# *Ethical Challenges of Deactivation of Cardiac Devices in Advanced Heart Failure*

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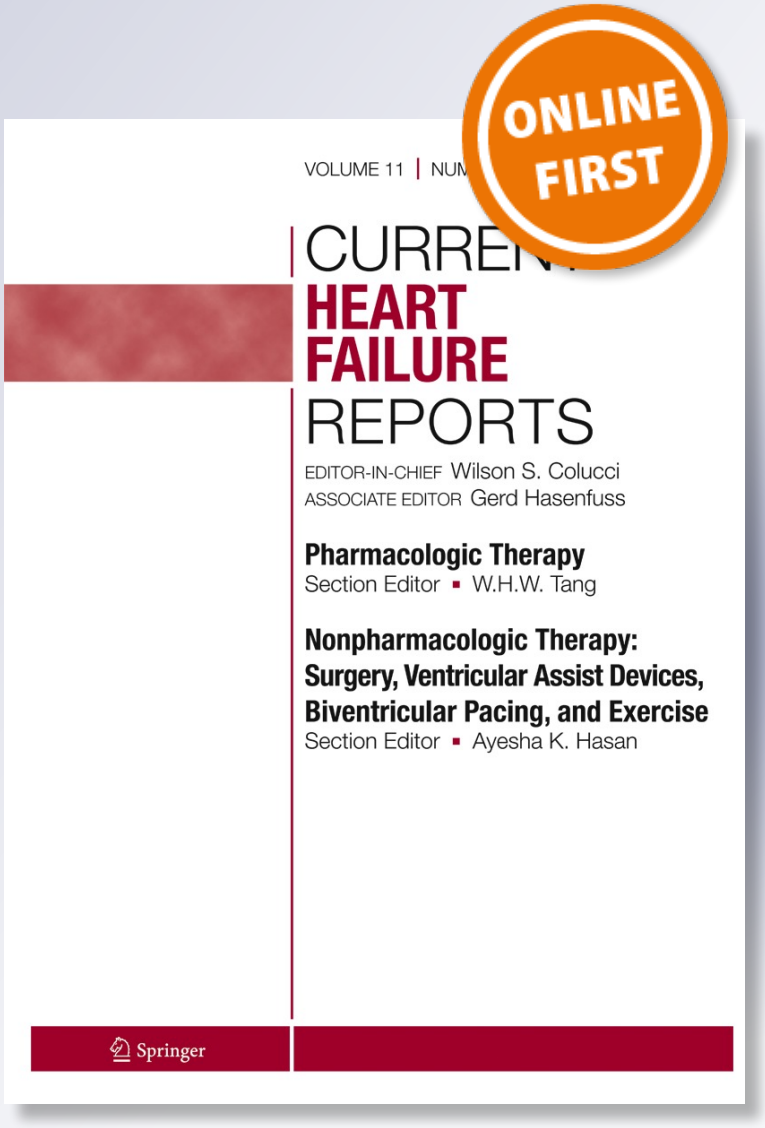


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HOT TOPIC

# Ethical Challenges of Deactivation of Cardiac Devices in Advanced Heart Failure

**Hassan Chamsi-Pasha · Mohammed A. Chamsi-Pasha · Mohammed Ali Albar**



**Abstract** More than 23 million adults worldwide have heart failure (HF). Although survival after heart failure diagnosis has improved over time, mortality from heart failure remains high. At the end of life, the chronic HF patient often becomes increasingly symptomatic, and may have other life-limiting comorbidities as well. Multiple trials have shown a clear mortality benefit with the use of implantable cardioverter defibrillators (ICDs) in patients with cardiomyopathy and ventricular arrhythmia. However, patients who have an ICD may be denied the chance of a sudden cardiac death, and instead are committed to a slower terminal decline, with frequent DC shocks that can be painful and decrease the quality of life, greatly contributing to their distress and that of their families during this period. While patients with ICDs are routinely counseled with regard to the benefits of ICDs, they have a poor understanding of the options for device deactivation and related ethical and legal implications. Deactivating an ICD or not performing a generator change is both legal and ethical, and is supported by guidelines from both sides of the Atlantic. Patient autonomy is paramount, and no patient is committed to any therapy that they no longer wish to receive. Left ventricular assist devices (LVADs) were initially used as bridge in patients awaiting heart transplantation, but they are currently implanted as destination therapy (DT) in patients with end-stage heart failure who have failed to respond to optimal medical therapy and who are ineligible for cardiac transplantation. The decision-making process for initiation and deactivation of LVAD is becoming more and more ethically and clinically challenging, particularly for elderly patients.

