Chapter 15
Ethical Aspects of Withdrawing Cardiac Device Therapy at End of Life

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Abstract Cardiac device therapies are associated with improved survival in patients at risk for sudden cardiac death due to ventricular arrhythmias. The number of implants for both primary and secondary prevention continues to rise both in the United States and European countries. As the population ages and technology advances, patients with implantable devices continue to live longer. When terminal illness becomes apparent, patient's goals may change to comfort care and painful shocks from ICDs become unwanted and inappropriate. This chapter discusses the challenges that patients and medical caregivers face as these patients deal with terminal illnesses. It also discusses the latest information available in the medical literature related to ethics and patient's and physician's attitudes. Ethics will aid the clinician's management of the goals of care related to potentially complex end-of-life issues. With some pre-planning a potentially stressful situation can become more manageable for all those involved.

Keywords End-of-life • Deactivation • ICD withdrawal • Terminally ill and ICD • Withdrawing cardiac device • Withholding CIED's

Cardiovascular Implantable Electronic Devices (CIEDs) have been associated with reduced mortality in patients with structural heart disease [1–4]. Cardiac resynchronization therapy (CRT) devices have recently been shown to improve congestive heart failure symptoms as well as survival [5]. As indications for device therapy continue to expand, the population of patients with these devices continues to grow [6]. Despite the tremendous advances in technology, all patients will reach the end of their lives, due to their underlying heart condition, such as end stage congestive heart failure but additionally diseases such as severe lung disease, neurological disorders such as Parkinson's disease, dementia, fatal infections as well as terminal cancers will also lead to their death. Unplanned events can also occur such as

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automobile accidents or other forms of trauma leading to similar terminal scenarios. Due to the nature of physiological changes such as electrolyte imbalance, hypoxia or pH changes that can occur with many of these illnesses there is a higher probability that supraventricular or ventricular arrhythmias are triggered especially during an acute decompensation. The defibrillator functions as programmed and thus, appropriate as well as inappropriate therapies, including shocks, are delivered to the patient. In patients suffering from terminal illness, these shocks are painful and may be intolerable and inconsistent with treatment goals [7]. Because of the potentially higher number of shocks what had been a tolerable experience because it was life-saving, is no longer appropriate.

In the last weeks of their lives, 20% of ICD patients receive shocks which are painful and known to decrease quality of life [7]. This greatly contributes to the distress of patients and their families. In patients with terminal illnesses, minimizing discomfort and maintaining quality of life should be a priority for everyone involved in their care.

The goals of this chapter are:

- To educate clinicians regarding the legal, ethical, religious principles and rights and responsibilities of health care providers associated with withdrawal of life-sustaining therapies, specifically CIED deactivation or removal, in patients who have made this decision.
- Discuss published data regarding variations in current clinical practices, knowledge, perception and provider preferences.
- Develop a framework or strategies to guide the health care providers involved in assisting patient and families when a request is made to withdraw CIED therapy.
- Encourage a team/multidisciplinary approach to care for these patients and their families.

Although the main focus of this discussion is on patients nearing the end of life, it will also address patients who have made a decision for device deactivation at other times of their lives.

The issue of managing patients nearing end of life was initially addressed in the 2008 ACC/AHA/HRS Guidelines for device therapy of Cardiac Rhythm Abnormalities [8]. As the number of ICD implants continued to rise and the number of instances where therapy withdrawal becomes appropriate, the interest and number of publications in this area has risen. Two excellent consensus statements have been written outlining the principles and suggested best practices of Cardiovascular Implantable Electronic Devices (CIEDs) management in patients nearing end of life. These provide a very balanced and detailed discussion to guide health care providers in the management of what can be a very stressful time for all those involved, including but not limited to health care providers, patients, their families as well as industry professionals.

