Patient (2014) 7:243–260
DOI 10.1007/s40271-014-0055-2

REVIEW ARTICLE

Making Decisions About Implantable Cardioverter-Defibrillators from Implantation to End of Life: An Integrative Review of Patients' Perspectives

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Abstract Implantable cardioverter-defibrillators (ICDs) are used for patients at risk of sudden cardiac death. Patients considering ICD therapy are faced with several preference-sensitive decisions. Our aim was to explore patients' ICD decision-making experiences from the decision to implant to the consideration of deactivation at end of life. We conducted an integrative review using Whittemore and Knafl's five steps. MEDLINE, CINAHL, PubMed, PsycINFO, and the Cochrane library were searched from 2000 to 2013. Eligible studies focused on the patient response regarding ICD decision-making. Key themes were identified and used as a framework to discuss findings through the chronological course of decisions faced by these patients. Of 354 potential citations, 25 articles were included. The trajectory of key decision points was whether or not to initiate ICD therapy, replace the battery, and deactivate at end of life. Three common themes from patients' perspectives were the influence of the patient–practitioner consultation on knowledge uptake, patients' decision-making preference, and their desire to live. Patients faced with ICD-related decisions often misunderstood the functionality of their ICD, or overestimated its benefit. They also expressed mixed preferences for the desire to be involved in decisions. The decisions around ICDs are particularly difficult for patients given the life and death trade off. Clinicians involved in the care of these patients could better support them by verifying their understanding and eliciting their preferences. Using a shared decision-making approach has the potential to achieve improved patient outcomes.

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Key Points for Decision Makers

When a patient is identified as a potential candidate for an implantable cardioverter-defibrillator (ICD), they embark upon a decision-making trajectory for the tenure of their implanted device.

To achieve informed consent, patients need to understand their options (including the option to deactivate the device) and the benefits and harms of ICD therapy.

Given the chronic nature of the condition, patients will need to revisit their decision to maintain ICD therapy with battery changes and/or as their health state changes.

Clinicians could better support patients facing these decisions by using a shared decision-making approach.

1 Introduction

Clinical evidence supports the use of implantable cardioverter-defibrillators (ICDs) for patients at risk of sustained ventricular arrhythmias and sudden cardiac death [1–3].

ICD therapy used for patients who have survived a cardiac arrest or a sustained ventricular arrhythmia is referred to as a secondary prevention indication [4]. Primary prevention ICDs are indicated in patients who have been identified as high risk for sudden cardiac death based on their underlying cardiac condition, but who have not yet had a sustained ventricular arrhythmia [4]. Along with its life-saving potential, ICDs are associated with procedural risks [5–7], inappropriate shocks [8], psychological risks [9, 10], and the potential for harm and suffering at end of life [11–13]. ICD therapy is considered a preference-sensitive treatment choice, as an individual can value its benefits and burdens differently than others [14]. Moreover, a person's value for their life-saving device may diminish as their health and contextual circumstances change [15]. The goal for preference-sensitive decisions is to achieve a higher quality decision based on current scientific evidence and consistent with patients' informed values and preferences [16, 17].

Patients with ICDs are faced with a series of decisions, including the initial implantation, battery replacement, and deactivation. Each ICD decision point warrants careful consideration to verify that patients understand their treatment options, and to ensure that their preferences are actively elicited and honored. This can be achieved by adopting a shared decision-making approach where clinicians and patients share the best available evidence when faced with health-related decisions, and where patients are supported to consider options to achieve informed preferences [18]. Shared decision-making supports the tenets of patient-centered care [19–21]. Healthcare professionals' ethical and legal responsibilities of informing patients prior to medical interventions are explicitly clear. To achieve informed consent, a patient must have received all relevant information about a treatment, including the treatment's nature, benefits, risks, and alternatives, and have their related queries answered prior to making a decision [22]. However, engaging informed patients in their personal medical decisions and honoring their preferences is more challenging. An increasing number of patients have shifted from being passive bystanders to active participants in the clinical decision-making process. Yet many patients feel uncertain about the best course of action and need support to be engaged in decisions about their health [23].

The aim of our integrative review was to explore patients' decision-making experiences regarding ICDs from the decision to implant to the consideration of deactivation at end of life, in the interest of helping healthcare professionals enhance the care and support they provide.

2 Methods

We conducted an integrative review using Whittemore and Knalf's five-step approach [24]. The five steps include the identification of a problem, literature review, data evaluation, data analysis, and the dissemination of findings. As a theoretical framework, we used the Ottawa Decision Support Framework, which asserts that patients and their support networks' unresolved decisional needs affect decisional quality [25].

A search strategy was designed with a reference librarian and conducted using MEDLINE, CINAHL, PubMed, PsycINFO, and the Cochrane library from January 2000 to November 2013. We restricted the search to the last 13 years given the dramatic increase in ICD utilization in the early 2000s; particularly when ICDs for primary prevention became indicated. The following terms were searched: implantable defibrillators, ventricular arrhythmia, cardiac arrhythmia, patient preference, decision-making, choice behaviour, patient participation, deactivation, and end of life. We included original quantitative and qualitative research articles that directly studied the patient response regarding ICD decision-making. Patients had to be 18 years of age or older, and ICD eligibility could be for either primary or secondary prevention. Exclusion criteria were articles that did not incorporate the patient's perspective, if they solely focused on living with or adjusting to the ICD, or if they only included other implantable devices such as pacemakers and cardiac resynchronization therapy. Case studies, reviews, discussion papers, and those not published in English were excluded. Reference lists of included articles were reviewed.

Titles and abstracts were screened for inclusion. Full texts were reviewed for eligible articles by KBL and article inclusion was verified with DDM. Study appraisal was conducted by KBL using the Mixed Methods Appraisal Tool [26, 27], which evaluates the methodological quality of each study on criteria specific to its design. For each criteria met, one point is allocated, for a maximum of four points. Scores are divided by four then multiplied by 100 to get a percentage score. For mixed methods studies, the overall quality score cannot exceed the score of its weakest component. As this review was an attempt to capture a comprehensive account of patient preferences, the tool was not used to exclude studies but rather to appraise their methodological quality.

To identify themes, qualitative data analysis was approached using a constant comparative method. Data reduction involved the extraction, coding, and grouping of data into systematic categories. Using an iterative process, data were compared to identify patterns, relationships, and themes. These were used to interpret the data, and the final themes were verified with the original articles for accuracy and confirmability.

