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Deactivation of Implantable Cardioverter-Defibrillators in Heart Failure

A Systematic Review

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Implantable cardioverter-defibrillator aids in the prevention of cardiac arrest by delivering an electrical shock in the presence of life-threatening ventricular arrhythmias. Although implantable cardioverter-defibrillators are essential to sustain life in patients with end-stage heart failure, it is important to consider the option for prompt deactivation of implantable cardioverter-defibrillators to prevent inappropriate electrical shocks at the end of life where death is inevitable. In this systematic review, available literature was reviewed, using six electronic databases, to identify problems that may delay the deactivation of implantable cardioverter-defibrillators and address possible considerations for implantable cardioverter-defibrillator management to improve end-of-life care. Studies reported low occurrence of deactivation discussions, lack of knowledge regarding implantable cardioverter-defibrillator deactivation among most patients, and provider's perception of being unqualified to initiate discussion and perform deactivation of implantable cardioverter-defibrillator. A need for additional patient and provider education and periodic discussions between patient and provider on implantable cardioverter-defibrillator deactivation should occur, as well as development of protocol or policy to guide care at the end of life.

KEY WORDS

deactivation, end of life, heart failure, implantable cardioverter-defibrillator

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According to the Centers for Disease Control and Prevention, it is estimated that more than 5.74 million adults in the United States are experiencing heart failure (HF).[1] The prevalence of HF is expected to rise to 46% by 2030, resulting in an estimated 8.0 million people living with HF.[2] Currently one in nine deaths is related to HF in the United States, with an estimated mortality rate of 40% within the first year of diagnosis and an increasing risk up to 75% at 5 years.[2]

With advancements in technology, implantable cardioverter-defibrillator (ICD) devices can extend life expectancy in patients with HF.[3] They are routinely used in patients with end-stage HF[3] to prevent cardiac arrest by recognizing life-threatening cardiac arrhythmias and generating internal electrical shocks in an attempt to restore a normal cardiac rhythm.[4]

It is estimated that 31% of patients with ICDs will experience one or multiple shocks within the last 24 hours of life, with 24% of patients receiving at least one shock within the last hour of life.[5] Patients can consequently experience pain after each electrical shock; this effect can further provoke negative responses of anxiety and distress in both patients and caregivers.[6] Although ICDs provide lifesaving therapy that is evidently beneficial to patients, it is essential to consider whether the continuation of ICD therapy is appropriate in patients with end-stage HF and at the end of life when death becomes inevitable.

The purpose of this systematic literature review was to identify problems that may delay the deactivation of ICD and address possible considerations for ICD management to improve end-of-life care in adult patients with HF.

METHODS

Six electronic databases of Cumulative Index to Nursing and Allied Health Literature, Cochrane, EMBASE, Ovid, PubMed, and Scopus were used for this literature review. The key words used were "deactivation," "end-of-life," "heart failure," and "implantable cardioverter-defibrillator." In each database, the initial literature search process was replicated in the exact manner that included all four key

words separated by the word "and" and searched within "All Fields" or "Search All Text" of the articles.

The search results were then limited to (1) clinical studies in the past 10 years (2007-2017), (2) adults 18 years or older, and (3) English language. The inclusion criteria were as follows: (1) quantitative or qualitative studies, (2) patients with ICD, (3) patients with HF, (4) full-text articles, (5) outcomes that identify problems that may delay the deactivation of ICD, and (6) end-of-life considerations of patients with an ICD.

A total of 242 articles were identified from the six databases: Cumulative Index to Nursing and Allied Health Literature (n = 2), Cochrane (n = 2), EMBASE (n = 14), Ovid (n = 10), PubMed (n = 9), and Scopus (n = 205). Duplication of the articles was removed, resulting in 211 articles to screen. During the screening process, 145 articles were excluded resulting in 66 full-text articles to assess for eligibility. A net total of nine studies that met the inclusion criteria noted previously were included in this literature review, composed of five quantitative studies and four qualitative studies. For further details regarding the screening and selection process of these studies, see Figure.