The United States Expert Consensus was developed by the Heart Rhythm Society (HRS) in collaboration with and endorsed by American College of Cardiology

(ACC), American Geriatric Society (AGS), American Academy Of Hospice and Palliative Medicine (AAHPM), American Heart Association,(AHA), European Heart Rhythm Association (EHRA) and Hospice and Palliative Nurses Association (HPNA) and published in 2010 [9]. The European Heart Rhythm Association published similar guidelines several months later [10]. It highlights the differences arising from the diversity of national laws in Europe. There are countries where the deactivation of anti-bradycardia pacing function in a pacemaker dependent patient is prohibited by law. It is therefore important to be aware of the laws that apply to the country of practice.

Legal, Ethical and Religious Issues in Withdrawing Cardiac Device Therapy

This discussion begins with a clinical scenario that will help illustrate some of the salient points:

A 65 year old retired college professor is admitted to the hospital with altered mental status. She had a permanent pacemaker implanted for complete heart block (CHB) 5 years prior to the current illness. She resulted being pacemaker dependent at every office pacemaker evaluation. She is now critically ill with sepsis, a newly diagnosed stroke and as part of the clinical evaluation was found to have metastatic ovarian cancer. She has an older spouse and 3 children. She has no advance directive (AD). Her oncologist contacts her cardiologist who implanted the pacemaker to consult regarding the patient's request to have her pacemaker turned off as she feels it is keeping her alive against her wishes. Her cardiologist is hesitant to deactivate the pacemaker given his own personal values as well as the fact that opinions are divided among her family members.

Question #1. Does She Have the Capacity to Make Such a Request Given the Acuity of Her Illness? How Is That Determination Made?

The following discussion on basic legal principles will shed some light into this question.

Legal Principles

Request for deactivation of a CIED, can originate with the patient, a family member or a health care provider who feels it should be considered based on their knowledge of the CIED's function. Some of these requests are made based on knowledge or the

lack thereof. It is known that many patients and family members have not thought about or are not aware of the consequences of CIED device shocks associated with illnesses near the end of life [11]. Others have misconceptions of being kept artificially alive by CIED's [11].

Before any deactivation or removal is performed or non-replacement of a device is elected, the patient or surrogate must give consent. *Informed consent* is paramount and is at the very core of these discussions. As very clearly explained by Zellner et al. "Informed consent derives from the ethical principle of respect for persons; autonomy is maximized when patients understand the nature of their diagnoses and treatment options and participate in decisions about their care [12]. Informed consent is the most important legal doctrine in the clinician patient relationship. Clinicians are ethically and legally obligated to ensure that patients are informed and allowed to participate in decision making regarding their diagnoses and treatment options" [13, 14].

The elements of informed consent include information, patient voluntariness, and patient decision-making capacity. *Decision-making capacity* is a clinical term and refers to a patient's ability to make informed health care-related decisions. Clinicians determine decision-making capacity by whether a patient is able to:

1. Make and communicate choices.
2. Understand relevant information.
3. Appreciate the clinical situation and its consequences.
4. Manipulate information rationally.
5. Make a decision that is consistent with the patient's values and goals [14–16].

Because of these requirements, proof of decision making capacity can vary according to the complexity of the decision that has to be made; e.g., the graver the consequences of the decision, the greater the proof of decision-making capacity the clinician should require. Clinicians should not presume incapacity in patients who make clinical decisions contrary to the clinicians' recommendations [13, 14]. In contrast, *competence* is a legal term and is determined by courts [16]. In most situations it is acceptable to act on the physician's determination of capacity without formal legal declaration of incompetence" [14]. According to the July 2010 Heart Rhythm Society consensus document, a psychiatry consult is not necessary to determine capacity [9]. The physician determines that a patient is gravely ill and therefore not able to make an informed decision. Some of these capacity decisions can change as clinical conditions improve or deteriorate.

Most patients who have lost decision-making capacity due to illness have not been declared incompetent by the courts [9, 13]. With the loss of capacity, the decision making will fall to a surrogate. "For patients who lack decision-making capacity and those declared incompetent by a court, clinicians must rely on *surrogates* to make decisions. If the patient has an advance directive (AD) that identifies a surrogate, legally as well as ethically the patient's choice of surrogate must be respected [13].