3 Findings

3.1 Study Demographics

A total of 354 articles were identified. Of 68 studies reviewed as full text, 50 were excluded as they did not directly relate to the patient's decision-making experience. Hand searching of reference lists of included articles revealed six articles. A more recent article meeting inclusion criteria was identified during the peer review process, resulting in a total of 25 included studies.

Details of the 25 included studies that addressed the patients' perspectives surrounding ICD decision-making are described in Table 1. The number of patients with ICDs per study ranged from 8 to 3,067 patients and totaled 5,321 across all studies. There were 1,205 women, and 3,788 men. Two studies did not report sex of participants. Studies either included patients with primary prevention ICDs (seven studies), secondary prevention (one), both (six), or did not report (11). Across studies, there were various cardiac etiologies, length of time with the ICD, and total shocks received. Perspectives of family members and support systems were only sought in one retrospective study assessing end-of-life experiences for deceased patients as remembered by their next of kin.

We identified three common decision points: the decision to implant the ICD (eight studies), replace the battery (one), deactivate ICD therapies (14), and both ICD replacement and deactivation (two) (see Table 1).

3.2 Themes

Three key themes emerged from this analysis: the influence of the patient–practitioner consultation on knowledge uptake, patients' decision-making preference, and their desire to live. Each category influenced the other, and were all mediated by factors such as the patient's health status, social influence, and trust in their physician. These themes will be explored through the chronological course of decisions faced by patients with ICDs.

3.2.1 The Decision to Implant the Implantable Cardioverter-Defibrillators (ICDs) (Eight Studies)

The decision to implant an ICD was studied by the authors of eight studies, three of which included the perspective of patients who declined the ICD. Aside from these patients, all others had already accepted or received their ICD. None of these studies captured the process while the patient was contemplating the decision. Six studies utilized qualitative methodologies, including semi-structured interviews (three), grounded theory (two), and the combination of focus groups and individualized interviews (one). There was one mixed methods study, and one non-experimental survey study.

3.2.1.1 The Influence of the Patient–Practitioner Consultation Hauptman et al. [28] asserted that patient–physician communication is characterized by the omission of information. Several studies have supported this belief. Some patients could not recall discussions regarding treatment alternatives to the ICD [29, 30], operative complications [31], ICD recalls [28], psychological risks [28], or prognosis [29]. The overestimation of device benefits and misunderstanding of device function were also frequently reported [32–38]. For some patients, the best source of understanding the ICD's impact on lifestyle was the opportunity to personally experience its benefits and burdens [28, 39, 40]. In one study, some patients' inability to recall was attributed to altered cognition, as the initial consultation occurred in the hospital, mere days or weeks following a cardiac arrest [29]. Alternatively, in a cohort of 75 patients, 79 % believed they had received sufficient information prior to implantation. In that same cohort, 83 % claimed to understand the reason for ICD implantation, yet when a subgroup of 25 were asked to describe, no patient suggested the termination of potentially life-threatening arrhythmia [31].

The length of time used to deliberate about the ICD when first offered differed amongst patients. The entire process took only minutes for some, and up to 2 years for others [30]. In particular, patients who were actively involved in decision-making required more time to reflect [41]. Another study reported that all decisions were made quickly—particularly for those in hospital—as very few subjects were offered time to contemplate the decision [28]. Some patients accepted the ICD, after reconsideration of their initial refusal [30]. This suggests that preferences can fluctuate within the same individual over time [30].

3.2.1.2 Types of Decision-Making Preferences Patients faced with the decision to accept or decline an ICD approached their decision-making either actively or passively [30, 31, 39, 42]. ICD uptake or refusal did not appear to correlate with a person's degree of involvement [30]. Active decision makers were engaged, sought multiple opinions and information from various sources, and assumed control [30, 39]. They carefully considered their health state, balanced their risk for sudden cardiac death against the benefits of the device, and contemplated the impact of their potential sudden death on their family [30, 42]. Despite this perceived independence, active decision makers sought reassurance from both their practitioners and family members [42]. Passive decision makers showed signs of indifference, and deferred decision-making control to others [28, 30, 31, 39, 42]. In three studies, this was

Table 1 Summary of all included articles in this review, including their purpose, method, participant information, main findings, and their quality appraisal with MMAT scores

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Implantation				
Agard et al. [29], Sweden	Explore how pts referred for secondary prevention ICD experience the consent procedure and view their role in the DMP Qualitative, semi-structured interviews with content analysis	$n = 31$ 19 % women; mean age 65 y; 61 % ICM; mean implant time 40 months; 39 % prior shocks	None were informed of alternatives to ICD therapy. None were informed of their prognosis by their physician Participants did not perceive a lack of information or a lack of participation in the DMP Pts were content with adopting a passive role in DM None regretted the decision of having an ICD implanted	MMAT score: 75 % Limitations: no details provided regarding the interview guide development; not all interviews were transcribed and analyzed in their entirety; no mention of reflexivity or bracketing; short interviews, thus limited engagement; limited generalizability as only secondary prevention pts were included
Carroll et al. [30], Canada	Explore pts' DMP to reach the decision to accept or decline an ICD for primary prevention Qualitative, grounded theory with constant comparative method	$n = 44$ 34 accepted and 10 declined ICD; 25 % women; mean age 65 y; 64 % ICM; 52 % with post-secondary education or higher	Pts adopted DM approaches along an active to passive continuum Three major factors influenced pts' DM: trust, social influences, and health state Majority of pts preferred that physicians made the final treatment choice Pts could not recall alternatives to ICD therapy	MMAT score: 100 % Limitations: Limited to primary prevention pts; recall bias Strengths: Multi-center recruitment (3); data sources triangulated; member checking; interview guide was revised over the course of the data collection period; data saturation achieved; pts' voices represented by direct quotes
Groarke et al. [31], Ireland	Examine understanding and perspectives of pts with primary and secondary prevention ICDs on various aspects of ICD therapy Non-experimental, cross-sectional survey via telephone interviews	$n = 75$ 17 % women; median age at time of implant 64 y; mean implant time 36 months 85 % primary prevention	Pts' understanding of the risks, benefits, and functions of ICD therapy is poor Pts overestimate the benefits of ICD therapy 83 % of pts claimed to understand the reason for ICD implantation, yet no pt suggested the termination of life-threatening arrhythmia when asked to describe 53 % preferred that the doctor make the decision. 47 % want to receive all necessary information before making their decision. 93 % are satisfied with their decision to accept ICD therapy. 12 % will want to deactivate therapies in the setting of terminal illness	MMAT score: 100 % Limitations: Retrospective design; small sample size; study-specific survey Strengths: Multi-center recruitment (2); random sampling