RESULTS

In this literature review of nine studies published between 2008 and 2016, a total of 25 132 adult participants were evaluated; of that, 24 770 participants were patients with ICDs and 362 participants were physicians who encounter patients with ICDs. Eight of the nine studies were class III level of evidence, and one study was class II. No randomization was conducted in any of the studies. For a summary description of the study design, patient demographics, clinical characteristics, outcome assessment, and results of each study, see Table.

Findings were organized into three categories of (1) clinical practice and management of ICD deactivation, (2) patient perceptions of ICD deactivation, and (3) provider perceptions of ICD deactivation. These categories provide a methodical approach to identify contributing factors that may delay the deactivation of ICD, thus addressing possible considerations to improve end-of-life ICD management in adults with end-stage HF.

Clinical Practice and Management of ICD Deactivation

This section evaluates clinical practice and the logistics pertaining to the management of ICD deactivation using four quantitative retrospective studies. Three of the four studies focus on circumstances of ICD deactivation, including the use of advance directives (ADs) and consent forms. The fourth article evaluates the clinical outcome in relation to timing of ICD deactivation.

In one study, 150 patient records were reviewed for data-related features of the ethics related to the circumstances of cardiac device deactivation in patients.[8] Of the 150 patients, 135 patients had ICDs and 15 patients had pacemakers. Requests for deactivation of cardiovascular implantable electronic devices were made by 74 patients (49%), whereas the remainder of requests were made by surrogate decision makers (51%). Most patients died shortly in a median (range) of 2 days after deactivation, a reflection of how severe the progression of illness was during the time frame in which the decision to deactivate the ICD was made. There were 64 patients (43%) with palliative medicine consultations, but only in 44 patients (69%) was cardiovascular implantable electronic device management addressed. Eighty-five patients (57%) had ADs, but only one patient had specifically mentioned the management of his/her ICD during the end-of-life phase. Most cardiac device deactivations were carried out by nurses (55%), followed by physicians (31%) and industry-employed allied professionals (15%).[8]

Another study retrospectively evaluated 24 291 patients with HF during 44 768 admissions within a 5-year time frame.[9] Only 3077 patients (12.7%) had documented ADs. Those with ADs had significantly more palliative care consults than those without ADs (23.0% vs 9.9%, $P \leq .0001$). Older age, female sex, white race, higher socioeconomic status, higher risk for adverse in-hospital outcomes, length of stay greater than 5 days, hospice discharge, palliative care consult, and a "do not resuscitate" (DNR) order were all associated with a higher chance of having documented ADs.

Another aspect of the clinical practice regarding ICD deactivation is the consenting process for the initial placement of an ICD. A retrospective cohort study of 91 patients evaluated the documentation specifically addressing end-of-life discussion when obtaining consent for first-time ICD placement.[15] Only one patient had a consent form with documentation stating the option for ICD deactivation at the end of life,[15] noting that, if the patient feels dissatisfied with the quality of life or became disinterested in ICD therapy, deactivation could occur.

A retrospective cohort study examined patterns of ICD management near the end of life and the clinical outcomes.[16] Ninety-eight patients were examined and categorized into three groups: group 1 had 15 patients who underwent ICD deactivation, group 2 had 36 patients without ICD deactivation but were in hospice care or had DNR orders, and group 3 included 83 patients without ICD deactivation who were not in hospice care and did not have a DNR order.[16] Within the 24-hour period before death, no shock was delivered to any patients in group 1 in contrast to shocks delivered in groups 2 (one patient) and 3 (three patients). In group 1, the requests for deactivation were often initiated by patients and family members (53%) and commonly influenced by the patient's rapid