In the absence of an AD, clinicians must identify the legally recognized appropriate surrogate. The ideal surrogate is one who best understands the patient's health care-related goals and preferences. In the United States, most states specify by law a hierarchy of surrogate decision-makers (e.g., spouse, followed by adult child, etc.). Clinicians should be aware of the definition of legal surrogate in their locality [17]. When making decisions, a surrogate should adhere to the instructions in the patient's AD (if one exists) and base decisions on the patient's (not the surrogate's) values and preferences if known (i.e., the "substituted judgment" standard) [18].

A corollary to informed consent is *informed refusal*. A patient has the right to refuse any treatment, even if the treatment prolongs life and death would follow a decision not to use it. A patient also has the right to refuse a previously consented treatment if the treatment no longer meets the patient's health care goals, specifically if those goals have changed (e.g., from prolonging life to minimizing discomforts), or if the perceived burdens of the ongoing treatment now outweigh the perceived benefits of that treatment (e.g., quality of life) [19–21]. Honoring these decisions is an integral part of patient-centered care. As described in the AMA Statement on end-of-life care, "[patients are entitled] to trustworthy assurances that preferences for withholding or withdrawing treatment will be honored" [13].

It may not be appreciated by clinicians that "If a clinician initiates or continues a treatment that a patient (or his/her surrogate) has refused, then ethically and legally the clinician is committing *battery*, regardless of the clinician's intent" [14, 15, 22, 23].

After a long discussion with his pastor (religious support), the spouse decides to abide by his wife's wishes and he asks the cardiologist to deactivate his wife's pacemaker. He gives him a written document stating so.

As per the newer 2010 HRS consensus statement, written consent by the patient or surrogate is not required for CIED deactivation [9]. The conversations and rationale for the actions to be undertaken however should be clearly documented by the health care practitioner in the patient's medical record.

Question #2. Is It Legal for the Health Care Provider to Deactivate the Pacemaker According to the Patient and Surrogate Wishes?

The legal precedents and ethical principles are clear on this issue. The patient has the right to refuse and request the withdrawal of CIED therapies regardless of whether he or she is terminally ill or not, and regardless of whether the therapies prolong life and hence death would follow as a consequence of a decision not to use them [13, 14].

Question #3. The Cardiologist Feels Deactivating the Pacemaker in This Pacemaker Dependent Patient Is Akin to "Pulling the Plug" and He Does Not Want to Be Part of Physician Assisted Suicide or Euthanasia. Is Deactivation in This Setting Physician Assisted Suicide (PAS) or Euthanasia?

This issue is very well presented by Zellner et al. [12] in their response to an article in Circulation under the Controversies in Arrhythmia and Electrophysiology by Kay and Bittner and also addressed in the 2010 HRS consensus statement: [9] "Clinicians may be concerned that withdrawing life-sustaining treatments such as CIED therapies amounts to assisted suicide or euthanasia. However, two factors differentiate withdrawal of an unwanted therapy from assisted suicide and euthanasia: the intent of the clinician, and the cause of death." First, in withdrawing an unwanted therapy, the clinician's intent is not to hasten the patient's death, but rather, to remove a treatment that is perceived by the patient as a burden [9, 12]. In contrast, in assisted suicide, the patient intentionally terminates his/her own life using a lethal method provided or prescribed by a clinician. In euthanasia, the physician intentionally terminates the patient's life (e.g. lethal injection). Second, in assisted suicide and euthanasia, the cause of death is the intervention provided, prescribed, or administered by the clinician. In contrast, when a patient dies after a treatment is refused or withdrawn, the cause of death is the underlying disease [12]. United States Supreme Court decisions have made a clear distinction between withholding or withdrawing life-sustaining treatments, and assisted suicide or euthanasia" [24]. The Court ruled that all patients have a constitutional right to refuse treatment, but no one has a constitutional right to assisted suicide or euthanasia. In another case, the Court ruled that "clinicians can legally (and should, from an ethical perspective) provide patients with whatever treatments are needed to alleviate suffering (such as morphine) even if the treatments might hasten death. Criminality is determined by the clinician's intent" [9, 25]. This is a very passionate subject with an extensive body of philosophical literature addressing these issues. For those who want to research this further they can refer to the work of Sulmasy [26].