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Hauptman et al. [28], USA	Examine pt–physician communication at the time the decision is made to implant a primary prevention ICD Qualitative, focus groups, and separate standardized pt interviews	$n = 41$ 51 % women; mean age 61 y	Pt–physician communication about ICDs is unclear and omits important information about peri-procedural risks, psychological implications, QOL, and potential long-term complications The degree to which pts felt informed before the implant procedure was 5.7 out of 10 Decisions were made quickly, particularly with admitted pts Many older participants deferred the decision to family members	MMAT score: 50 % Limitations: Study not powered to analyze the effects of key demographic variables on communication Strength: Multi-center recruitment (3)
Kantor et al. [42], USA	Determine the factors most influential when a pt is making a decision regarding ICD implantation Does demographic or geographic location affect influencing factors? Mixed methods. Telephone interviews	$n = 191$ 27 % women; 71 % Caucasian; mean implant time 65 months; 61 % without prior shocks	Reasons for deciding for ICD implantation were categorized into two themes: contributing factors (physical, psychological, social, and no decision) and their relation with their physician Active vs. passive DM was interwoven in the identified themes Substantial differences among regions and gender were found for contributing factors towards the decision	MMAT score: 50 % Limitations: 40.5 % response rate; cultural bias; recall bias Strengths: subjects recruited from three different regions of the USA; inter-rater reliability
Matlock et al. [41], USA	Reveal what pts with HF identify as difficult decisions, and to describe features associated with those decisions Qualitative, in-depth, semi-structured interviews using descriptive theme analysis	$n = 22$ (27 % women; mean age 69 y) $n = 12$ with ICDs	Pts were classified as either active or passive decision-makers Accepting the ICD was classified as a difficult decision by 4 active and 1 passive decision makers Active decision makers weighed concerns for side effects, family and QOL. They required time for reflection and wanted second opinions Passive decision-makers placed importance on trust in God, trust in the physician and power of the physician	MMAT score: 75 % Strengths: Bracketing and reflexivity; inter-rater reliability

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Matlock et al. [39], USA	Understand cardiologists and pts' perspectives about DM surrounding ICD implantation for primary prevention, specifically exploring how benefits and risks were discussed Qualitative, semi structured, in-depth interviews using a constant comparative analysis method	$n = 20$ pts, 14 accepted and 6 declined ICD 40 % women; 65 % Caucasian; mean age 59 y	Shared DM does not occur when pt and physicians are considering ICD implantation For those who accepted the ICD, three themes emerged: (i) desire to avoid death; (ii) desire to follow doctor's advice; (iii) discovery of the risks after implantation Many of those who declined the ICD believed it was unnecessary, the risks related to sudden cardiac death did not apply to them, and that the burdens outweigh the benefits. One pt weighed the trade-off between a prolonged death vs. SCD	MMAT score: 100 % Limitations: Data saturation not achieved in pts who declined an ICD Strengths: Bracketing and reflexivity; member checking; triangulation of data sources
Yuhas et al. [40], USA	Explore pts' attitudes and perceptions of ICDs to better understand pt-related barriers to primary prevention implantation Qualitative, grounded theory. Semi-structured, open-ended telephone interviews with constant comparative analysis	$n = 25$ 12 accepted and 13 declined ICD 28 % women; 100 % Caucasian; mean age 69 y	Five themes emerged Those who declined the ICD (i) lacked insight into their own risk potential for SCD; (ii) did not perceive it was strongly recommended; (iii) not interested in lengthening their life through invasive interventions. Amongst those who accepted and declined, (iv) concerns about recall, malfunction, and surgical risk were common; (v) inaccurate perceptions of ICD-related risks and lifestyle changes were clarified with the acceptors but not discussed with the decliners	MMAT score: 100 % Limitations: Cultural bias; response rate/rate of participation Strengths: Triangulation of data sources (3 sites); inter-rater reliability; pts' voices represented by direct quotes; interviews occurred prior to implantation, shortly after consultation with their physician
Battery replacement				
Gibson et al. [43], USA	Assess pts' DMP related to device replacement vs. maintenance when affected by a device recall Non-experimental, comparative survey study with quantitative analysis	$n = 81$ 31 were affected by a recall Mean age 63 y; 68 % Caucasian; 80 % with secondary education and higher	Majority of pts affected by the recall kept their original device. Six pts decided to replace, and five were undecided Most pts accurately estimated, but the majority overestimated, the odds of device failure	MMAT score: 50 % Limitations: Selection bias; sample size may be too small to capture variations in responses to device recalls; single center

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Battery replacement and deactivation—deactivation in hypothetical terms				
Fluur et al. [33], Sweden	Describe pts' experiences regarding complex decisions such as battery replacement and deactivation of the ICD Qualitative, semi-structured, in-depth interviews using content analysis	$n = 37$ 38 % women; median age 64 y; 43 % ICM; 43 % NICM; median implant time 54 months	Identified a major theme: "Being a part of an uncertain illness trajectory" Analysis revealed two categories: (i) "Standing at crossroads" when deliberating battery replacement; (ii) "Progressing from one phase to another" when thinking about the option to deactivate at EOL Discussions about EOL issues with clinicians were rare When asked, the majority stated they would not choose to deactivate the ICD No definitive answer on the right timing for these discussions	MMAT score: 75 % Limitations: Pts in the end-stage of a terminal illness were excluded Strengths: Triangulation of data sources and investigators; quota sampling; pt voice represented by direct quotes
Thylén et al. [44], Sweden	Identify factors associated with pts' experiences of EOL discussions, attitudes towards EOL discussions, and attitudes towards withdrawal of therapy Non-experimental, correlational study with survey	$n = 3{,}067$; 20 % women; mean age 66 y; mean implant time 4.7 y; prior shocks 35 %; 66.8 % secondary education and higher	Regarding battery replacement: The majority of pts (79 %) would replace their battery when it has reached end of service, even if no shocks had been delivered, 16 % were undecided, and 5 % would not replace. Younger pts, those with lower levels of education, and those with depressive symptoms were more likely to state that they did not want the battery replaced. At a 'very advanced age', 63 % would replace, 27 % did not know, and 10 % would not. If seriously ill, 55 % would replace, 34 % did not know, and 11 % would not Regarding deactivation: The majority (86 %) had not discussed deactivation with their physician. Most thought it would be best at EOL (69 %), yet 50 % also said they would like it discussed at implantation. 40 % said they would never want to discuss it. Many pts were unable to foresee what they would do if terminally ill	MMAT score: 75 % Limitations: 55 % response rate; eligibility criteria unclear; unclear if those with CRT-D were asked to consider deactivation/withdrawal of shocking therapy only or all functions of their device Strengths: Large sample size; details regarding pts' psychological morbidity