**Keywords** Implantable cardioverter defibrillator · Left ventricular assist device · Heart failure · End of life · Ethics · Bioethics · Cardiac resynchronization therapy · Cardiac devices

## Introduction

Heart failure (HF) is the most common cause of hospitalization for people aged 65 years and older, with a median age of 75 years for all HF hospitalizations. The number of heart failure patients is increasing worldwide. Approximately 1–2 % of the adult population in developed countries suffer from this chronic disease [1].

Advances in the treatment of HF have included the use of implantable devices such as implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT), and left ventricular assist devices (LVADs) [2]. Across the world, ICD implantation has become a common and standard treatment for primary and secondary prevention of sudden cardiac death in patients with poor left ventricular function. CRT improves cardiac function in selected patients with advanced HF, thereby reducing mortality and hospitalization and improving quality of life. ICDs improve survival by terminating fatal arrhythmias, but they have no effect on cardiac function or heart failure symptoms [3••].

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LVADs were originally developed to bridge patients with end-stage HF to cardiac transplant. More recently, these devices have become "destination therapy" for advanced HF patients with contraindications to heart transplant [2].

Despite the presence of guidelines delineating the theoretical and practical aspects of the process of deactivation of cardiovascular implantable electronic devices (CIEDs) (i.e., ICDs, pacemakers, and CRT devices), there is still significant skepticism on the part of both patients and health care providers regarding the ethical and legal implications associated with discontinuation of these devices [4].

## Implantable Cardioverter-Defibrillator (ICD)

ICD is the treatment of choice for patients with poor left ventricular function who are at risk of sudden cardiac death due to ventricular arrhythmias. Both European and North American guidelines state that an ICD is appropriate in patients who fit the criteria, have a good quality of life, and have a life expectancy of more than 1 year [5, 6].

Although ICD effectively reduces the risk of sudden cardiac death, it cannot prevent death from heart failure or non-cardiac diseases [7]. Patients with ICDs may later develop terminal illness due to worsening of their underlying heart disease or other chronic non-cardiac disease. Older patients are more likely to have multiple comorbidities that worsen after initial implantation and thereby reduce the survival benefit [8•]. Approximately one-third of patients newly fitted with ICDs in Western countries are at least 70 years old [7].

When a patient with an implantable defibrillator approaches the end of life, whether as a result of refractory heart failure or due to non-cardiac disease, discussion with regard to ending ICD treatment may be indicated. ICDs can create an extra burden for patients, particularly from inappropriate discharges and prevention of a rapid death [3••].

Twenty percent of implantable defibrillator patients receive shocks in the last weeks of their lives [9]. Shocks can be quite painful and psychologically stressful, without prolonging a reasonable quality of life, which contradicts comfort care goals. Side effects associated with shocks include transient loss of consciousness, uncontrolled defecation, enuresis, nausea, and vomiting, which can have an adverse effect on the patient's dignity [10]. Additionally, the rate of depression in defibrillator patients is approximately 20 % [11].

A related issue is the decision whether to replace a generator that is approaching end of life at a time when there is little expected improvement in lifespan and quality of life to balance against the cost and complications of replacement [8•]. For a device near its end of battery life, the generator should not be replaced without careful review of whether active defibrillation is consistent with the overall goals of care and anticipated duration of good-quality survival [3••].

### Informed Consent

The respect for autonomy and individual personhood support a patient's right to dictate decisions about their treatment, and detailed informed consent to a procedure is a fundamental right. The patient has the right to refuse any treatment or to withdraw a previous consent to treatment if it no longer satisfies their health care goals or if the perceived hardship of such treatment outweighs its perceived benefits [8•, 12]. The published guidelines stress that before an ICD can be deactivated, a detailed individual discussion with the patient must always take place and must be recorded. The option and ease of ICD deactivation should be discussed prior to implantation and again in the event of major changes in clinical status or transitions in goals of care [13]. Surrogates have the same moral authority to speak for patients who no longer have the capacity to make decisions. Patients or their surrogates may request deactivation of an ICD device to avoid protraction of the dying process or to avoid a specific issue associated with the ICD, such as DC shocks. Most patients are hesitant to accept ICD deactivation, however, even when death from another cause is not far away [14]. They tend to overestimate the capacity of the device to prevent death, so it is not uncommon for them to view consent for ICD deactivation as an act of suicide [15]. Patients should understand that the device can be easily switched off should they come to a point where hardship outweighs benefits, or when the patient reaches a stage where they desire a natural death [2].