On a personal level many physicians have not totally come to terms with the philosophical aspects of this issue. This is especially true with regards to the legal aspects of deactivating a pacemaker in a pacemaker dependent patient. A number of surveys have been published in the medical literature expressing the attitudes of physicians of various specialties and subspecialties towards this issue. Over the past decade the comfort level in making these decisions has increased and the associated anxiety has decreased [27, 28].

Question #4. Is the Health Care Provider Obligated to Carry Out the Patient's Wishes?

If a healthcare provider is not able to perform the requested deactivation function, he or she has the right to refuse, but the patient cannot be abandoned and the patient should be referred to a provider who feels comfortable carrying out the wishes of the patient. These wishes are supported by the laws of the United States as discussed above. Even if a patient is not terminally ill, device deactivation can be justified based on the perceived balance of the benefits vs. burdens of such device therapy [12].

Question #5. Is This Clinical Scenario Preventable?

In unexpected situations where undesired ICD shocks are delivered, emergency deactivation can occur. However, situations of surrogates struggling with making a determination or carrying out the wishes of the patient can be prevented by doctor-patient interactions before an illness becomes serious. As stated by Lewis et al. [29], "the time has come to teach and understand" even though two excellent guideline consensus papers on the management of CIED in patients nearing end-of-life exist, there are still a significant number of patients that are dying with their devices active and who are experiencing significant discomfort [7, 29, 30]. The fact that many patients are dying with their ICD devices in an active mode is confirmed by Kramer and colleagues in a recent Circulation publication reporting new data on hospice utilization following cardioverter defibrillator implantation in the older patient population. This is based on data obtained from the National Cardiovascular Data Registry (NCDR) and the Medicare Hospice Data Base and is discussed in more detail below [31].

These CIED end-of-life issues and challenges can be potentially preventable in many cases by evaluating patients and dialoging with them well in advance. These discussions are likely to take place in the primary care doctor's office. As already discussed, there are an increasing number of primary prevention devices that are being implanted [6]. Most of the care that these uncomplicated patients receive is being performed by their primary care providers such as internists, family practitioners or nurse practitioners. These providers may not be knowledgeable as to how CIEDs function nor the technique for withdrawing therapy at the end of life. The issues associated with cardiac device withdrawal are usually not addressed at the CME conferences that they attend [32]. The bulk of this literature has appeared in

either the electrophysiology or palliative care literature. In order for these efforts to be successful there has to be a team approach and a greater educational effort directed at all medical specialties, as they all will be coming into contact with a device patient at one point or another. There has to be a network where health care providers are able to consult with each other regardless of their specialty, that enables them to face issues associated with cardiac device withdrawal.

Another potential barrier that has made the teaching and the planning for end-of-life care including withdrawal of device therapy more difficult has been the increased mobility of the patient due to either health insurance plan coverage changes or socio-economic mobility. For example, families moving from one county to another or to different states in search of a better life. A dialogue started by one particular group of medical healthcare providers in terms of teaching and end-of-life planning may not be reinforced or carried out at all in a different facility.

Data on Current Knowledge, Clinical Practices and Perceptions

Patient Knowledge, Perception and Attitudes Towards ICD Withdrawal at End-of-Life

Most of the studies regarding this issue have been done in the form of interviews or surveys and involved a small number of patients. A small study of 54 patients from the United Kingdom by Rafael et al. [33] demonstrated that most patients were not aware that the ICD could be deactivated. Approximately 84% of the patients wanted to be involved in the deactivation decision of end-of-life issues. Forty percent of patients surveyed felt that this discussion should be held prior to ICD implantation while 16% felt it should be done while the patient was terminally ill and 5% felt it should be done in the last days of life. In another survey study from Prague, 109 patients completed 13 survey questions [34]. About 45% of patients stated that they had never considered ICD deactivation during near end-of-life situations. The topic had only been discussed with 7.3% of patients and 40% of patients wanted more information about ICD deactivation. However 41% of patients who had ICDs for secondary prevention and 22% of patients for primary prevention refused additional information or further discussion on the topic [34].