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Deactivation—deactivation in hypothetical terms				
Berger et al. [51], USA	Assess whether ICD recipients have considered preferences for disabling the ICD at time of implant, and at time of survey Assess whether ICD pts have advanced directives and whether they address ICD use Non-experimental, exploratory study with self-administered survey with open and closed-ended questions	$n = 57$ 17 % women; 91 % Caucasian; mean implant time 25 months; 79 % secondary education and higher	At implant, 53/57 did not have preferences for disabling. Two of which has wanted deactivation for cardiac function improvement At time of survey, 36/57 did not have preferences for deactivation 21/57 described situations in which they would want deactivation Advanced directives were prepared by 35/57 subjects, yet none addressed the use of their ICD People with advanced directives were more likely to express preferences for deactivation than those without them	MMAT score: 75 % Limitations: Cultural bias; retrospective; selection bias
Dodson et al. [32], USA	Assess pts' understanding of the benefits and harms of the ICD Examine preferences for ICD deactivation in the context of five key domains of health including functional, cognitive, and medical illness Non-experimental, descriptive, cohort telephone survey	$n = 95$ 28% women; 81% Caucasian; mean age 71 y; mean implant time 48 months; 29% with prior shock(s)	31/95 (33%) pts reported unknown or no benefits to the ICD Following an informational script regarding the benefits and harms of ICD therapy, 67/95 (71%) subjects wanted ICD deactivation in 1 or more scenarios	MMAT score: 100% Limitations: Single center; selection bias Strengths: ICD (mis)information was clarified prior to pts making a decision regarding deactivation
Goldstein et al. [34], USA	Identify barriers to ICD deactivation discussions in pts with advanced illness Qualitative focus groups	$n = 15$ Two >1 y with ICD, no shock; eight >1 y with ICD, shock; five <1 y with ICD, no shock; 33 % women; median age 69 y; 27 % secondary preventions; 87 % secondary education and higher	No pt had ever discussed deactivation with their physician, or knew that deactivation was an option All pts believed the ICD was exclusively beneficial Some subjects expressed that the physician should make the decision	MMAT score: 100 % Limitations: Single center; small sample size; recall bias
Habal et al. [35], Canada	Determine HF pts' awareness, comprehension, and utilization of advanced care directives Assess pts' knowledge of the process of CPR and their current resuscitation preferences Non-experimental, descriptive, semi-structured survey study	$n = 41$ total pts $n = 19$ with ICD. Demographics unknown for subset of pts with ICDs	Focused on subset of pts with ICDs 2/19 (11 %) reported discussing possibility of ICD deactivation with their physician Following clarification, 9/19 (47 %) stated they would want their ICD turned off should their condition deteriorate. Five/19 (26 %) would not want it deactivated	MMAT score: 75 % Limitations: Convenience sampling; single center; small sample size

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Kapa et al. [46], USA	Determine opinions of pts, medical professionals, and legal professionals regarding withdrawal of ICDs at EOL Non-experimental, descriptive, survey	$N = 246$ pts 54 % women 60 % >50 y old	Opinions regarding the appropriateness and legality of therapy withdrawal varies widely 85 % of pts agreed or strongly agreed that an ICD can be turned off at EOL Significantly more pts disagreed with turning off the ICD than medical professionals ($p = 0.001$) 20 % of pts thought turning off the ICD could be considered akin to physician-assisted suicide or euthanasia 53 % of pts agreed it was legal turning off an ICD in a pt who no longer wanted shocks	MMAT score: 50 % Limitations: Response rate (12 %); unclear what pt population was surveyed; unclear what percentage of pts surveyed had an ICD
Kirkpatrick et al. [36], USA	Determine whether pts with ICDs have advanced directives and whether they address the handling of their ICD at the EOL Explore pts' preferences for ICD deactivation in the setting of a DNR order and/or admission to hospice Non-experimental, descriptive, telephone survey	$n = 278$ 30 % women; 85 % Caucasian; median age 61 y; mean implant time 61 months; 100 % secondary education and higher; 38 % with prior shock(s); mean number of shocks 4.69	140 subjects had either a living will or a power of attorney. Those with advanced directives were significantly older ($p < 0.0001$). Only 3 (2 %) of these subjects included a plan for their ICD 96 % had never discussed what to do with their ICD at EOL with a medical professional When asked if they would deactivate their ICD in an EOL situation, 42 % said it would depend on the situation, 28 % said they would want it deactivated and 11 % said they would leave it turned on	MMAT score: 75 % Limitations: Study objectives not explicitly stated; single center; cultural bias Strengths: Triangulation of data collection time points
Kramer et al. [47], USA	Identify the ethical beliefs and legal knowledge of pts with hypertrophic cardiomyopathy relating to EOL care and the withdrawal of ICD therapy Non-experimental, descriptive, online survey	$n = 546$ 57 % with ICD; 47 % women; 92.5 % Caucasian; mean age 49 y; 76 % secondary education and higher	Widespread uncertainty and confusion regarding the legal status of ICD deactivation 57 % were unsure if ICD deactivation was legal 198 pts with an ICD had advanced directives, and only 15 (8 %) specifically addressed their ICD	MMAT score: 100 % Limitations: Study-specific survey; cultural bias; limited generalizability; unclear if 43 % of respondents without ICDs were informed about and understood the device, its treatment, and the implications of deactivation

