
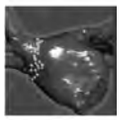


Addressing end-of-life management in patients with implantable cardioverter defibrillators and pacemakers

"Appropriate end-of-life management of these devices [cardiovascular implantable electronic devices] can be difficult, as clinicians attempt to balance autonomy with the wellbeing of the patient and the obligation to avoid harm."

KEYWORDS: cardiovascular implantable electronic devices ■ deactivation ■ end of life ■ explantation ■ reuse

Sachin Logani

Hospital of the University of Pennsylvania, 3400 Spruce Street, 9021 Gates Pavilion, Philadelphia, PA 19104, USA

James N Kirkpatrick

Author for correspondence: Hospital of the University of Pennsylvania, 3400 Spruce Street, 9021 Gates Pavilion, Philadelphia, PA 19104, USA
Fax: +1 215 615 3652
james.kirkpatrick@uphs.upenn.edu

Modern medicine benefits from technological advances that both extend life and also improve the quality of life. Cardiovascular implantable electronic devices (CIEDs), including implantable cardioverter defibrillators (ICDs) and permanent pacemakers (PPMs), are commonly used to treat cardiac rhythm disorders. An aging population in the USA, combined with expanding indications, promises an exponential increase in the utilization of these devices. However, challenging ethical dilemmas arise. Mortality rates among CEID recipients remain high due to worsening underlying cardiac disorders, as well as the development of other terminal illnesses [1,2]. Appropriate end-of-life management of these devices can be difficult, as clinicians attempt to balance autonomy with the wellbeing of the patient and the obligation to avoid harm. Furthermore, how these devices should be handled after a patient's death poses other challenges, as well as opportunities.

Device deactivation

As the end of life nears, a repeatedly discharging ICD may cause unnecessary pain and prolong the dying process. According to reports, up to 25% of patients receive ICD shocks at the end of life [3,4]. PPM, whose initial purpose may have been to improve quality of life in an otherwise healthy person, may become burdensome and also prolong the dying process in a terminally ill patient. Because ICDs and PPMs are completely internal (as opposed to mechanical ventilation, hemodialysis and cardiopulmonary resuscitation) and are often implanted when patients are relatively healthy, patients and physicians may not regard them as 'artificial life support'. Under certain circumstances, such as in a PPM-dependent patient, turning off the device may be seen as physician-assisted suicide or euthanasia. Physicians may balk at such requests.

Because of the proliferation of CEIDs, patients and physicians increasingly face important questions. Should an ICD be deactivated in a terminally ill cancer patient? Should a PPM be turned off in a patient with recurrent disabling heart failure symptoms? Do physicians have the right to deactivate devices for reasons of futility? Do patients have the right to have the device turned off against physicians' recommendations?

We contend that the principles applicable to the deactivation of CEIDs parallel those applicable to other devices and treatments. Patient have the right to refuse or request the deactivation of any life-sustaining device, including ICDs and PPMs. We agree with the Heart Rhythm Society (HRS), the American College of Cardiology and other professional societies, who recently published a consensus document on device deactivation in patients nearing the end of life [5]. This document emphasizes that, in legal and ethical terms, device deactivation is neither physician-assisted suicide nor euthanasia.

The document also encourages patients to execute some form of advanced directive indicating how their device should be handled at the end of life. As a corollary, the document encourages early and frequent discussions between the physician and the patient regarding the burdens and benefits of device therapy at the end of life. Studies suggest that physicians rarely initiate these discussions [3]. If they happen at all, discussions tend to take place hours or minutes before death, often after

part of future medicine fsg

patients have lost decision-making capacity. Even though most patients want to be involved in discussions about end-of-life decision-making [6], only a minority of electrophysiologists (EPs) believe that discussions regarding device deactivation should occur at the time of device implantation [7]. Likely barriers to such discussions include uncertainty regarding the patient's prognosis, time constraints, and perceived ethical and legal barriers regarding device deactivation. It also remains unclear if these discussions should be initiated by the patient's primary care physician, the cardiologist or the implanting EP [8]. We contend that a form indicating the patient's wishes regarding end-of-life device management could be incorporated into the preprocedural consent document or an advance directive [9].