In a larger study from Sweden, published in PACE in 2014, Stromberg et al. surveyed 3067 patients [35]. The broad aim of the study was to correlate knowledge in relation to end-of-life issues and decisions. The instrument had three domains including experiences, attitudes and knowledge. The experience domain included ten items about patients' actual discussion experiences such as "I have discussed what a battery replacement involves with my ICD doctor or nurse". The answers were scored in a simple yes or no; can't understand, agree or don't agree format. The attitude domain included 18 items about "patient's attitudes toward potential future events." Example: "I want to have the battery in my ICD replaced even if I am

seriously ill suffering from another disease". Or "I want to have the defibrillator shocks in my ICD even if dying of cancer or another serious disease". In the knowledge domain, they were presented with 11 statements concerning end-of-life issues as well as their knowledge of practical functions of the ICD. Only 3% of respondents scored correctly on all of the 11 knowledge questions. Approximately 29% of participants had insufficient knowledge. The authors conclude that insufficient knowledge was associated with indecisiveness in making decisions about ICD deactivation in end-of-life situations and in making decisions about replacing a defibrillator even if seriously ill or dying from a terminal illness [35].

In a more homogeneous study group from the Thoraxcenter Erasmus Medical Center Database in Rotterdam, Netherlands a total of 294 patients completed the survey out of the intended 440 [11]. They were divided into three groups based on the length of ICD therapy from recent implantations to implantation of more than 10 years. Sixty-eight percent of the patients were aware that it was possible to turn the ICD off and 95% of the patients believed that it was important to inform the patient about this possibility. Additionally, 84% of the patients indicated a choice for or against ICD deactivation. The authors concluded that the wish for a "worthy death" at the end-of-life was an independent predictor of a favorable attitude. During the studies the author noted that there was a trend for anxiety and suggested that physicians should take into account patient's anxiety levels when discussing the issue of deactivation [11].

The results of these studies highlight the lack of consensus among patients with implantable devices on the issues of device deactivation at the end of life. However, a large number of patients seem receptive to the idea of better understanding and having open discussions regarding the subject, therefore there is fertile ground for these discussions take place prior to the initial defibrillation implantation. The same can be said for the completion and filing out of an advanced directive (AD). A study from the Mayo Clinic in 2012 showed that about one third of patients in their studies had an advanced directive but only two patients specifically mentioned the ICD in the AD [36]. The conclusion from this paper is that patients should be encouraged to have an advanced directive, which should be updated if done prior to ICD implantation and they should be very clear their desire of deactivation of the ICD or the pacemaker in order to avoid any ethical dilemmas. Clinicians tend to prefer treatment specific statements as opposed to general statements regarding life-sustaining treatments. Is important to emphasize that the thrust of this discussion is not to promote device deactivation or withdrawal of device therapy as a goal of care but to support the patient's decision to have control over his medical treatment and to do it in such a way that allows patients and their families to have an honorable and peaceful death.

Patient opinions regarding who has the responsibility for discussing device deactivation or advanced directives with them were also varied and lacked consensus. In a study from the University of Pennsylvania, Kirkpatrick et al. reported that 35% of responders said the electrophysiologist should discuss the AD; 45% said it should be the general cardiologist and 14% said the primary care physician [37]. Ideally, the physician who has the greatest rapport with the patient should be the one approaching the issue early in the implantation process with support from the cardiologist or electrophysiologist if necessary. Even though a primary care provider

may not be able to go into an in depth discussion of the technical aspects or logistics of cardiac device deactivation, they can approach the subject of the goals of care towards the end of life in the same manner that a Do Not Resuscitate (DNR) order is obtained. Even though there is a DNR order in place, a number of these CIED patients do not have their devices deactivated prior to death. The reasons are multifactorial and can include a simple oversight of the existence of an ICD by the care team. Surprisingly, a significant number of ICD patients that qualify for hospice care do not even have DNR orders towards the end-of-life [31]. The reality is, that most of these discussions do not occur at the time of implant and goals of care change over time. Thus, these discussions require updates to assure that therapies are consistent with treatment goals in the near and long term. Continued educational efforts at every level are paramount and we cannot make assumptions that CIED patients know or have retained information on basic ICD functioning. As discussed earlier [35] lack of device function knowledge could be associated with inability to make some critical end-of-life decisions.

