Navigating complexities in implantable cardioverter-defibrillator therapy: insights, challenges, and patient-centred approaches

Yilmaz, D.

Chapter 1

General introduction and outline of the thesis

List of abbreviations

SCD	Sudden Cardiac Death
ICD	Implantable Cardioverter-Defibrillator
CVD	Cardiovascular Disease
ZIN	Dutch Healthcare Institution
EHRA	European Heart Rhythm Association
HRS	Heart Rhythm Association
PG	Pulse Generator
SDM	Shared Decision Making
DA	Decision Aid
CRT-D	Cardiac Resynchronization Therapy with Defibrillation

Sudden Cardiac Death and Implantable Cardioverter-Defibrillators

Cardiovascular diseases pose a significant global health challenge. Cardiovascular disease (CVD) remains the most common cause of death in Europe(1). More than 60 million potential years of life are lost to CVD in Europe annually(1). Moreover, it has been previously estimated that Sudden cardiac death (SCD) from cardiac arrest is a major global health problem accounting for an estimated 15%–20% of all deaths(2). Individuals at risk include those with a history of heart disease, heart attack survivors, or those with specific structural or genetic abnormalities of the heart (2). Therefore, several decades ago, the Implantable Cardioverter-Defibrillators (ICD) was developed to prevent sudden cardiac death in patients at risk. ICD therapy has been shown to be effective in reducing sudden cardiac death and all-cause mortality in selected patient groups (3). These devices have become a cornerstone in both primary and secondary prevention strategies against SCD. In the Netherlands, 6000 ICDs are implanted annually in patients at risk of SCD (4). It is estimated that 83% of these patients, will never experience a life threatening arrhythmia after ICD implantation (4). Considering the rising health care costs in general, and substantial part of patients that never receive ICD tachytherapy, The Dutch Healthcare Institution (ZIN) has published a report, encouraging more stringent patient selection. They estimated that improvements in patient selection, may result in an annual cost reduction of 19,8 million euros per year (4).

Primary Prevention

Primary prevention ICDs are implanted in individuals at high risk of developing malignant ventricular arrhythmias (5). This proactive approach aims to prevent death from life-threatening arrhythmias through ICD tachytherapy. The majority of this population at risk of ventricular arrythmias consists of patients with structural, mainly ischemic heart disease either or not with symptoms of heart failure with reduced ejection fraction (5).

Secondary Prevention

Secondary prevention strategies involve the use of ICDs in individuals who have already experienced life-threatening arrhythmias and/or are survivors of a cardiac arrest attributed to a ventricular tachyarrhythmia. This application serves to mitigate the risk of death due to recurrent events, offering a lifeline to those with a history of severe cardiac arrhythmias that remain at risk (5).

Concerns of ICD therapy

Despite technological advances, challenges persist in identifying individuals at risk, understanding the complex underlying causes of SCD, and identifying potential risks. While ICDs have revolutionized the management of the risk for SCD, they are not without limitations and potential drawbacks. Understanding of their impact on patient care is important for the recognition of these drawbacks for thorough patient selection and counselling. Drawbacks to be taken into account during patient selection for ICD therapy, are:

1. Peri- and post-procedural complications
   The surgical implantation of ICDs carries inherent risks, including the possibility of infection at the device site. Additionally, patients may experience complications related to lead placement, such as lead dislodgement or venous thrombosis (6-8). Even though rates of severe complications are low, less severe complications still occur rather frequently: procedure-related mortality 0-0.1%, pneumothorax 0.4%-2.8%, pericardial effusion 1.3%, clinical tamponade 0.5-1.5%, pocket hematoma 0.2%-16%, infection 0.6-3.4%, lead dislodgement 1.2%-3.3% (9).
2. Inappropriate shocks
   ICDs are designed to deliver shocks when necessary, but at times, they may misinterpret non-lethal arrhythmias or noise as life-threatening events, leading to inappropriate shocks. These shocks can be painful and distressing for patients (11). Technological advancements continually address these concerns, but malfunctions still occur (7).
3. Psychological Impact
   Living with an ICD can have profound psychological implications for patients. The awareness of having a device that intervenes during life-threatening situations can lead to anxiety, depression, or a reduced quality of life (12, 13). On the other hand, people may feel safe due the the presence of the device.
4. Cost and Resource Utilization
   The initial cost of implanting an ICD, along with ongoing monitoring and potential device replacements, contributes to the economic burden of healthcare. This cost factor necessitates careful consideration of healthcare resource allocation and patient selection (14, 15).
5. Limited Benefit in Certain Populations
   While ICD therapy significantly reduce the risk of sudden cardiac death in specific patient groups, their benefits might be limited in certain populations, such as those with significant comorbidities or a limited life expectancy (16, 17).