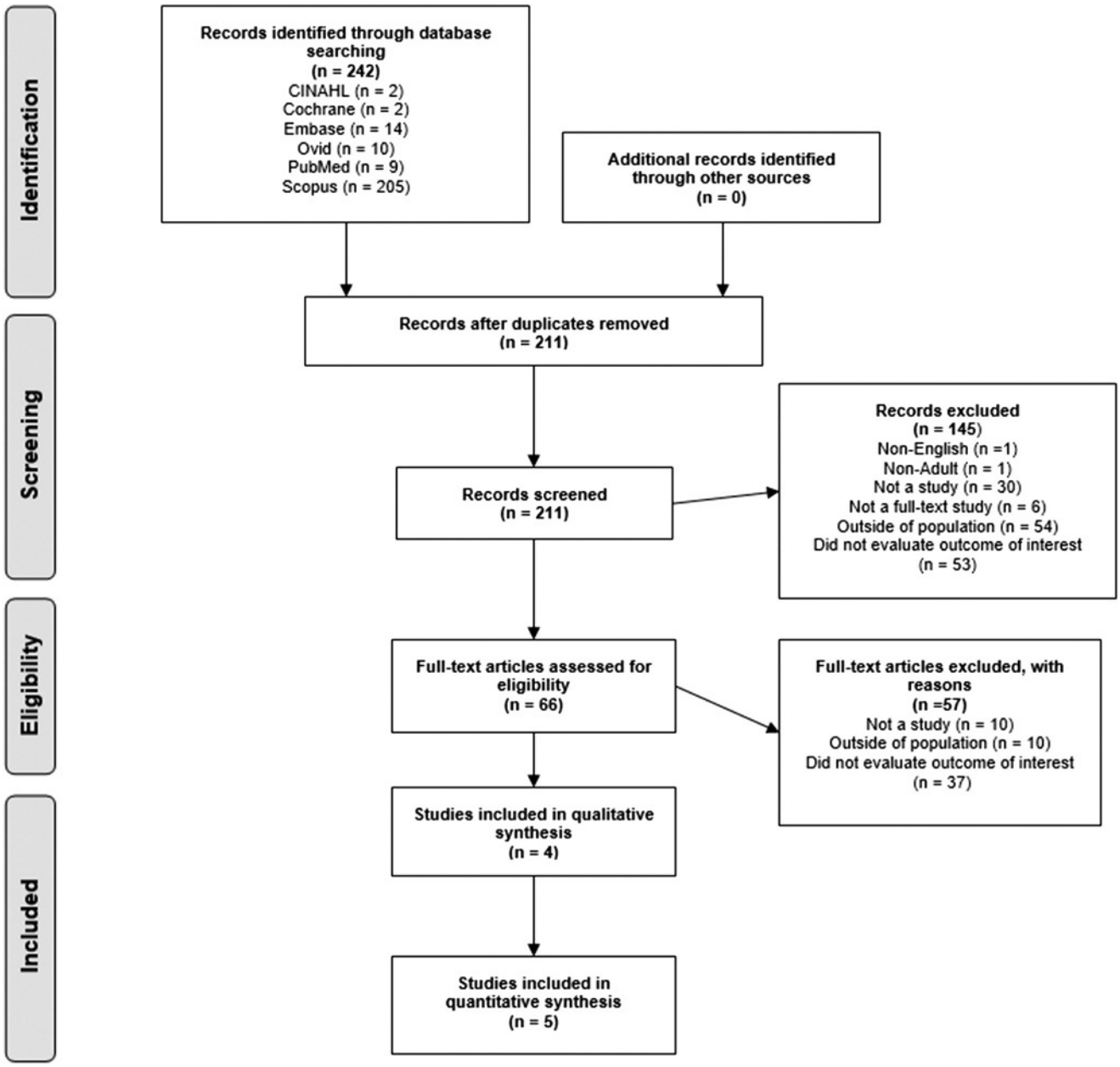

FIGURE. PRISMA Flow Diagram.[7]

deterioration in clinical status during hospitalization and desire for comfort care rather than aggressive treatments.

Patient Perceptions of ICD Deactivation

This section evaluates the patient perceptions of ICD deactivation using two qualitative studies and one quantitative study.