Post-mortem recovery of devices for product improvement

Although ICDs and PPMs have been shown to prolong life, there are limited data on the long-term reliability of these devices [10]. Furthermore, it is sometimes unclear whether a patient's death occurred due to progressive underlying disease or device malfunction. Following a series of high profile CEID recalls, the HRS recommended that all explanted devices be returned to the manufacturer for analysis in order to improve product design [11]. Post-mortem device retrieval and return to the manufacturer requires cooperation between patients, physicians, manufacturers and funeral directors. The current literature suggests that, although most EPs and funeral directors believe that post-mortem device retrieval and return to the manufacturer is feasible, it is rarely accomplished [12]. The majority of devices explanted post-mortem are thrown away or remain at the funeral home [13].

> "*In addition to aiding quality improvement, post-mortem device recovery presents an opportunity to improve medical care in the developing world.*"

A major barrier to post-mortem device retrieval is the lack of written consent from the patient or next-of-kin authorizing the retrieval. Device extraction without written consent represents a breach of professional conduct [10]. Most patients are willing to sign device advance directives regarding post-mortem device disposition [13]. The HRS recommends that physicians obtain such consent expressing the patient's wishes regarding post-mortem device destination while the patient is alive. It may be reasonable to incorporate this consent into the same form used to determine the patient's wishes regarding device handling at the end of life.

Other barriers to post-mortem device retrieval from funeral homes include the lack of a single universal programmer able to interrogate various explanted device models, and the lack of collaboration between the EP community and the funeral industry. It has been proposed that the creation of a central agency responsible for collecting and interrogating explanted devices may improve device return rates. However, limited data suggests that EPs do not believe a central agency is necessary [12]. Perhaps a more effective method may involve providing incentives to industry representatives to recover devices post-mortem, as well as recovery of devices after change-out for infection or battery depletion.

> "*...a 'device living will' may improve donation rates of reuseable devices, leading to a reduction in morbidity and mortality in LMICs.*"

Post-mortem recovery for reuse

In addition to aiding quality improvement, post-mortem device recovery presents an opportunity to improve medical care in the developing world. Significant disparities exist between the number of devices implanted per year in the Western world as compared with the number implanted per year in low-to-middle income countries (LMICs) [14]. However, the burden of cardiac disease in these LMICs continues to mount, with approximately 14 million deaths per year due to cardiovascular causes [15]. For example, Chaga's disease, a vector-borne illness endemic to many South American countries, results in mortality largely due to chronic inflammatory cardiomyopathy leading to congestive heart failure and rhythm disturbances [16]. However, limited access often prevents needed PPMs from being implanted in this population.

Since a large percentage of PPM recipients in developed nations are elderly patients with a limited life expectancy, and the expected longevity of a PPM is around 10 years, a large number of potentially reusable PPMs with adequate battery life may be available for reuse if explanted after death. The safety of PPM reuse is well documented in the literature [17], and the Project My Heart – Your Heart initiative is working to increase awareness of PPM reuse overseas. PPM

donation and reuse remain a challenge due to barriers such as lack of informed consent and fear of infection or device malfunction [18]. Previous reports suggest that only a small number of explanted devices are donated for reuse [12,13], even though a large percentage of funeral directors, patients with implanted devices and members of the general population support PPM reutilization [19]. Patients may also choose to have their device donated to veterinary hospitals for reuse in pets [17]. We contend that a 'device living will' may improve donation rates of reuseable devices, leading to a reduction in morbidity and mortality in LMICs.

Future perspective

Though the increasing use of CEIDs extends and improves the quality of life, these devices can prolong or cause suffering at the end of life. If we are to improve care at the end of CEID patients' lives, clinicians must familiarize themselves with ethical issues surrounding the use and deactivation of ICDs and PPMs. Clinicians should engage patients early on in discussions regarding end-of-life device deactivation. Such discussions may involve a specific device living will, ideally executed at the time of device implantation or the first follow-up visit. This document should include not only the patient's wishes regarding device handling at the end of life but also outline the patient's wishes for post-mortem device disposal. Adoption of a device living will may lead to more timely withdrawal of undesired CEID support in terminally ill patients. At the same time, it has the potential to increase post-mortem device retrieval to aid product development and improve health in underserved nations.