To date, there has been no demonstrated ownership of this issue by any particular specialty. This educational process can take place through cooperation with other specialties, physicians can reach out to each other and consult each other permitting the patient to access to the most accurate information.

There are pamphlets with educational information from medical specialty societies such as the Heart Rhythm Society addressing this issue for patients and their care givers [38]. They discuss the purpose of cardiac devices and options that are available to deactivate an ICD or pacemaker. These pamphlets can be given to patients at the time of their device discharge teaching as part of their discharge packet. It goes without saying that there has to be an introductory discussion otherwise the booklet becomes another "dust catcher" or "trash" as it is the fate of many educational brochures. It should also be available in the device clinics to educate patients and caregivers at all times during their device evaluations. New patients to the device clinic from other geographic areas who have not had any education on this subject should also be exposed. This educational tool can serve as a link for approaching what can be a difficult subject for some medical providers, patients and families. Table 15.1 adapted from the 2010 HRS consensus statement contains useful ideas that we feel can be incorporated in a teaching/planning strategy [9].

Table 15.1 Communicating with patients and families about goals of care relating to CIEDs

1.	Determine what patients/families know about their illness
2.	Determine what patients/families know about the role the device plays in their health both now and in the future
3.	Determine what additional information patients/families want to know about their illness
4.	Correct or clarify any misunderstandings about the current illness and possible outcomes, including the role of the device
5.	Determine the patient/family's overall goals of care and desired outcomes
6.	Using the stated goals as a guide, work to tailor treatments, and in this case, management of the cardiac device in conformity to these goals

Adapted from HRS Expert Consensus Statement [9]

Clinicians' Knowledge, Perception and Attitudes Towards ICD Withdrawal at End-of-Life

There is limited data evaluating the perception, opinions or perspectives of healthcare providers with regards to withdrawal or withholding of device therapy or dealing with these issues at end-of-life. What can be said in reviewing the literature is that some of these opinions and perspectives have changed significantly over the last decade. Farber et al. in 2006 surveyed 1000 internist and internal medicine subspecialists about their views on withholding or withdrawing life-sustaining treatment [28]. Only 41% of those surveyed responded. The survey included 32 hypothetical cases where 51% of responders were willing to withhold or withdraw treatment in all of the 32 hypothetical scenarios. Respondents were less likely to withhold or withdraw treatments in patients who were not terminally ill. The authors noted that 49% of respondents would be unwilling to withhold or withdraw treatment in at least one scenario. This is in contrast to the results of a study from the Mayo Clinic from 2010 where 658 medical and legal professionals were surveyed, (that survey also included patients) [39]. In this study there was almost complete consensus among legal professionals, medical professionals and patients that if a terminally ill patient requested that his or her ICD be turned off that they would agree. The opinions began to differ when it came to turning off a pacemaker in a pacemaker dependent patient. In this case, 81% of legal professionals compared to 58% of medical professionals agreed with turning off the pacemaker in a pacemaker dependent patient. Medical professionals were more likely to perceive turning off an ICD as being legal compared to turning off a pacemaker (85 vs. 41% $P < 0.001$) [39].

Even though there have been significant educational and philosophical discussions over the years regarding this issue in the medical literature, healthcare providers continue to struggle in coming to terms with some of these decisions. It is clearly easier for legal professionals to see pacemakers and defibrillators as similar and to accept readily withdrawal or withholding medical therapies even in non-critically ill patients. Obviously, they have a comfort level that most physicians will probably never achieve. This is highlighted in a recent online survey conducted by physicians from the University of Pennsylvania and New York University Langone Medical Center [27]. Email surveys were sent out to 1894 electrophysiology practitioners. Out of these 384 responses were collected. The sample included respondents from Europe, Asia, Australia, South America and Africa but the majority were from North America (78%). The electrophysiologists surveyed felt that deactivation of the ICD shocking function in agreement with patient wishes and a pre-existing DNR order would not be considered physician-assisted suicide (93.2%). Surprisingly, however, only 77.1% felt that it was not ethical/moral for doctors to deactivate ICD *against* patients' or family/surrogates' wishes. The international sample of responders considered ICD and pacemaker deactivation to be ethically distinct. Cardiac pacemakers were considered to be like dialysis therapy that keep these patients alive [27]. These views as mentioned above are different compared to legal professionals.