A qualitative study consisting of 15 patients with ICDs were assigned to one of four focus groups. Assignments were based on the time of ICD implantation and whether the patients have ever received electrical shock(s) from their ICD.[10] In all four groups, patients did not understand accurately the indication for an ICD and its role in the context of their health. All patients described having anxiety regarding future shocks but viewed ICD therapy as exclusively beneficial to their health. None of the participants recalled having a discussion with their provider about deactivation and knew that the option of ICD deactivation existed. Three participants stated that they would look to providers to tell them when to deactivate their ICDs.

Another qualitative study also addressed patient perceptions in the setting of semistructured face-to-face interviews with 25 patients.[14] Patients identified three stages where they felt the discussions of ICD deactivation should occur: (1) before implantation, (2) with any significant

TABLE Summary of Evidence

Reference: Study Topic	Level of Evidence, Study Design, N, and Demographics	Findings and Conclusion
Buchhalter et al,[8] 2014: ''Features and Outcomes of Patients Who Underwent Cardiac Device Deactivation''	Level of evidence, 3 Retrospective cohort N = 150 patients; 135 patients with ICDs and 15 patients with PM Median age, 79 y; age range, 31-95 y 101 men	• 99% had poor or terminal prognoses. • 79% underwent deactivation of tachycardia therapies only. • 21% underwent brady therapies with or without tachy therapies. • 51% of deactivation requests were made by surrogates. • 57% had advanced directives. • Only one mentioned the device. • Most requests for implantable electronic device deactivation were for ICD tachy therapies only. • Many requests were made by surrogates. • AD rarely discussed device management. • Regardless of therapy, most patients died shortly after device deactivation. • Patients with devices should engage in advance care planning to ensure that future care is consistent with their preferences.
Butler et al,[9] 2015: ''Advance Directives Among Hospitalized Patients With Heart Failure''	Level of evidence, 3 Retrospective cohort N = 24 291	• Older age, female sex, white race, higher socioeconomic status, higher risk for adverse in-hospital outcomes, LOS > 5 d, hospice D/C, palliative care C/S, and DNR order were all associated with a significantly higher chance of having documented ADs. • More than 80% of the patients did not have ADs in medical records at the end of study period. • Less than 17% of the patients older than 65 y and <9% of the patients had ADs. • Modest trend of increasing ADs from 2008 to 2013 • Most patients did not have documented ADs on record. • Major opportunities exist for all subgroups with HF to improve documentation of ADs.
Goldstein et al,[10] 2008: patient's attitudes toward deactivation of ICDs	Level of evidence, 3 Qualitative study N = 15	• Even with misunderstanding of their device, patients in all groups described anxiety when thinking about future shocks regardless of whether they had previously experienced a shock. • Regardless of whether or not the participant received a shock, all participants described ICD as only beneficial. • Three stated that they would look to providers to tell them when to deactivate ICD. • Large part of the group was spent explaining to patients that, as their health change, there might come a point at which they would want the device deactivated. • Patients would not engage in conversations about device deactivation nor did they seem willing to have conversations with providers. • None of the patients recalled having a conversation with providers about deactivation, and none knew that deactivation was an option.

(continues)