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Pederson et al. [48], the Netherlands	Examine pts' perspective on (i) their knowledge and wishes for information about deactivation of the ICD toward the EOL, and (ii) the prevalence of pts in favor of deactivation and the correlates of a favorable attitude. Considers ICDs for both primary and secondary prevention Non-experimental, descriptive survey study	$n = 294$ 28 % women; mean age 59 y; 28 % secondary prevention; 87 % secondary education and higher; 12 % with prior shock(s)	68 % knew that the ICD could be deactivated at EOL. 95 % of pts believed that recipients should be informed about the possibility of turning off the ICD A favorable attitude toward deactivation was related to the avoidance of shock-related pain, anxiety, poor QOL, and the wish for a worthy death	MMAT score: 100 % Limitations: Positively worded vignettes Strengths: Details regarding pts' psychological morbidity
Raphael et al. [45], UK	Explore pts' recollection of the consent procedure prior to ICD implantation (for both primary and secondary prevention) Determine the degree to which pts want to discuss device deactivation and in what circumstances Qualitative, comparative, structured interviews	$n = 54$ 20 % women; mean age 72 y; 80 % ICM; 48 % primary prevention; mean implant time 37 months	38 % of pts knew the device could be deactivated 84 % of pts want to be involved in deactivation decisions Most pts would consider deactivation if they were unwell, rather than if receiving shocks Mode of death appears important to pts Two barriers to EOL discussions: pt's understanding of the device, and physician willingness to broach the subject	MMAT score: 50 % Limitations: Recall bias; single center; questionnaire not validated with no details about its origin; no details regarding the qualitative analysis
Stewart et al. [37], USA	Examine pts' expectations from their primary prevention ICD Non-experimental, descriptive, written survey	$n = 105$ 65 % with ICDs 30 % women; mean age 58 y; 40 % NYHA class III–IV	HF pts anticipate long survival, overestimate survival benefits from their ICD, and are reluctant to deactivate it	MMAT score: 50 % Limitations: Study-specific survey; limited generalizability; unclear if 35 % of respondents without ICDs were informed about and understood the device, its treatment, and the implications of deactivation
Strachan et al. [38], Canada	Explore pts' perspectives of EOL issues relating to the ICD at the time of their initial decision to either accept or decline a primary prevention ICD Qualitative, grounded theory with a constant comparative approach	$n = 30$ 24 accepted and 6 declined ICD 20 % women	Three themes emerged: (i) QOL vs quantity of life; (ii) preferred mode of death; (iii) technical realities of the ICD Most subjects focused on the prevention of SCD, and not death by any other cause Most pts had not considered that a time would come when they would want to have to device turned off or removed, but agreed that it was an important discussion to have	MMAT score: 100 % Limitations: interviews were conducted shortly after the device was implanted. Would knowing this information earlier have impacted their decision to implant? Strengths: Member checking sent to all subjects, and completed and returned by half; went beyond the point of data saturation; pts' voice represented by direct quotes

Table 1 continued

References, country	Purpose and method	Participants	Main findings	Critical appraisal with MMAT score
Deactivation—deactivation at EOL				
Goldstein et al. [11], USA	Describe the frequency, timing, and correlates of ICD deactivation discussions Non-experimental descriptive study Telephone survey of the next of kin of deceased pts	$n = 100$ Deceased pts: median age 76 y at death; 27 % women; median implant time 27 months Interviewed next of kin: median age 67; majority were spouses	27 % of next of kin recalled a discussion regarding deactivation of the ICD with their clinician. 21 % chose to deactivate. These discussions all took place in the last few days or hours of the pt's life. 27 pts received shocks in the last month of life, 8 received a shock from their ICD in the minutes before death Having a DNR order and a higher Charlson comorbidity score was statistically significant with having a discussion about deactivation	MMAT score: 100 % Limitations: Relied on reports from the next of kin; recall bias (interviews occurred a median of 2.3 y after pt death); single center Strengths: inter-rater reliability
Kobza and Erne [49], Switzerland	Evaluate whether deceased pts with a primary or secondary ICD and a malignant tumor desired deactivation of their ICD prior to EOL Non-experimental, chart review with descriptive quantitative analysis	$n = 8$ 13 % women; median implant time 58 months; 38 % primary prevention; 88 % prior shocks	In 6 of 8 pts, the option of disabling the device was discussed extensively, and none wished to abandon therapies	MMAT score: 75 % Limitations: Retrospective design; no mention of a standard protocol for deactivation discussion; small sample size
Lewis et al. [50], USA	Review the impact of a multidisciplinary strategy used to identify terminally ill pts and initiate withdrawal of ICD shock therapy as part of a comprehensive comfort care approach Non-experimental, chart review with descriptive quantitative analysis	$n = 63$ Two groups of deceased pts emerged: $n = 20$ whose ICD was turned off because a terminal illness was identified $n = 43$ not identified as terminally ill with ICD therapies on	Of those whose terminal illness was identified in the clinic, 20/20 (100 %) had their shock therapy turned off before death None of the 43 pts not identified as terminally ill had their shock therapy disabled prior to death. They received shocks significantly closer to their time of death vs. the other group ($p = 0.04$)	MMAT score: 75 % Limitations: Randomization of pts could have been considered; no mention if a standardized protocol for deactivation discussion was developed and used

CPR cardiopulmonary resuscitation, *CRT-D* cardiac resynchronization therapy defibrillator, *DM* decision-making; *DMP* decision-making process, *DNR* do not resuscitate, *EOL* end of life, *HF* heart failure, *ICD* implantable cardioverter-defibrillator, *ICM* ischemic cardiomyopathy, *MMAT* mixed methods appraisal tool [25, 26], *NICM* non-ischemic cardiomyopathy, *NYHA* New York Heart Association, *pt(s)* patient(s), *QOL* quality of life, *SCD* sudden cardiac death actually the preferred decision-making style [29–31]. Due to the perceived complexity of the information, some patients did not believe they were adequately prepared to make the decision [29, 30, 41]. Some did not even see the decision as theirs to make [30, 42]. Reasons for this include the fact that their life had been threatened and living was the only option [29, 42], trust in God [39], and trust in their physician's recommendation [29, 30, 39, 41].