These views or opinions are influenced by a number of factors including prior experiences, social up-bringing, religion as well as other unknown variables. In a recent survey published in the Journal Religious Health, physician religiosity was associated with finding withdrawal more ethically problematic, but not finding it more psychologically difficult [40]. The authors concluded that most United States physicians find withdrawing life-sustaining therapies not only more psychologically difficult but more ethically problematic than withholding such treatment.

Framework or Strategies to Guide Providers in the Withdrawal of Device Therapies

As background to this section, the legal, ethical and religious principles surrounding withdrawal of cardiac device therapies have been discussed. The perceptions of patients as well as healthcare providers that are available in the medical literature were reviewed. It is now important to develop a framework for providers to engage patients in identifying goals of care and execute strategies for CIED therapy withdrawal if appropriate. Withdrawal of cardiac device therapy can be requested at any time by patients or caregivers. The most familiar scenario is that associated with the potential of frequent painful shocks toward the end-of-life especially in the setting of a terminal illness. Goldstein et al. reported that 20% of patients can receive painful shocks which can decrease the quality of life during the last days or weeks of their lives [7].

Other authors have reported that up to 31% of patients received shocks in the last 24 h of life [30]. In a MADIT-II trial Substudy, Sherazi et al. reported similar findings [41]. Lewis et al. confirmed this, but in addition they demonstrated that a strategy that minimizes pain and suffering at end-of-life can be implemented [29]. This was a retrospective study that reviewed the charts of 90 patients who died between 1994 and 2004. Sixty-three patients were included. Group 1 (20) were patients whose defibrillator was turned off through a comprehensive comfort care approach. Group 2 (43) included patients whose clinical course was so rapid that the defibrillator could not be turned off before their illness arose. As the pacing function was not withdrawn in either group, important information regarding pacing at the end-of-life was not addressed in this study. The patients in Group 1 had chronic illnesses that were identified from a medical history obtained during their visits to the clinic. Ideally, the goals of care would be to avoid painful or inappropriate shocks towards the end-of-life. In this study even with careful planning patients in Group 1 received shocks but significantly less than those in Group 2 [29]. The timing of a compassionate care strategy can be difficult because shock therapy needs to be available to patients up until death from the terminal illness is imminent. In Group 1, the actual time between the device being turned off and death was short at 49 +/−89 days [29]. Adopting a compassionate strategy as discussed above can potentially alleviate stressful end-of-life situations for healthcare providers, patients and their loved ones.

Ten years after the above paper was written, the demographics are much different. The number of primary prevention ICDs in elderly patients with chronic illness has increased dramatically, with over 50,000 devices being inserted annually in patients over the age of 65 [42]. The recent study by Kramer et al. is the only study to date to evaluate hospice care in ICD patients over 65 years of age [31]. Only patients that were matched to the Medicare database were included. Probabilistic matching to the Medicare data yielded the final analytic cohort of 194,969 patients. The results showed that 11.5% of patients were enrolled in hospice during the 5 year follow-up period. For those patients that were enrolled in hospice, the median time from ICD implantation to hospice enrollment was 1.3 years. A total of 36.8% of decedents received hospice services. The data presented above according to the authors "underscores the need for hospital hospice providers to prepare to care for dying ICD patients including establishing protocols for turning off such devices and avoiding shocks at end-of-life" [31]. This includes simple measures such as having a doughnut magnet that when applied over the defibrillator site can inhibit shocking therapies from the defibrillator as long as the magnet is in contact with the skin or thin clothing over the device. Once the magnet is removed ICD function can resume as was initially programmed (Fig. 15.1). This problem is further compounded by the fact that 5 years post implantation 51% of the older ICD patients were either dead or in a hospice and thus calls for a greater understanding of the broader palliative care needs of the older ICD patients and how to improve strategies to deliver that care. Even though the emphasis of this chapter is on withdrawing cardiac device