Regardless of national law, the deactivation of an ICD against the patient's will or against the will of the patient's representative, or even unilateral (paternalistic) deactivation, is not permitted. Pre-implantation informed consent discussions should encourage the patient to complete an advance directive (AD). If the patient designates an agent, then it would be worthwhile for the patient and agent to have a discussion specifically about the device [16].

Most advance directives do not address CIED deactivation in end-of-life situations [17••]. In a study of 278 patients with an ICD, more than half had completed an AD, but only three had included a plan for their ICD. Most (86 %) of the patients had never considered what to do with their ICD if they had a serious illness and were unlikely to survive [17••].

Today, most discussions regarding ICD deactivation occur only in the last hours or days of life. The majority of patients would like to discuss these issues in advance and want to be involved in end-of-life decisions [18, 19]. While most clinicians agree that ICD deactivation is ethical and legal, many are reluctant to discuss the issue with their patients. Difficulty in

initiating such conversations is commonly due to lack of training and misperceptions about the legality of such action [20].

## What do Guidelines Say?

It is mandatory for the treating physician to provide guidance to patients facing decisions regarding ICD deactivation or electing not to replace a generator.

Both the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA) state that patients with advanced heart failure at the end of life are prone to develop frequent arrhythmias due to hypoxia, sepsis, worsening heart failure, and electrolyte imbalance [13]. This may precipitate ICD shocks, which can be so frequent and troublesome that the harm derived from the ICD outweighs its benefits.

The AHRS clearly affirms that "carrying out a request to withdraw life-sustaining treatment is neither physician-assisted suicide (PAS) nor euthanasia" and that "the right to refuse or request the withdrawal of a treatment is a personal right of the patient and does not depend on the type of the treatment."

There is disagreement within the medical community with respect to deactivation. For example, Rady et al. [21] consider such an act either PAS or euthanasia. However, the AHRS clearly describes PAS and euthanasia as the "addition" of a new modality to effect the patient's death, whereas deactivation is "removal." The intention of the physician is of paramount importance in determining the approval of the practice [16].

A number of important legal and ethical principles should be considered before deactivating an ICD or not replacing a generator in a patient with a functioning ICD. These principles are sanctioned by both the Heart Rhythm Society in North America and the EHRA in Europe, and include the following [13, 22]:

(1) A patient or surrogate decision-maker has the legal right to refuse or request the withdrawal of ICD therapy.
(2) If a patient has the capacity to understand the nature and consequences of their decisions, then they are legally competent to make those decisions.
(3) There are no ethical or legal differences between refusing ICD insertion and requesting withdrawal of ICD therapy either by deactivating the device or not performing generator replacement.
(4) Legally and ethically, carrying out a request to withdraw ICD therapy is neither physician-assisted suicide nor euthanasia.
(5) A clinician is not obligated to personally carry out ICD deactivation if it is in conflict with their personal values. In these circumstances, the clinician should involve a colleague who is willing to carry out the procedure [22].

European consensus recommendations reflect a similar perspective, with the exception that CIED deactivation must be carried out in accordance with local national laws. For instance, in some European countries, it is illegal to deactivate a pacemaker but not an ICD [13]. In all other respects, the guidelines are broadly in harmony, and argue for CIED deactivation as an extension of patients' rights to dictate their own treatment. Both guidelines note that major religious traditions support both patient autonomy and the right of the physician to withhold or withdraw treatment considered to be futile or inappropriate [4].

Ethics consultation should be sought in any situation in which the clinician or clinicians disagree with a request for device deactivation [23]. According to consensus guidelines, health care providers who are experienced in electrophysiology should perform deactivation where possible. This includes device physicians, nurses, and technologists.

## Deactivation of CRT Device

As with other CIEDs, informed consent for CRT devices should include detailed discussion about benefits, risks, and other alternatives, as well as the possibility that the device may fail to improve symptoms. Effective CRT alleviates symptoms of heart failure, and withdrawing such therapy, in many cases, would simply increase patients' discomfort in their final days. One exception may be when class IV heart failure symptoms are so intractable that resultant death is imminent. In this scenario, turning off CRT may accelerate the dying process, while appropriately shortening the period of breathless suffering [24].

In the United States, an ICD is often implanted along with a CRT device. In these circumstances, informed consent discussions for both the CRT and the defibrillator should clarify the point at which discontinuation of the defibrillator alone can be made [2]. Patients who have CRT-D devices should have the same opportunity for an advance directive discussion about ICDs at the end of life, as described above [25].