6. Battery Depletion
   ICDs are powered by batteries that have a finite lifespan. Regular device check-ups are necessary to monitor battery status. When the battery nears depletion, the device requires replacement through an additional surgical procedure (10). Fortunately, battery life has increased during the past decade, e.g. for a single lead ICD's from approximately 7 to 15 years.
7. Ethical Considerations
   Decision-making regarding ICD implantation involves ethical considerations, especially in patients with advanced illnesses or limited life expectancy. Shared decision-making becomes crucial in balancing potential benefits and drawbacks (17–19).

End-of-life issues

Position papers by international societies such as the European Heart Rhythm Association (EHRA) and Heart Rhythm Association (HRS) encourage that end-of-life issues should be a part of pre-procedural counselling (20–23). The urgency of this recommendation is substantiated by the fact that up to half of all patients in a European ICD cohort do not have tachytherapy functions disabled at the time of death (24), leaving them prone for painful shocks in the last week of their life (20, 21, 23, 25).

Patient's clinical situations as well as their preferences may change over time. Although in the first decades, it used to be common practice to continue ICD therapy until death, perceptions have changed. Physicians are increasingly aware that ICD therapy is not a lifelong commitment. As time passes, patients can be withdrawn from ICD therapy if they choose - or if the clinical benefit of continuing ICD therapy is considered absent. Moreover, patient preferences can change with the progression of age and the involvement of a new comorbidity. Considering ICD pulse-generator will last for only 5 to 10 years, the moment for pulse-generator exchange due to battery depletion, provides an excellent moment for discussing continuation of ICD therapy.

Whereas doctors may reconsider the indication and appropriateness of the ICD with certain patients, it has been shown previously that more than half of the patients who had already an ICD replacement. at time of battery depletion, were not aware that they had a choice (26). Only a minority of patients have been reported to consider non-replacement under certain circumstances, such as serious illness and/or advanced age (26). This illustrates the importance of shared decision-making, also when a patient is up for an ICD replacement.

In summary, unlike in the past when it was thought that an ICD indication was fixed, we now think of ICD therapy as more fluid in terms of indication and appropriateness. Patient preferences with respect to continuation of discontinuation of ICD therapy should be discussed.

Importance of Shared Decision-Making in Implantable Cardioverter-Defibrillator (ICD) Patients

Shared decision-making (SDM) plays a pivotal role in the care of patients (and their relatives) considering or receiving ICDs. This collaborative approach involves active participation and communication between healthcare providers and patients, considering individual values, preferences, and clinical evidence (29). There are many aspects to the process of SDM in the context of ICDs:

1. Informed Choices
   ICD therapy involves decisions, such as whether to undergo the implantation of an ICD for primary or secondary prevention indication and/ or whether to undergo a pulse generator exchange at time of battery depletion. SDM ensures that patients receive comprehensive information about their condition, treatment options, potential risks, and expected benefits. This empowers patients to make informed choices aligned with their individual values and preferences.
2. Quality of Life Considerations
   The psychological and lifestyle impact of living with an ICD is substantial. Some patient even choose not to have an ICD, due to the potential impact on their quality of life. In contrast, other patients, e.g. in whom an ICD is no longer indicated, have a hard time with withdrawing from ICD therapy because of the of the secure feeling it provides them.Engaging in SDM allows patients to discuss their concerns, fears, and expectations. Healthcare providers can offer insights into how ICD therapy might influence a patient's quality of life, helping individuals weigh the potential benefits against the drawbacks.
3. Patient-Centered Care
   SDM places patients at the center of the decision-making process. It acknowledges their autonomy and engages them as active and central participants in determining their healthcare pathway. This patient-centered approach fosters a sense of control and ownership, which positively impacts patient satisfaction and adherence to treatment plans.