Those who declined the ICD could also be distinguished as active or passive decision makers [30, 39, 40]. Passive decision makers either minimized their risk of sudden cardiac death [30, 39, 40], were disinterested [30], or perceived the ICD to be a purely elective option [40]. Decliners who adopted an active decision-making style carefully balanced the benefits and harms, and determined that the burdens outweighed the benefits [30, 39]. Others reported that they were pleased with the current status of their lives and preferred to avoid invasive life-prolonging procedures [30, 40]. One patient considered the benefit of a sudden death against other modes of death [39].

3.2.1.3 The Will to Live When patients were first informed of their risk for sudden cardiac death, fear and uncertainty about the future characterized many of their responses [28, 30, 31]. The risk of sudden death and the chance for survival are powerful incentives for patients to accept an ICD. For the majority of patients faced with this reality, living was the only option [30, 39]. For many, the inconveniences of the device were worth the possibility that life could be saved. Accepting the ICD was a means to control fear and achieve a sense of security [28, 31, 42].

Four studies included patients who declined the ICD [30, 38–40]. One patient understood that an ICD would deny him the "luxury of a sudden death." (p. 9) [38]. Another patient weighed quality versus quantity of life and preferred to live out the former. Some patients expressed that accepting the ICD equated with acceptance of their risk for sudden death, which they would rather ignore [30]. It is impossible to know the distribution of patients who accepted versus declined an ICD; however, for those with ICDs, satisfaction rates ranged from 93 to 100 % [29, 31].

3.2.2 The Decision to Replace the Battery (Three Studies)

Three studies included in this review considered patient preferences at ICD battery replacement. One survey study was concerned with the decision to replace the battery when an ICD had been recalled by the manufacturer. A semi-structured interview-based study and a survey study considered patients opinions and their hypothetical choice between replacement and non-replacement for a depleted battery.

3.2.2.1 The Influence of the Patient–Practitioner Consultation Gibson et al. [43] focused on patients' decision-making processes when an ICD had been recalled by the manufacturer. All 31 patients were sent a notification letter from their physician, yet only 61 % of patients remembered receiving it. The letter was supplemented by an in-clinic discussion. Although patients did not have to think back to the initial consultation to remember the implications of a recall, over 33 % of patients incorrectly recalled the risk of device failure and 71 % overestimated the rate of failure. A total of 19 % of patients chose to remove and replace their recalled device, 16 % were undecided, and 65 % chose not to replace it. The option of removal and non-replacement was not discussed. Fluur et al. [33] conducted semi-structured interviews and focused on patients' knowledge of the ICD, and their thoughts on the battery replacement process. This study revealed similar misunderstandings of device functions and overestimation of device benefits. Some patients could not think of an occurrence when the ICD could cause harm, which could explain why the majority had never reflected on any other option but to replace the battery. In the survey study by Thylén et al. [44], 25 % of their sample had undergone battery replacement in the past. The remaining 75 % answered the survey's battery replacement questions hypothetically. Discussions about battery replacement occurred 43 % of the time, but it was unclear if the option of non-replacement was part of their discussions. Even if ICD therapies were not needed during the first generator's life, 79 % said they would replace the battery, 16 % could not decide, and 5 % would not. Younger patients, those with lower education levels, and those with depressive symptoms were more likely to not want replacement. If very old or seriously ill, the proportions changed slightly to 63 and 55 % wanting replacement, 27 and 34 % were unsure, and 10 and 11 %, respectively, did not want the battery replaced in these circumstances [44].

3.2.2.2 Types of Decision-Making Preferences Little information was provided about patients' preferred level of involvement in decision-making in these three studies. For patients affected by the recall, there was no information as to how or why that decision was made [43]. Fluur et al. [33] identified this replacement decision as "standing at crossroads," whereby some individuals could choose an option without question, while others deliberately reflected. Active decision makers deliberately reflected about the future and their prognosis. Some reported they "had already lived on overtime" (p. 205) [33] and therefore considered the battery replacement non-imperative. Others deferred the decision to their trusted physician, reflecting a passive decision-making style [33]. These patients ignored their illness trajectory, and rather, lived 1 day at a time [33].

3.2.2.3 The Will to Live At this decision point, patients described the ICD objectively, rather than in existential terms. Replacement of the ICD was considered a necessity, “like an auxiliary engine that required regular service”. (p. 205) [33]. Others would not live without it because they considered it their lifesaver from all causes of death [33]. Some patients understood that their health status was poor and their heart condition would continue to deteriorate, and thus deliberated replacement. Regardless of shock history, the vast majority stated they would replace the battery [33]. In some cases, patients had been advised by their physician not to replace the battery, but nevertheless proceeded with the change.

3.2.3 The Decision to Deactivate ICD Therapies (16 Studies)

Of 16 articles that explored patients’ preferences regarding the decision to deactivate their ICD, 13 measured patients’ preferences in hypothetical scenarios (such as terminal illness and decreased quality of life) and three reviewed the decisions and expressed preferences of deceased patients—or their next of kin—in the last moments before their death. There was a combination of qualitative methodologies, such as focus groups (one), interviews (one), grounded theory (one), non-experimental survey studies (11), and chart reviews (two).

3.2.3.1 The Influence of the Patient–Practitioner Consultation Inaccuracies prevailed when patients were questioned about ICD deactivation. Raphael et al. [45] identified two barriers to deactivation discussions: the patient’s understanding of the device, and the physician’s willingness to broach the subject. Patients in four studies believed that deactivation would cause immediate death and was akin to euthanasia or assisted suicide [33, 36, 46, 47]. One of these studies found that 57 % of their patient cohort questioned the legality of ICD deactivation [47]. In five studies, the majority of participants had never discussed the possibility of deactivation with their physician, and therefore were unaware of the option [33–36, 38, 44]. However, in two recently published articles, Raphael et al. [45] and Pederson et al. [48] reported that 38 and 68 % of patients, respectively, knew that device deactivation was possible. Knowing when to broach this topic of discussion with patients has been debated. Fear of reducing hope or causing distress has often delayed this conversation. Yet, according to findings from an interview-based study, none of the 54 subjects found the topic distressing [45]. In fact, those who had previously received shocks were more likely to think deactivation should be discussed [44, 45]. Of surveyed patients, 49–52 % believed that device deactivation should be addressed prior to insertion [44, 45, 48]. Others preferred to discuss it when life expectancy decreased and when end of life neared [33, 44, 45, 48]. Thylén et al. [44] reported that 40 % of patients never wanted the physician to initiate a discussion, with 85 % stating that they would prefer to broach the topic on their own terms.

