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

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Chapter 5

Implantable cardioverter-defibrillators and the older patient: the Dutch clinical practice.

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Abstract

Background and objective

Balance between benefit and burden of implantable cardioverter-defibrillator (ICD) therapy is more debatable in older patients, compared to younger patients. Of around 6000 yearly implanted ICDs in the Netherlands, 1:4 is received by patients ≥75 years. We aimed to evaluate the current clinical practice in the Netherlands for ICD implants and generator replacements, with a special focus on the older ICD patients.

Research design and methods

Cardiologists from all Dutch ICD implanting centres (n=28) were interviewed. Questions aimed to evaluate out-patient care, pre-operative patient assessment, end-of-life-care counselling, evaluation of social and cognitive wellbeing, clinical evaluation of all patients prior to ICD replacement and the consideration of the option to downgrade or not replace a device.

Results

Implanting cardiologists from all 28 implanting centres were approached for an interview. Response rate was 86%. Management appeared diverse. Age ≥80 was consistently reported as incentive for more extensive patient evaluation. Patients were invited for counselling prior to device replacements in only the minority (46%) of hospitals. Downgrade or non-replacement was performed in rare cases. End-of-life care discussions were not standard procedure in 67% of the hospitals. Evaluation of social and cognitive wellbeing of patients was based solely on the general clinical impression of the physician in 83%, or not at all assessed in 8% of the centres.

Discussion and implication

A structured framework for care and evaluation of cognitive and/or physical limitations is currently absent in most hospitals. At time of ICD (re-)evaluation, several factors may be considered before deciding on (continuation of) ICD therapy: patient preferences and comorbidity, the need for pacemaker therapy, primary versus secondary prevention, procedural risks and patient preferences.

Background

The perception of 'old age' varies amongst practitioners. The prevailing definition is currently older patients aged >75 with geriatric comorbidity, or simply 80 years of age and older in the general population. [1 2] Over the past decades, Implantable Cardioverter-defibrillators (ICDs) have become the cornerstone in the prevention of sudden cardiac death in selected patient populations, including older patients. In 2019, 6260 ICDs) were implanted in the Netherlands.[3] This included de novo implants and generator exchanges due to battery depletion. It should however be noted that ICD therapy is not without downsides. In a cohort of older patients, up to 1 in 4 patients experienced device-related complications.[4] The European guidelines state multidisciplinary clinical assessment combined with patient preferences should guide the decision making for potential ICD implantation.[5, 6] Moreover, in certain older patients, recent developments have questioned or even disproved the potential benefit of defibrillator therapy. [7-9] In this context, drawbacks and complications of ICD therapy (inappropriate shocks, pocket infections) are more emphasized. These considerations are even more important at the of time of pulse generator replacements, which provide an opportunity to re-evaluate whether it is desired to continue ICD therapy, weighing out ICD benefit, potential harm including higher rates of complications, and patient preferences and quality of life regarding the continuous prevention of sudden cardiac death. [10]

We aimed to evaluate the current clinical practice in the Netherlands for ICD implants and generator replacement, with a special focus on the older ICD patients.

Methods

For this descriptive study, a cross-sectional survey study was performed with representatives from all Dutch ICD implanting centres. In the Netherlands, 28 centres are qualified and certified by the Netherlands Society of Cardiology (NVVC) to perform implantable cardioverter-defibrillator procedures.[11] The responsible representatives from the cardiac devices departments of these centres were contacted through contact information provided by the NVVC. These Cardiologists were interviewed using surveys comprised of open-end questions addressing: the out-patient care for ICD patients, pre-operative patient education on end-of-life-care issues, ICD nurse involvement, social and cognitive evaluation of patients, clinical evaluation of all patients prior to ICD replacement and the consideration of the option to downgrade or not replace a device. In addition, all participants were asked to define what age they perceived to be 'an old patient' and comment. (*See appendix 1 for survey questions, supplementary data).* Questions on the survey

were designed based on clinical experience and outcome of interest. Desired outcome parameters were predefined. Responses were recorded on audiotape with permission from the participants and transcribed as text. Answers were analysed by the primary investigator and matched and scored accordingly to the predefined outcome parameter. Categorical variables were scored binary and are depicted as frequencies (percentage of total). Continuous variables were scored numerically and are presented as mean ± SD or median with interquartile range (IQR) [25th to 75th percentile] based on their distribution. The scientific review board of the Leiden University Medical Center Department of Cardiology and Leiden University Medical Center medical ethics committee approved the study.