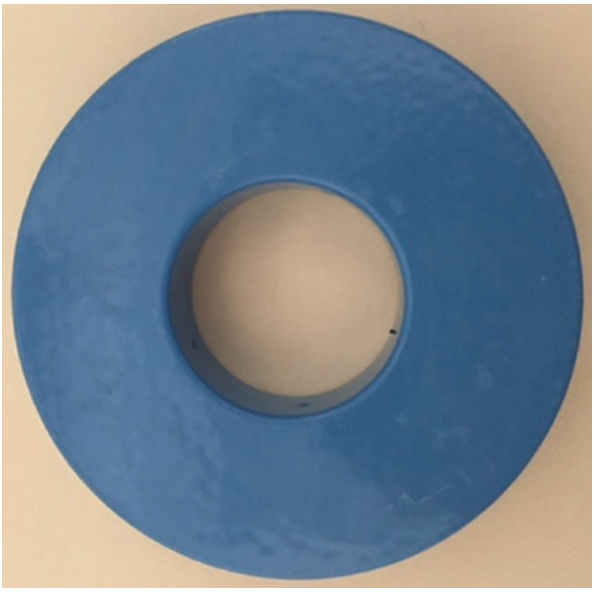

Fig. 15.1 A "doughnut" magnet used to disable therapies from an implantable defibrillator. This magnet is placed directly over the ICD to stop unwanted ICD shocks

therapy, in our opinion the hospice data presented above highlights the importance of appropriate patient selection for ICD therapy while refraining from offering it to very high risk patients, whose prognosis from other comorbid conditions tips the scale of the potential risk/benefit ratio [43].

The appropriate selection criteria for patients who will benefit the most from a primary prevention ICD has eluded electrophysiologists for years. This area is very fertile for future research especially when it comes to elderly patients with multiple comorbidities. In the data presented by Kramer and Associates, some of the factors that were most strongly associated with shorter time to hospice enrollment where older age, Class IV heart failure, and ejection fraction less than 20% [31]. If we had a better way of risk stratifying these patients who will be entering hospice soon after their device implantation perhaps these withdrawal issues could be minimized. As reviewed earlier it is easier for physicians to accept withholding device therapies than withdrawing and the decision could be made even easier with more guideline appropriate data [27, 37, 39]. With better patient selection, the problem of withholding therapies would not completely resolve but could potentially be decreased. In the current literature, there are a number of already published clinical variables that can help identify potentially high risk patients for death not preventable by an ICD. Perhaps an algorithm can be developed to help manage this clinical issue. Updating recommendations to the device therapy guidelines based on current or new data seems like a good place to start.

Conclusion

As discussed above the pain from an implantable cardioverter defibrillator ICD shock during the terminal phase of an illness or the anxiety of potentially receiving such a shock can be contrary to the goal of dying a peaceful death in comfort and dignity. When a patient with an ICD develops a new diagnosis of a terminal illness, the options of disabling defibrillator therapies should be included in the broader discussion of end-of-life care much like a do not resuscitate status is discussed. Over the years physicians have become more comfortable with obtaining a “code status” i.e. DNR status in patients who have chronic terminal illnesses. Discussions regarding deactivation of ICDs or turning off pacemakers could achieve the same level. Patients with these implantable devices should be encouraged to complete an advanced directive in which they should specify their decisions regarding the device. Educating patients about the many options available would aid patients in making these decisions. Early education and conversations at the time of referral for device implantation can make end of life transition more focused on comfort and not on frantically attempting to stop undesired shocks. Careful thought and consideration should be given when offering device therapies to patients who have competing risks and who will have minimal benefit from preventing an arrhythmic death. It is important to remember that according to current device therapy guidelines

implantation in those whose potential survival is less than a year is considered a class III indication.

It is our hope that the information provided in this chapter will help to educate and support healthcare providers, in making these challenging and emotionally draining decisions.

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