TABLE Summary of Evidence, Continued

Reference: Study Topic	Level of Evidence, Study Design, N, and Demographics	Findings and Conclusion
Herman et al,[11] 2013: patients' views on deactivation of ICDs	Level of evidence, 3 Qualitative study N = 109	• Most patients felt safer after ICD implantation perceiving that their health had improved. • Patients often overestimate the benefits and have unrealistically high expectations regarding ICD implantation. • No difference between those who have been shocked vs those who had not. • Increased number of secondary prevention patients—no interest in discussing deactivation. • Half of the patients had considered switching off their ICD as part of their near end-of-life decisions. • Before ICD implantation, there was a complete discussion with the patient regarding the benefits. • Most patients wish to be better informed regarding ICD deactivation as part of their near end-of-life decision-making process. • Preimplant awareness was 79.8% ± 27.6%. • 90.8% of the patients felt safer after ICD implantation, • 78% ICDs, primary prevention; 22% of the patients had secondary prevention. • 37.7% of primary prevention vs 25% from the secondary prevention group indicated that they would consider deactivation of their ICDs. • 45.9% of the total patients indicated that they had never thought of ICD deactivation. • 7.3% reported that they had discussed the topic with a doctor. • 40.1% of the patients wanted more information regarding ICD deactivation. • 28 (25.7%) categorically refused any additional information on deactivation.
Kelley et al,[12] 2009: management of ICDs at the end of life	Level of evidence, 3 Qualitative study N = 1558	• Providers take patients' circumstances into account basing discussion on the quality of their relationship with the patient, patient's perceived QOL, and code status/DNR order. • Geriatricians and general internists reported inadequate knowledge and awareness of ICD fxn. • Providers delay or postpone discussion of ICD deactivation in lieu of more aggressive treatments. • Providers believe that discussion of ICD deactivation is not their responsibility. • 35% stated that they might discuss deactivation. • 12% would postpone discussions until later time. • 21% suggested that additional treatments or therapies should be tried before discussing device deactivation. • 17% of providers thought that they should be the ones to first address the discussion. • 9% stated that they did not have enough education/awareness to discuss deactivation.

(continues)

TABLE Summary of Evidence, Continued

Reference: Study Topic	Level of Evidence, Study Design, N, and Demographics	Findings and Conclusion
Kramer et al,[13] 2010: views of physicians regarding ICD deactivations	Level of evidence, 3 Quantitative study N = 185 providers	• Providers more often reported having participated in the withdrawal or removal of: ○ Mechanical ventilation (86.1% vs 33.9%, $P < .0001$) ○ Dialysis (60.6% vs 33.9%, $P < .001$) ○ Feeding tubes (73.8% vs 33.9%, $P < .0001$) • Providers were consistently less comfortable discussing cessation of PMs and ICDs compared with other life-sustaining therapies (P .005). • Only 65% of providers correctly identified legal status of euthanasia in the United States. • 20% accurately reported the legal status of provider-assisted suicide in the United States. • Compared with deactivation of ICD, providers more often characterized deactivation of a PM in a pacemaker-dependent patient as ''provider-assisted suicide'' (19% vs 10%, $P = .027$) or euthanasia (9% vs 1%, $P < .001$).
MacIver et al,[14] 2016: patient perceptions of ICD deactivation discussions	Level of evidence, 3 Qualitative study N = 25	• Patients identified three stages where they felt ICD deactivation should be discussed: 1. before implantation 2. with any significant deterioration but while they were of sound mind to engage in and communicate their preferences 3. at the end of life, where patients wished further review of their previously established preferences and decisions about ICD deactivation • Most patients (n = 17, 68%) said that they would consider deactivation, six (24%) were undecided, and two (8%) were adamant that they would never turn it off.
Niewald et al,[15] 2013: documented consent process for ICDs and implications for end-of-life care	Level of evidence, 3 Retrospective cohort N = 91 patients	• Only 1 of 91 had documentation of a discussion regarding device impact on future end-of-life care.
Sherazi et al,[16] 2013: end-of-life care in patients with ICDs	Level of evidence, 3 Retrospective cohort N = 98 patients Group 1, with ICD deactivation Group 2, without ICD deactivation who were in hospice care or had DNR orders Group 3, without ICD deactivation who were not in hospice care nor had DNR orders	• 52% of all deaths occurred first after ICD implantation • Groups 2 and 3 (n = 83), no documentation of discussion regarding ICD deactivation • Group 1 (n = 15), with ICD deactivation from 0 to 71 d before death • Group 2 (n = 36), without ICD deactivation who were in hospice care or had DNR orders • Group 3 (n = 47), without ICD deactivation who were not in hospice care nor had DNR orders • 19 patients received 59 appropriate shocks; 7 patients received 17 inappropriate shocks in last 30 d • Most common symptoms associated with shock therapy: syncope, presyncope, palpitations, and dyspnea; but for a large proportion of patients, symptoms associated with shock remained unknown.