Information resources

More information regarding device reuse may be obtained by contacting Bill Daem, founder of Heart Too Heart (+1 406 656 7687) or by visiting the Project My Heart – Your Heart website: www.myheartyourheart.org. Further information regarding the device living will may be obtained by contacting James Kirkpatrick at james.kirkpatrick@uphs.upenn.edu. Readers are also referred to the Code of Professional Conduct (National Funeral Directors Association): www.nfda.org/files/CodeofConduct.pdf.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Bibliography

1 Cleland JG, Daubert JC, Erdmann E *et al.* The effect of cardiac resynchronization on morbidity and mortality in heart failure. *N. Engl. J. Med.* 352(15), 1539–1549 (2005).

2 Moss AJ, Zareba W, Hall WJ *et al.* Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N. Engl. J. Med.* 346(12), 877–883 (2002).

3 Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Management of implantable cardioverter defibrillators in end-of-life care. *Ann. Intern. Med.* 141(11), 835–838 (2004).

4 Nambisan V, Chao D. Dying and defibrillation: a shocking experience. *Palliat. Med.* 18(5), 482–483 (2004).

5 Lampert R, Hayes DL, Annas GJ *et al.* HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm* 7(7), 1008–1026 (2010).

6 Heyland DK, Frank C, Groll D *et al.* Understanding cardiopulmonary resuscitation decision making: perspectives of seriously ill hospitalized patients and family members. *Chest* 130(2), 419–428 (2006).

7 Goldstein N. National survey of physicians to determine practice patterns and opinions about ICD deactivation in patients with advanced illness [abstract]. Annual Assembly of the American Academy of Hospice and Palliative Medicine and Hospice and Palliative Nurses Association, Tampa, FL. February 2, 2008. *J. Palliat. Med.* 11, 333 (2008).

8 Lewis WR, Luebke DL, Johnson NJ, Harrington MD, Costantini O, Aulisio MP. Withdrawing implantable defibrillator shock therapy in terminally ill patients. *Am. J. Med.* 119(10), 892–896 (2006).

9 Berger JT, Gorski M, Cohen T. Advance health planning and treatment preferences among recipients of implantable cardioverter defibrillators: an exploratory study. *J. Clin. Ethics* 17(1), 72–78 (2006).

10 Maisel WH, Sweeney MO, Stevenson WG, Ellison KE, Epstein LM. Recalls and safety alerts involving pacemakers and implantable cardioverter-defibrillator generators. *JAMA* 286(7), 793–799 (2001).

11 Carlson MD, Wilkoff BL, Maisel WH *et al.* Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines Endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and the International Coalition of Pacing and Electrophysiology Organizations (COPE). *Heart Rhythm* 3(10), 1250–1273 (2006).

12 Logani S, Gottlieb M, Verdino RJ, Baman TS, Eagle KA, Kirkpatrick JN. Recovery of pacemakers and defibrillators for analysis and device advance directives: electrophysiologists' perspectives. *Pacing Clin. Electrophysiol.* 34(6), 659–665 (2011).

13 Kirkpatrick JN, Ghani SN, Burke MC, Knight BP. Postmortem interrogation and retrieval of implantable pacemakers and defibrillators: a survey of morticians and patients. *J. Cardiovasc. Electrophysiol.* 18(5), 478–482 (2007).

14 Mond HG, Irwin M, Morillo C, Ector H. The world survey of cardiac pacing and cardioverter defibrillators: calendar year 2001. *Pacing Clin. Electrophysiol.* 27(7), 955–964 (2004).

15 Joshi R, Jan S, Wu Y, Macmahon S. Global inequalities in access to cardiovascular health care: our greatest challenge. *J. Am. Coll. Cardiol.* 52(23), 1817–1825 (2008).

16 Kirchhoff LV, Weiss LM, Wittner M, Tanowitz HB. Parasitic diseases of the heart. *Front. Biosci.* 9, 706–723 (2004).

17 Baman TS, Meier P, Romero J *et al.* Safety of pacemaker reutilization: a meta-analysis with implications for underserved nations. *Circ. Arrhythm Electrophysiol.* 4(3), 318–323 (2011).

18 Kirkpatrick JN, Papini C, Baman TS *et al.* Reuse of pacemakers and defibrillators in developing countries: logistical, legal, and ethical barriers and solutions. *Heart Rhythm* 7(11), 1623–1627 (2010).

19 Gakenheimer L, Lange DC, Romero J *et al.* Societal views of pacemaker reutilization for those with untreated symptomatic bradycardia in underserved nations. *J. Interv. Card. Electrophysiol.* 30(3), 261–266 (2011).