4. Addressing Ethical Dilemmas
   Decisions about ICD implantation often involve ethical considerations, especially in cases of advanced disease or limited life expectancy. Shared decision-making provides a platform to openly discuss these ethical dilemmas. Patients can express their values and preferences and healthcare providers can offer guidance, fostering a collaborative resolution.
5. Reducing Decisional Conflict
   The complexity of decisions on ICD implantation can lead to a decisional conflict, with patients feeling uncertain or struggling with their choices. SDM helps clarify expectations, understand possible outcomes, and reduce decisional conflict. This contributes to a more confident and satisfied patient population.
6. Enhancing Adherence
   Patients who actively participate in decision-making processes are more likely to adhere to treatment plans. Understanding the rationale behind ICD therapy and feeling involved in the decision promotes a sense of commitment to the prescribed care (both pharmacological and life-style measures), potentially improving long-term adherence.
7. Tailoring Care to Individual Needs
   Each patient's situation is unique, and SDM enables customized care plans. By understanding the patient's values, lifestyle, and expectations, healthcare providers can tailor recommendations for ICD therapy and optimize the match between medical interventions and individual needs.
8. Improved Communication
   SDM enhances communication between patients and healthcare providers. This transparent and open dialogue builds trust, addresses misconceptions, and facilitates shared responsibility for health outcomes. Effective communication is particularly crucial in managing expectations and addressing concerns related to ICD therapy.

Overall, shared decision-making is an integral part of the ethical, patient-centered, and personalized care of individuals considering or receiving ICD therapy. It is consistent with the principles of autonomy, beneficence, and respect for persons, and contributes to a collaborative healthcare environment that prioritizes the well-being and values of each patient (29).

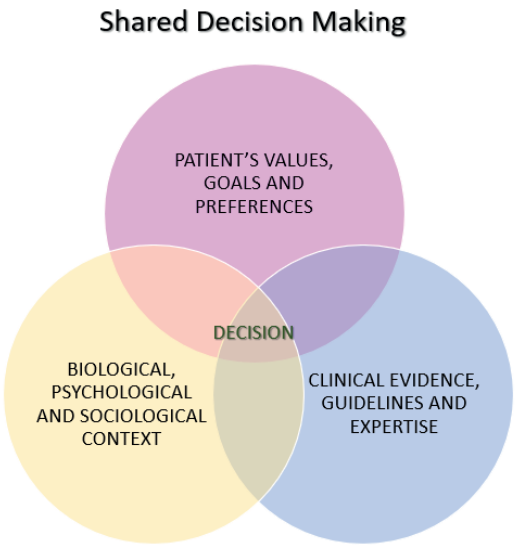

Figure: Key factors contributing to the shared decision-making process.
Image adapted from colitisconversations.org/Benefits_to_care

Role of Decision Aids in Shared Decision-Making for ICD patients

Decision aids (DAs) are valuable tools in the shared decision-making process (30), especially for patients facing complex choices such as whether to undergo an ICD implantation. These aids facilitate communication between healthcare providers and patients, providing structured information to support informed decisions aligned with individual values (29, 30).

1. Clarification of Information
   Decision aids can present comprehensive, evidence-based information about ICDs, including their purpose, benefits, and potential risks. They clarify technical details in a patient-friendly manner, ensuring that patients have a solid understanding of the intervention.
2. Visual Representation
   Visual aids, such as diagrams or videos, help convey complex concepts related to ICDs. These aids enhance patient understanding and serve as visual reinforcement during discussions about device operation and the implantation procedure.

3. Clarification of Values
   DAs guide patients in clarifying their values and preferences regarding ICD therapy. Interactive exercises and prompts help people think about what is most important to them, and facilitate conversation about how ICD treatment aligns with their personal goals.
4. Risk-Benefit Assessment
   DAs provide balanced information about the potential benefits and risks of ICD therapy. This supports patients in weighing the pros and cons based on their individual health status, lifestyle, and values.
5. Facilitating Communication
   By fostering understanding and clarification of personal values, DAs contribute to more meaningful discussions between patients and healthcare providers. Patients can express their concerns, ask questions, and actively participate in the decision-making process.