Abbreviations: DNR, do not resuscitate; fxn, functions; ICD, implantable cardioverter-defibrillator; LOS, length of stay; PM, pace maker; QOL, quality of life.

health deterioration, and (3) at the end of life, which was defined as terminal deterioration. Most patients (68%) said that they would consider ICD deactivation, whereas 24% were undecided, and 8% were adamant that they would never deactivate the ICD.

Another quantitative study addressed the patient views of ICD deactivation by surveying 109 patients from routine outpatient follow-up visits.[11] From this survey, 99 patients (91%) felt safer after ICD implantation, and 66 patients (61%) reported a sense of improved health status after implantation. Only eight patients (7%) had discussions with their providers regarding ICD deactivations. Fifty patients (46%) indicated that they had never considered ICD deactivation during end-of-life situations. Forty-four patients (40%) wanted more information about ICD deactivation in contrast to 29 patients (27%) who refused any additional information pertaining to deactivation. In looking at correlations between answers, patients who indicated that they felt safer after ICD implantation were less likely to consider deactivating their ICDs ($r = -0.245$, $P < .005$), patients who considered ICD deactivation also indicated that it would be a personal decision without family discussion ($r = 0.238$, $P < .05$), and patients who live alone would consider ICD deactivation in near end-of-life situations ($r = -0.21$, $P < .025$).

Three of these studies[10,11,14] all share similar findings identifying that most patients are uninformed about ICD deactivation, most patients are interested in learning more about deactivation of ICD, and there exist some patients who refuse to engage in any discussion pertaining to ICD deactivation.

Provider Perceptions of ICD Deactivation

This section evaluates provider attitudes toward ICD deactivation using one qualitative study and one quantitative study.

A qualitative study was conducted with 177 completed surveys by physicians regarding discussion surrounding ICD deactivation.[12] Thirty-eight physicians (36%) reported that initiating the discussion of ICD deactivation would depend on specific circumstances, with only 24 physicians (13%) accepting responsibility for these discussions. Only 27 physicians (15%) believed that the topic of ICD deactivation is important, and 13 physicians (7%) expressed that patient or family should be the first to initiate the discussion. In readiness to pursue palliative care, 38 physicians (21%) preferred initiating life-prolonging therapies in contrast to six physicians (3%) who endorsed deactivation discussion and suggested additional palliative treatments. Sixteen physicians (9%) expressed lack of education and awareness regarding ICDs.

In the quantitative study, a convenience sample survey was used to examined providers' experiences and ethical/legal views surrounding ICD deactivation using a 0-to-10 Likert scale.[13] In the 185 responses, there was a significant finding ($P = .005$) that physicians are less comfortable discussing deactivation of ICDs compared with other life-sustaining therapies, such as ventilation, dialysis, and tube feeds. One hundred twenty physicians (65%) correctly identified legal status of euthanasia in the United States, but only 37 physicians (20%) can accurately report legal status of "physician-assisted suicide."

Both of these studies[12,13] identified that physicians do not feel comfortable and are not prepared to have ICD deactivation discussions.

DISCUSSION

Discussions with patients about deactivating ICDs are uncommon, and thus, patients are not informed about this option at the end of life.[8] There are a variety of reasons these conversations do not occur, and this literature review reveals some of the causes. These causes are categorized into three foci in a strategic attempt to clarify this controversial topic. They are (1) clinical practice and management of ICD deactivation, (2) patient perceptions of ICD deactivation, and (3) provider perceptions of ICD deactivation.

Clinical Practice and Management of ICD Deactivation

Ethically complex situations are increasingly more common with the advancements of medicine and technology used to extend life expectancy in acute and chronic illnesses. Historically, ICD deactivation has not been approached in a consistent manner. In this section, some barriers and complexities to managing ICDs at the end of life become evident. Implantable cardioverter-defibrillators are often not deactivated until the patient's condition becomes severe. As evident in a previously mentioned study,[8] the findings indicate that perhaps patients are waiting too long to request ICD deactivation, thus promoting the need for an early initiation of discussions regarding ICD deactivation. This point is further supported in a second study[16] that noted that the most common event leading to the deactivation of an ICD was a rapid decline in the patient's condition. Patients are waiting until their condition markedly declines before requesting that their ICDs be deactivated. When patients are hospitalized, they are often cared for by providers other than their usual primary care provider. This promotes inconsistency with the patients' care leading to fragmented care and, ultimately, lack of provider trust during these difficult situations.