## Features and Outcomes of CIED Deactivation

Little is known about patients who undergo CIED deactivation. In a retrospective study, Buchhalter et al. [26••] described the features and outcomes of 150 consecutive patients (median age 79 years) who underwent CIED deactivations at the Mayo Clinic. Nearly all patients in the study (99 %) had poor or terminal prognoses. Most requests for CIED deactivation (79 %) were for implantable cardioverter-defibrillator–delivered tachycardia therapies only, and many of these requests were made by surrogates. A majority of deactivations (55 %) were carried out by nurses. Although 85 patients (57 %) had

advance directives, in only one was the device mentioned. Palliative medicine (PM) consultations occurred with 64 patients (43 %). Regardless of device therapy, most patients died shortly after device deactivation. As such, a device deactivation decision may reflect the seriousness of the patient's underlying illness [26••].

## Left Ventricular Assist Device (LVAD)

Heart transplantation (HTx) is the treatment of choice in patients with severely symptomatic end-stage heart failure. Due to the shortage of donor organs and the protracted waiting list for HTx, left ventricular assist devices (LVADs) have been used as a bridge to HTx. With the increased durability of these devices and the improved relatively long-term (2 years) survival, they are now considered a good alternative to HTx, particularly for patients ineligible for HTx due to advanced age or the presence of comorbidities [27]. In these cases, the device is implanted as a long-term intervention with the goal of prolonging life for 2–5 years and alleviating heart failure symptoms [28].

Despite the improved survival and quality of life observed in most LVAD destination therapy patients, serious problems such as stroke, gastrointestinal bleeding, infection, and (rarely) device malfunction may occur and worsen the prognosis [29]. The frequency and severity of these complications increase significantly in the presence of associated comorbidities. Clearly, the important decision whether to pursue this option warrants extensive discussion [30].

Both patients and their families need education and support to cope with the practical, psychological, and social consequences of LVAD implantation [1]. The explosion of DT LVAD has raised several ethical questions [25]. Should a candidate patient for LVAD complete an advance directive? Should the palliative care process start prior to placement of LVAD? And how should the process of LVAD deactivation take place [25]?

The ethical issues are centered on three decision points: patient selection, initiation of the device, and deactivation of the device. The candidate for LVAD should be capable of caring for himself or herself and being alert for potential problems. Patients discharged home are expected to initiate their self-care, including battery recharging, system checks, alarm recognition, and device management. As such, a history of stroke, neuropathy, dementia, or other cognitive changes may preclude LVAD placement as a viable option. A multidisciplinary palliative care team should be involved with all patients being considered for LVAD placement at or before the time of informed consent [31].

### Informed Consent

Optimal informed consent includes not only a description of an operative procedure, but also an understanding of the full range of benefits and risks for the therapy being offered as well as all reasonable treatment alternatives [3••].

Boothroyd et al. [32•] recently outlined the full range of expected outcomes for patients, their caregivers, and the clinicians who are charged with conveying such information. They addressed three principle domains relevant to DT LVAD decision-making: (1) risks and benefits of implantation; (2) expectations for daily life with a permanent LVAD; and (3) end-of-life issues, including device deactivation. With the limited information found in the literature, they included tables wisely describing both what we know and what we do not know on this subject [33].

The risk/benefit calculation must be acceptable to the physician, and the patient or surrogate must agree that initiation of treatment is most in keeping with the patient's values, goals, and preferences [28].

Advance directives have been proposed as a tool to facilitate advance care planning (ACP). They can enhance patient autonomy and provide physicians and surrogates with insights into patients' health care-related goals, values, and preferences [34]. Pre-implantation discussions should also encourage completion of AD. DT LVAD patients are more likely to have documented care directives in their medical charts if they were formally involved in advance care preparedness planning [32•, 34].

### Is LVAD Deactivation Morally Permissible?

For patients who are at the end of their lives, continued circulatory support by an LVAD may become undesirable. Consensus has developed within the transplant ethics community that deactivation of a LVAD is appropriate. Grounds for ethical permissibility are usually based on the well-established ethical and legal consensus that competent, informed patients (or their surrogates) have the right to request the withdrawal of any life-sustaining intervention they perceive as excessively onerous relative to benefits [3••, 34–37].

Some ethicists, however, remain opposed to device deactivation in many circumstances [38], and it is not uncommon for clinicians to object to deactivation of a LVAD. Usually the premise of the argument is that the LVAD is a long-term, continuous, and constitutive (taking over a function that the body can no longer perform) life-sustaining intervention [37], and that deactivation of such device may result in immediate or nearly immediate death. However, it is also true that many long-term, continuous, constitutive life-sustaining interventions (e.g., mechanical ventilation, hemodialysis) are routinely withdrawn [36, 37].