In conclusion, decision aids are crucial tools in shared decision-making for ICD patients by providing accessible information, promoting the clarification of values, and facilitating informed discussions. Their integration into clinical practice enhances the collaborative decision-making process, empowering patients to actively participate in decisions about their healthcare.

Outline of the thesis

The thesis explores technical and decision-making aspects of ICD therapy in patients with heart disease. It examines the clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy, the impact of chronic total coronary occlusion on ventricular arrhythmias and mortality, and shared decision-making around ICD therapy. The thesis also evaluates the clinical practice of ICD therapy in end-of-life scenarios.

Chapter 2 of the thesis focuses on the technical aspects of ICD therapy, comparing the long-term clinical outcomes of subcutaneous versus transvenous ICD therapy. The chapter also discusses the practical considerations of device selection, including patient characteristics, indication for therapy, and the potential risks and benefits of each device type. **Chapter 3** evaluates the impact of a chronic total coronary occlusion on ventricular arrhythmias and long-term mortality in patients with ischemic cardiomyopathy and an ICD. **Chapter 4A** examines the risk of painful shocks in the last moments of life in patients with an ICD. **Chapter 4B** investigates the causes of death in patients who had their tachytherapy deactivated in a large

population over a 10-year period. **Chapter 5** examines the use of ICD therapy in elderly patients in Dutch clinical practice. **Chapter 6** describes the development of a decision aid for shared decision-making in the Dutch ICD patient population. The chapter discusses the effectiveness of the decision aid in improving patient knowledge and satisfaction with the decision-making process. Finally, **chapter 7** reports on the randomized controlled trial that aimed to evaluate the use of a decision aid for patients undergoing an elective pulse generator exchange for their implantable cardioverter-defibrillator and assessed shared decision-making levels, decisional conflict, and knowledge before and after the intervention.

References

1. Townsend N, Kazakiewicz D, Lucy Wright F, Timmis A, Huculeci R, Torbica A, et al. Epidemiology of cardiovascular disease in Europe. Nat Rev Cardiol. 2022;19(2):133-43.
2. Hayashi M, Shimizu W, Albert CM. The spectrum of epidemiology underlying sudden cardiac death. Circ Res. 2015;116(12):1887-906.
3. Rajabali A, Heist EK. Sudden cardiac death: a critical appraisal of the implantable cardioverter defibrillator. Int J Clin Pract. 2014;68(4):458-64.
4. Nederland Z. Verbetersignalement Zinnige Zorg Implanteerbare Cardioverter-Defibrillator (ICD). 2023.
5. Zeppenfeld K, Tfelt-Hansen J, de Riva M, Winkel BG, Behr ER, Blom NA, et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Eur Heart J. 2022;43(40):3997-4126.
6. Lewis KB, Stacey D, Carroll SL, Boland L, Sikora L, Birnie D. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. Pacing Clin Electrophysiol. 2016;39(7):709-22.
7. van Rees JB, de Bie MK, Thijssen J, Borleffs CJ, Schalij MJ, van Erven L. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. J Am Coll Cardiol. 2011;58(10):995-1000.
8. de Bie MK, van Rees JB, Thijssen J, Borleffs CJ, Trines SA, Cannegieter SC, et al. Cardiac device infections are associated with a significant mortality risk. Heart Rhythm. 2012;9(4):494-8.
9. Burri H, Starck C, Auricchio A, Biffi M, Burri M, D'Avila A, et al. EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators: endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin-American Heart Rhythm Society (LAHRS). Europace. 2021;23(7):983-1008.
10. Siontis KC, Pantos I, Katritsis DG. Comparison of the longevity of implantable cardioverter-defibrillator devices by different manufacturers. Int J Cardiol. 2014;175(2):380-2.
11. Moss AJ, Schuger C, Beck CA, Brown MW, Cannom DS, Daubert JP, et al. Reduction in inappropriate therapy and mortality through ICD programming. N Engl J Med. 2012;367(24):2275-83.
12. Jagosz M, Jędrzejczyk-Patej E, Kowalska W, Mazurek M, Warwas S, Wiktor D, et al. Quality of life in patients with a subcutaneous vs. transvenous implantable cardioverter-defibrillator. Kardiol Pol. 2022;80(6):679-84.
13. Januszkiewicz Ł, Barra S, Providencia R, Conte G, de Asmundis C, Chun JKR, et al. Long-term quality of life and acceptance of implantable cardioverter-defibrillator therapy: results of the European Heart Rhythm Association survey. Europace. 2022;24(5):860-7.
14. Vohra J, Haqqani HM. The epidemiology and costs of implantable cardioverter-defibrillator therapy in Australia. Med J Aust. 2018;209(3):116-7.
15. Buxton M, Caine N, Chase D, Connelly D, Grace A, Jackson C, et al. A review of the evidence on the effects and costs of implantable cardioverter defibrillator therapy in different patient groups, and modelling of cost-effectiveness and cost-utility for these groups in a UK context. Health Technol Assess. 2006;10(27):iii-iv, ix-xi, 1-164.
16. Witt CM, Waks JW, Mehta RA, Friedman PA, Kramer DB, Buxton AE, et al. Risk of Appropriate Therapy and Death Before Therapy After Implantable Cardioverter-Defibrillator Generator Replacement. Circ Arrhythm Electrophysiol. 2018;11(8):e006155.
17. van Rees JB, Borleffs CJ, Thijssen J, de Bie MK, van Erven L, Cannegieter SC, et al. Prophylactic implantable cardioverter-defibrillator treatment in the elderly: therapy, adverse events, and survival gain. Europace. 2012;14(1):66-73.

