia therapies, the difference was small (3 vs 0 days), and the proportions of patients in each group who had died within 1 month following deactivation were similar (85% vs 94%). These findings suggest that a decision to deactivate a CIED reflects the seriousness of a given patient's underlying illness and his or her poor prognosis. Indeed, nearly all patients in our study had poor or terminal prognoses.

Strengths of this study were its size and comprehensive follow-up of all included patients. However, this study has several limitations. Our findings represent the experiences of patients at a single institution and may not be generalizable to patients elsewhere. The design of the study was retrospective and did not involve contact with the patients or surrogates; such contact might have provided additional insights regarding their perspectives on CIED deactivations. Some patients who underwent CIED implantation at our institution received postimplantation care elsewhere; these patients may have characteristics and outcomes that differ from those of the patients in our study. During the study period, several institutional policies regarding CIED deactivation were implemented. Thus, our results reflect, in part, the evolution of our institutional policies. It is possible that some patients who underwent CIED deactivation were not reported to our Heart Rhythm Service (eg, application of a magnet to an ICD in a hospice). Finally, from our data, we cannot precisely determine the percentage of patients with CIEDs who request device deactivation. During the 46-month study period, 4496 patients underwent CIED implantations at our institution. However, this number is not an appropriate denominator for determining the percentage of patients with CIEDs who undergo device deactivations. Future research should determine this percentage.

Future research should also focus on developing methods for improving informed decision making and advance care planning in patients with, or being considered for, CIEDs and how such decision making and planning affect patient outcomes. For example, patients ideally

should be informed of the permissibility of CIED deactivation during the consent process at the time of device implantation. However, it is unknown if doing so improves patient outcomes. Research also should clarify whether device-specific ADs improve patient outcomes. For example, in a patient with a cardiac resynchronization therapy with defibrillation and antitachycardia pacing capabilities device who also is PM-dependent, his or her AD might state that the patient wishes to discontinue antitachycardia therapies only vs discontinuing antitachycardia and CRT therapies while maintaining pacing vs discontinuing all therapies, and so on. Fundamentally, future research should clarify means for discerning patients' values, goals, and preferences, avoiding unwanted treatments, and palliating symptoms in patients with CIEDs who are approaching death. Finally, research should explore the perspectives of surrogates faced with CIED deactivation decisions.

In conclusion, most patients or their surrogates who request CIED deactivation request deactivation of ICD-delivered tachycardia therapies only. Requests for PM deactivation in PM-dependent patients are infrequent. Many CIED deactivation requests are made by surrogates. Although many patients with CIEDs have ADs, these documents rarely address device management. Patients with CIEDs should be encouraged to execute ADs with device-specific language to ensure that they receive care consistent with their preferences.

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Table 1

Characteristics of 150 Patients in the Study

Characteristic	All Patients	Deactivation		P Value
		Tachycardia Therapies Only (n = 118)	Bradycardia Therapies With or Without Tachycardia Therapies (n = 32)	
Sex, No. (%)				
Male	101 (67)	82 (69)	19 (59)	.29
Female	49 (33)	36 (31)	13 (41)	
Age at deactivation, median, y	79	79	79	.66
Race, No. (%)				
White	144 (96)	115 (97)	29 (91)	.26
Nonwhite	6 (4)	3 (3)	3 (9)	
Religion, No. (%)				
Protestant	97 (65)	75 (64)	22 (69)	.29
Catholic	38 (25)	32 (27)	6 (19)	
Non-Christian	15 (10)	11 (9)	4(13)	
Residence, No. (%)				
Olmsted County, MN	26 (17)	20 (17)	6 (19)	.55
Other county in MN	78 (52)	65 (55)	13 (41)	
Outside MN	46 (31)	34 (29)	12 (38)	
Person requesting CIED deactivation, No. (%)				
Patient	74 (49)	64 (54)	10 (31)	.02
Surrogate	76 (51)	54 (46)	22 (69)	
Palliative care consultation, No. (%)	64 (43)	53 (45)	11 (34)	.32
Ethics consultation, No. (%)	3(2)	1 (<1)	2 (6)	.12

Abbreviations: CIED, cardiovascular implantable electronic device; MN, Minnesota.

Table 2

Outcomes of 150 Patients Who Underwent Cardiovascular Implantable Electronic Device Deactivation

Outcome	All Patients	Deactivation		P Value
		Tachycardia Therapies Only (n = 118)	Bradycardia Therapies With or Without Tachycardia Therapies (n = 32)	
Survival, No. (%) ^a				
Dead	146 (97)	114 (97)	32 (100)	.58
Alive	4 (3)	4 (3)	0 (0)	
Survival after deactivation, median (range), d	2 (0-483)	3 (0-483)	0 (0-60)	<.001
Deaths after deactivation, No. (%) ^b				
1 d	40 (27)	23 (19)	17 (53)	<.001
1 wk	106 (71)	78 (66)	28 (88)	.04
1 mo	130 (87)	100 (85)	30 (94)	.52
1 y	145 (97)	113 (96)	32 (100)	>.99
2 y	146 (97)	114 (97)	32 (100)	>.99

^a As of September 1, 2012.

^b Within the time frame noted.