The studies concerned with patients’ preferences for deactivation at end of life revealed variations in preferred course of action. In one study of patients with malignant tumors, ICD deactivation was extensively discussed with six of eight patients [49]. None wished to abandon ICD therapy. Lewis et al. [50] conducted a post mortem chart review designed to assess the efficacy of a comprehensive care approach for 20 terminally ill patients with ICDs. All 20 patients requested deactivation of therapies, and therefore, did not experience shocks at end of life. These patients were compared with another group of deceased patients who were never classified as terminally ill. None had their shock therapy disabled, and 21 % received shocks within 30 days of their death, significantly closer to their time of death than the other group ($p = 0.04$). Goldstein et al. [34] reported that having a ‘do not resuscitate’ status and a higher Charlston co-morbidity score was statistically significant with having a discussion about ICD deactivation. Yet, there was no association between having a living will or healthcare proxy [34]. Of their 100-patient cohort, 27 next of kin recalled a discussion regarding ICD deactivation, six of which occurred in the last hours, and one in the last minutes prior to death.

3.2.3.2 Types of Decision-Making Preferences In regards to deactivation decisions, some patients preferred that the physician make the decision [34, 45], while others wanted to be involved [45, 49]. For example, in a study of deceased patients with malignant tumors, all patients were relieved that they were given the option to decide for themselves [49]. However, in a focus group study, the 15 patients would only discuss hypothetical deactivation in terms of their preferred role in decision-making [34]. Patient quotes were indicative of passive decision-making styles, and expressed that the physician should make the decision. Patients who thought deactivation should not be routinely discussed feared that the information may be too confusing, and that deactivation may prematurely end life and therefore it was a decision best left to the physician [45].

3.2.3.3 The Will to Live At initial implant, only 7–12 % of patients identified a time when they would consider the abandonment of ICD therapies [28, 51]. When ICD recipients were asked about deactivation in hypothetical terms, the majority showed great reluctance to turn off their device, even in the setting of multiple shocks [33, 37], if they were given a 1-month prognosis [37], or if dyspneic at rest [37]. Others expressed a desire to deactivate in the setting of terminal illness [32, 33, 35–37, 45, 51] or impaired quality of life [32, 48, 51], and to avoid shock-related pain [45, 48]. Thylén et al. [44] reported considerable indecisiveness, particularly from women, those with depressive symptoms, and those with worse ICD experiences, about engaging in deactivation discussions and expressing preferences.

The authors of the one study that reported the highest number of patients who would choose deactivation (71 %), had presented them with hypothetical scenarios representing various functional and cognitive limitations [32]. Another study reported that 47 % of patients with ICDs would deactivate it should their condition deteriorate [35]. Incidentally, these two groups selected their deactivation preferences immediately following an informational script of the benefits and burdens of ICD therapy, suggesting that a review of the ICD's function preceding these discussions may be useful to enhance understanding.

When asked about deactivation at end of life, some patients chose deactivation while others did not. In a retrospective chart study of eight deceased patients with malignant tumors, none wished to abandon therapies [49], whereas another study identified that all 20 patients with terminal illness requested deactivation [50]. In a third study, out of 100 patients, there were 27 device deactivation discussions for which 21 deactivations were requested and performed in the days, hours, or minutes before death [11]. The reduction of unwanted shocks is a benefit of device deactivation at end of life, as indicated by patients who preferred ICD deactivation to be able to have a quick and natural death [33, 45, 48].

4 Discussion

The purpose of this integrative review was to explore patients' perceptions or concerns about their decision-making experiences around ICDs in the interest of helping healthcare professionals enhance the care and support they provide. We also sought to reveal patients' perspectives and preferences regarding ICD decision-making, and what factors influence their decision-making. The three main themes that appeared to influence patients' decisions across studies were the influence of the patient–practitioner consultation on knowledge uptake, patients' decision-making preferences, and a patient's desire to live. The main findings of this review revealed a significant degree of misunderstanding and inaccurate recall of information regarding ICD function at all decision points. In terms of deactivation decisions, the majority of patients were not aware of this option. Furthermore, when they are informed, their preferences for deactivation need to be considered in the context of their health status. What a patient might opt to do when presented with a hypothetical scenario may differ what they may actually do when faced with terminal illness. Finally, our findings suggest that, for the majority of patients, their desire to live over-rules the inconveniences of the device—unless they have considered the value trade-off between a prolonged death versus a sudden one.

Patients' perceptions and misunderstandings of the functionality of ICDs impede ICD management, particularly in discussions about decisions. In contrast to our findings, 93 % of surveyed cardiologists believe patients understand the intricacies of device functioning [52]. These rates of misunderstanding do not solely reflect patient–practitioner communication problems, but also suggest that patients have difficulty with information uptake and assimilation. This may be explained by numerous factors as outlined here. There may be significant practice variations amongst clinicians or organizational cultures that may result in patients being offered different amounts, types, or sources of information [53]. Also, patients' decision-making preferences (whether active or passive) and health literacy levels may affect their ability to understand information. Comprehension is fundamental to informed consent [22]. Strategies are needed to verify patients' understanding of information. Patient decision aids are effective interventions that can help patients participate in these decisions. Patient decision aids are evidence-based tools that make explicit the decision to be made, provide information on options, benefits, and harms, and help patients clarify their values in association with the options [54]. Evidence from 115 randomized controlled trials show they improve patients' knowledge, expectations of outcomes, participation in decision-making, and improve the values–choice concordance [54]. Although decision aids are effective, none of the articles included in this review evaluated patient decision aids for patients facing decisions about ICDs. Patient decision aids for the initial decision to implant an ICD exist [55, 56]. The development and feasibility testing of a patient decision aid for primary prevention ICDs is ongoing [57].