Some may argue that device deactivation is comparable to active euthanasia. In active euthanasia, however, the primary cause of death is the introduction of a new pathology for the purpose of terminating the patient's life. In cases of device deactivation, the patients die of their underlying advanced heart disease. Moreover, the intent in LVAD deactivation is ending a treatment that is preventing natural progression of a pre-existing disease [35, 39].

A survey was conducted recently to assess the attitudes and practices of members of the Heart Failure Society of America (HFSA), European Society of Cardiology-Heart Failure Association (ESC-HFA), and the International Society for Heart & Lung Transplantation (ISHLT) regarding LVAD deactivation in patients approaching death. The results reflected various attitudes among clinicians. Of note, the survey revealed that more European than North American physicians considered withdrawing LVAD support a form of euthanasia [40].

### Palliative Care Team

The role of palliative medicine in the care of patients with advanced heart failure, including those who receive mechanical circulatory support devices (MCSD), has grown dramatically in the last decade. The ISHLT recommends that consultation with palliative medicine should be considered prior to MCSD implantation to facilitate discussion of end-of-life issues and to establish an advance directive or living will, particularly when a device is implanted as DT [41]. The purpose of preparedness planning is to help individuals formulate a plan to live as well as they can for as long as they can, while still achieving their overall goals of care [34].

### Before Deactivation

While there are no specific recommendations outlining when to consider LVAD deactivation, it seems prudent to initiate serious discussions with the patient (if still able to participate) and family when there is significant deterioration in the quality of life, development of other organ failure, or an irreversible catastrophic adverse event such as a major stroke or hemorrhage [3••].

Before the device is deactivated, it is critical to have a thorough discussion with patient/family about the patient's current clinical situation and prognosis, how the device will be stopped, how symptoms would be managed, and anticipated outcome (i.e., rapid death) [3••].

Special emphasis should be placed on the deactivation process. Ethics, psychiatry, palliative medicine, and chaplaincy services can be drawn upon to meet the needs of the patient, family, and team for competent, compassionate support. The involvement of palliative medicine also relieves those members of the team who object to deactivation from actually having to perform it [36].

### Deactivation Process

As the majority of patients are dependent on the LVAD, turning off the device can lead to rapid death. The process of LVAD discontinuation should be presented in a well-defined plan that is clearly explained to all participating members, and any concerns of the patient or family should be properly addressed. Families should be reassured that the patient will be kept comfortable and their dignity preserved after treatment is discontinued [42].

Families may agree with and accept the decision to allow natural death but find themselves unprepared for events during deactivation. They and their loved ones should have ample opportunities for visitation [42]. Survival after LVAD deactivation at the end of life ranges from a few minutes to a few days. Providers should carefully explain this variability to families, as it can be upsetting if a patient lives either a longer or shorter time than the family expects [42].

Without proper planning, staff may also find themselves unprepared for the events and responsibilities. Schaefer et al. [43] proposed a checklist to facilitate interdisciplinary preparation for LVAD deactivation. Priorities include effective communication with the family and among teams, required palliative care consultation, and coordination of interdisciplinary care at the bedside [43]. Every center implanting LVADs should have a process in place for discontinuing LVAD therapy.

## Conclusion

Although technological advances have extended the lifespan of heart failure patients and improved their quality of life, health professionals must remain cognizant of the complex ethical issues involved in the management of HF at the end of life. Physicians should initiate a deactivation conversation, ideally at the time of implantation of cardiac devices.

All specialists involved in the care of patients with ICDs should be aware that these can be deactivated, and that doing so when requested by a patient or surrogate is ethical, legal, and logistically simple. Legally, patients have the right to refuse any treatment, but do not have the right to demand mistreatment. Careful advance planning and clear communication with regard to patient goals and wishes supports patient autonomy while avoiding harm [2]. LVAD deactivation should be also seriously considered at the end of life.

Cardiovascular training programs should incorporate training in dealing with end-of-life situations in patients with advanced heart failure [25]. A multidisciplinary approach that includes doctors and nurses is critical to support and guide the

patient and family through this decision [44••]. It should be stressed that the goal is not to promote device deactivation, but to support patient's self-determination and control over their own medical treatment.

The ESC-HFA, ISHLT, and HFSA should develop a consensus statement on the management of these patients that includes ethical, legal, and religious principles and the role of palliative care consultation, as well as the logistics of the process of withdrawal of LVAD support, similar to the consensus statement regarding patients with CIEDs [22].

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**Compliance with Ethics Guidelines**

**Conflict of Interest** Hassan Chamsi-Pasha, Mohammed A. Chamsi-Pasha, and Mohammed Ali Albar declare that they have no conflict of interest.

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- •• Of major importance


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