18. Benjamin MM, Sorkness CA. Practical and ethical considerations in the management of pacemaker and implantable cardiac defibrillator devices in terminally ill patients. Proc (Bayl Univ Med Cent). 2017;30(2):157-60.

19. Hill L, McIlfatrick S, Taylor B, Dixon L, Harbinson M, Fitzsimons D. Patients' perception of implantable cardioverter defibrillator deactivation at the end of life. Palliat Med. 2015;29(4):310-23.

20. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J. 2015;36(41):2793-867.

21. Padeletti L, Arnar DO, Boncinelli L, Brachman J, Camm JA, Daubert JC, et al. EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2010;12(10):1480-9.

22. Wright GA, Klein GJ, Gula LJ. Ethical and legal perspective of implantable cardioverter defibrillator deactivation or implantable cardioverter defibrillator generator replacement in the elderly. Current opinion in cardiology. 2013;28(1):43-9.

23. Lampert R, Hayes DL, Annas GJ, Farley MA, Goldstein NE, Hamilton RM, et al. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. Heart rhythm. 2010;7(7):1008-26.

24. Yilmaz D, van der Heijden AC, Thijssen J, Schalij MJ, van Erven L. Patients With an ICD Remain at Risk for Painful Shocks in Last Moments of Life. J Am Coll Cardiol. 2017;70(13):1681-2.

25. Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Management of implantable cardioverter defibrillators in end-of-life care. Annals of internal medicine. 2004;141(11):835-8.

26. Lewis KB, Nery PB, Birnie DH. Decision making at the time of ICD generator change: patients' perspectives. JAMA Intern Med. 2014;174(9):1508-11.

27. Hauptman PJ, Chibnall JT, Guild C, Armbrecht ES. Patient perceptions, physician communication, and the implantable cardioverter-defibrillator. JAMA Intern Med. 2013;173(7):571-7.

28. Matlock DD, Jones J, Nowels CT, Jenkins A, Allen LA, Kutner JS. Evidence of Cognitive Bias in Decision Making Around Implantable-Cardioverter Defibrillators: A Qualitative Framework Analysis. J Card Fail. 2017;23(11):794-9.

29. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014(1):Cd001431.

30. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. BMC Med Inform Decis Mak. 2013;13 Suppl 2(Suppl 2):S2.