Many patients and next of kin are unaware of the possibility to deactivate the ICD. Our findings suggest that many of these discussions only occur when the practitioner chooses to introduce the subject—if they do at all. In many cases, this introduction occurs when end of life is near, limiting the time a patient and their family have to reflect upon this complex decision. If too late, patients may be subjected to unwanted shocks. By sharing this information earlier in the trajectory, patients are granted a degree of control to re-initiate the discussion when they are prepared. The majority (84 %) of over 3,000 surveyed patients with ICDs reported that broaching the topic themselves is their preference [44]. This information will also grant them the knowledge required to establish advanced directives. Few patients with ICDs have advanced directives, but those who do are more likely to express preferences for deactivation [51]. However, only 0–8 % of these included their preference for the ICD in their advanced directives [35, 47, 51]. The use of advanced directives has been cautioned, as some individuals may dramatically revise what they want and accept as treatment when faced with the alternative of death [58]. With this in mind, when eliciting patients' preferences for deactivation, their responses need to be considered in the context of their health status. What remains unclear is when healthy patients express their preferences for deactivation in certain scenarios, do these same preferences hold when they are terminally ill? Contextual influences are unpredictable and powerful, and so it is difficult to foresee how one may act when faced with decline and impending death.

For the most part, patients' desire to live trumped the inconveniences of the ICD. The ICD can be described in terms of a "one-value trade off" with death. In an existential sense, the ICD is meant to save a life of quality, but when considered from a different person's perspective or by the same person at a different time, it can be viewed with the potential for undue suffering and harm. The wide range of deactivation rates amongst the studies at end of life highlights the preference-sensitive nature of this decision. Increasingly, patients want control over their end-of-life experiences, and for ICD patients, discussing deactivation is an important and justifiable way to achieve this. The multidisciplinary comprehensive counseling approach adopted in Lewis et al. [50] may have helped terminally ill patients and their families understand and contextualize the trade-off more clearly. Practitioners need to be clear about the potential for pain and suffering from repeated firings at end of life, and that for some, a sudden death may be a better mode of dying.

There appears to be increasing interest in understanding how to integrate patient preferences into ICD decision-making, particularly given the number of articles published on this topic within the last 9 years (Fig. 1). Consideration for patient preferences emphasizes a patient-centered care approach, which is axiomatic to the delivery of quality care. Rather than idolize an increasing rate of implantation and productivity, we should begin to measure and improve the rate and quality of discussions that occur over the device's lifetime to ensure that patients' initial and subsequent decisions are informed and reflective of their preferences [59].

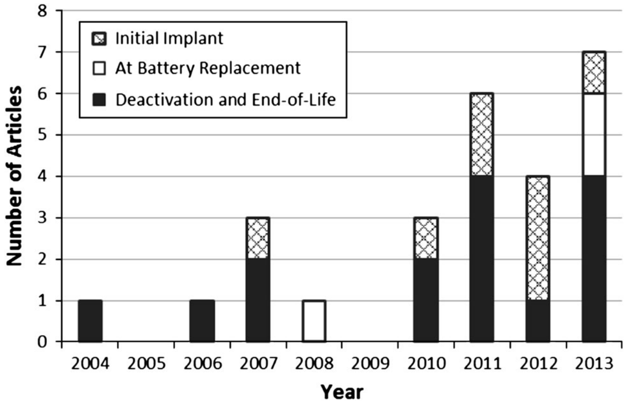

Fig. 1 Number of articles published per decision-making point on the patients' perspective in ICD decision-making from 2004 to 2013. This figure highlights the increase in the number of articles that have been published on the patients' perspective on ICD decision-making in the last 10 years. *ICD* implantable cardioverter-defibrillator

5 Limitations

Our findings are limited by the fact that various methodologies have been included, which do not lend themselves easily to a collective analysis. However, the five-step integrative review framework [24] we have utilized facilitates such combinations, and common themes were clearly revealed. Second, given the uniqueness of ICD therapy, these findings are not transferable to other forms of implantable devices. Third, there was little emphasis on the presence of family members and support persons during consultations. Their presence is an important component of patient-centered care [60], and they can adopt an influential role in information recall and decision-making. Some limitations were inherent to the studies included in the review. Many of the studies were from single centers and retrospective in nature. A high degree of recall bias may exist as subjects may not clearly remember the details of past discussions. Only two studies provided a clear blueprint of the consent procedures, making it difficult to know which factors contributed to better understanding and recall.

6 Future Directions

The legal and ethical imperative of informed consent binds clinicians to a comprehensive discussion prior to the initial implantation. Yet, this discussion should not be limited to that sole decision-making point. Nurses, physicians, and all other healthcare professionals involved in the care of these patients need to consider ICD therapy as a trajectory of dynamic decisions; decisions that are subject to review. The decision-making points highlighted in this review are three of plenty opportune moments to reiterate the benefits and burdens, confirm understanding, and present options in a balanced and transparent manner. Strategies are needed to bridge the gap in comprehension, such as confirmation of understanding, the use of decision support tools, and the presence of support persons. A patient's non-cardiac medical history should also be actively monitored to initiate timely deactivation discussion and allow adequate time for reflection and deliberation.

Future research should consider investigating the effect of patient decision-making styles and practitioners' consultation approach on patients' understanding and uptake of information. It remains unclear if a patient's mood or mental health state has any effect on ICD decision-making, and, if so, how these factors may influence the decision. Future multicenter research could be designed to dilute the effect of practice and institutional variations. Longitudinal studies could follow patients through this decision-making journey, and assess whether initial patient perceptions can predict future decision-making. Finally, there is a paucity of information regarding decision-making processes at battery replacement. More research is required to know how best to advocate for patients and their support persons at this increasingly common decision-making point.

7 Conclusion

The decisions around ICDs are particularly difficult for patients given the life and death trade off. Whether or not patients want to make decisions related to their ICDs, informed consent requires that patients understand the benefits and harms of ICDs and are aware of alternative options. By helping patients explore their preferences, they can be better supported to participate in several elements of a shared decision-making process and achieve higher-quality decisions. Otherwise, we risk inappropriately using a treatment modality that informed patients simply do not want, or, when standing at life's crossroads, may no longer value.

Acknowledgments The authors have no conflicts of interest to disclose. No funding was received for the completing of this study.

Disclosures The authors have no conflicts of interest to disclose. No funding was received for the completion of this study. Dr. Matlock was supported by a career development award from the National Institutes on Aging (K23AG040696).

Author contribution KBL—Conception and design, article selection, analysis and interpretation of data, drafting the article, final approval.

DS—Critical revision of the article for important intellectual content, final approval.

DDM—Conception and design, article selection, analysis and interpretation of data, revising the article, final approval.

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