An AD is a valuable tool to aid the management of care in patients who lose cognitive capacity. Advance directives provide family members and health care providers information that outlines a patient's preferences related to interventions in the event that a patient is incapable of making medical decisions. It was found that most patients with HF did not have an AD documented in their medical record[8]

and for those that did rarely was ICD deactivation mentioned. There is also very limited documentation noting the discussion of the ICD's impact on patients at the end of life.[15] These findings highlight a great need for discussions about ICDs and their effect on patients at the end of life. They also emphasize the need for including ICD management at the end of life into advanced care planning discussions.

Patient Perceptions of ICD Deactivation

The studies reviewing patient perceptions reveal that patients lack appropriate knowledge pertaining to their ICDs and the available option of ICD deactivation.[10,14] In many cases, patients do not understand the impact their ICDs have on their life, and they had never previously thought of deactivating their ICDs. Patients with ICDs deserve the right to be fully informed about the risks and benefits of ICD therapy, including how an ICD is cared for during the end of life before implantation of the device. The reason for patient's lack of knowledge regarding ICD is likely multifactorial, attributed by both patient and health care provider perceptions. Because patients are unaware of how the ICD functions and what may occur during the end-of-life period, patients may experience unnecessary ICD shocks and reduced quality of life at the end of life. In light of this, most patients within these studies desire more information regarding ICD deactivation at the end of life.[11]

Provider Perceptions of ICD Deactivation

There are many reasons ICD deactivation discussions do not occur routinely, and provider perceptions greatly influence the delay in discussions involving ICD deactivation at the end of life. Health care providers are tasked with the responsibility to ensure their patients have a complete understanding of ICD operations and when it may be time to deactivate before implantation of the device. It is also the health care providers' responsibility to ensure the patient understands their options regarding the management of their ICDs at the end of life. It was found that many physicians reported that they would initiate a discussion about ICD deactivation depending on the situation.[12] One example of such a situation is when a DNR order is generated. However, this can complicate care because, as mentioned previously, deactivation of ICDs is frequently preceded by a rapid deterioration in one's health status requiring hospitalization and the decision to deactivate the DNR status and initiate comfort care. Geriatricians and general internists stated that they lacked knowledge regarding ICDs. Findings showed that physicians felt more comfortable having discussions about deactivating life-sustaining treatments other than pacemakers and ICDs.[13] Other providers felt that it was the patient/family's responsibility or another physician's responsibility to initiate conversations regarding ICD deactivation.[13] Reasons for this could be that providers are not educated appropriately about the management of ICDs. Another reason could be that the primary care provider believes that the cardiologist should be initiating these conversations and vice versa. Regardless of the reason, patients are not having the conversations that are required to be fully informed about the ICD.

Methodological Limitations

There are several limitations to be acknowledged in this literature review. Because a randomized trial regarding end-of-life management of ICD deactivation in patients with HF has yet to be performed, only observation studies or studies that use historical data were used in the pooled analysis and, as such, are subject to bias. Most of the studies were composed of a small sample population originating from a single institution, thus limiting the generalizability of these results to larger populations.

CONCLUSION

In conclusion, the prevalence of ICDs is increasing as HF becomes more prevalent. There are a lack of patient and provider knowledge and provider discomfort in initiating a discussion around ICD deactivation. This suggests the need to educate providers on the importance of patient education about ICDs and the available options for ICD management at the end of life. Development of a protocol that would guide providers caring for patients with an ICD in ways to address end-of-life issues and concerns is needed, followed by studies to determine its effectiveness. In the meantime, education of patients and providers involved in the determination of end-of-life care is greatly needed.

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