Results

Twenty-four cardiologists were interviewed (response rate 86%; 3% female; mean age 49.5 ± 6.5 years, median clinical experience as a cardiologist 14.5 (IQR 11-18) years). Involved centres performed a median number of 237 (IQR 126-365) ICD procedures per year (table 1). Management appeared diverse amongst hospitals. All participant centres reported that they considered the age of 80 or older as a geriatric patient. However, most physicians commented that biological age, defined largely by comorbidity and social and cognitive wellbeing, was of more value in their decision making than the date of birth alone (table 2).

Answers from respondents included "calendar age is important, but there is a shift in what we perceive as old: 75 is the new 60" and "I value the mental and social wellbeing of my patients over their physical age".

Physicians consistently reported to perceive the age ≥80 years as incentive for more extensive patient evaluation and to have had cases in which devices were downgraded to pacemaker if indicated, or not replaced. In addition, evaluation of the social and cognitive wellbeing was solely based on the general clinical impression of the treating cardiologist in 83% of the centres and not addressed at all in 8% of the centres (table 2).

Answers from respondents included "I don't need extra tools to assess my patients. I have an established relationship with my patients for a long time, my clinical judgement allows me to assess whether they are suitable for an ICD" and "Usually my clinical judgement is enough, although in doubt I prefer to consult a geriatrician rather than use time consuming questionnaires that are not in my routine myself".

Patients were invited at the out-patient clinic prior to elective device replacements in 46% of the centres. Twenty-three (96%) of the centres involved an ICD nurse in the care of their patients. The ICD nurse was involved in pre-procedural discussions with patients, as well as their follow-up. In 17% of the centres, replacements as indicated during technical follow up were performed after evaluations based on medical records. End-of-life-care discussions were not part of standard pre-procedural consultation in 67% of the hospitals (table 2).

Discussion

This study shows that the need for ICD generator exchange is currently not rendered as a standard moment for patient counselling and evaluation of continued ICD care. From the point-of-view of device cardiologists, a structured framework for the care and evaluation of older patients or with cognitive and/or other physical limitations is currently absent in most hospitals in the Netherlands. Factors that may be taken into consideration before deciding on ICD therapy include social and cognitive wellbeing and comorbidity, the need for pacemaker therapy, primary or secondary prevention indication, procedural risks and patient preferences.

Patient screening

In this study, respondents defined old patients as 80 years and older. In addition, biological age with regards to comorbidity was more important than calendar age only. Currently, older patients received a quarter of the implanted ICDs in the Netherlands in 2019 according to the Netherlands' Heart Registry. [3] Multidimensional impairment is strongly related to the prognosis of older patients and thus the potential value of an ICD. However, the same factors predispose this group for peri-procedural complications. [12] This increases the demand for thoughtful patient selection and counselling. As is found in this study, a structured framework for this practice is currently absent. Most participating cardiologists rely on their own clinical judgement when evaluating their patients, which has previously been proven to be insufficient to fully comprehend a patient's situation.[13, 14] Standardized tools, including tools such as the Comprehensive geriatric assessment (CGA), were used on indication only in 8%. The CGA has nevertheless throughout the years proven beneficial as the multidimensional and multidisciplinary tool of choice in the holistic evaluation of a patient. [15] However, it is elaborate and time consuming and not currently implemented as a standard of care by the Dutch cardiologists. It can be discussed that it is perhaps more feasible to refer patients to geriatricians for a CGA, which is in line with a statement by one of the respondents in this study.

Pacing and downgrades

The cardiologists involved in the survey represented 24 centres responsible for a median number of 180 [IQR 128-365] ICD procedures per year. One of their centres implanted even up to 550 ICDs per year. All centres had encountered the issue of ICD tachytherapy deactivation or downgrading a device from an ICD to a pacemaker. Deactivating tachytherapy of an ICD is a non-invasive programming procedure. A significant number of the ICD patients, however, receive pacemaker therapy from the same device.[16, 17] When defibrillator therapy is no longer desired, exchanging for a pacemaker pulse generator would be appropriate in such cases. This is mechanically hampered because the ICD lead does not fit in the pulse generator header and may require implantation of a new additional pacing lead, which in turn increases the procedure associated risks. [18,19] This can potentially impede downgrades becoming part of routine clinical practice. More practical solutions such as an adaptor for the lead are yet to become available.[20]

Risks and preferences

Advance care planning and consultations regarding end-of-life issues were scarcely performed by the Dutch hospitals. Only 33% of the centres performed early advanced care planning discussions with all ICD patients. Benefit from ICD therapy in old ICD patients is not simply definable. Death from comorbidity outweighs the likelihood of receiving ICD therapy. Recent clinical trials, including a large European study, illustrated that a significant number of patients ≥75 years old have no benefit from ICD therapy. [4, 7, 21] This decrease however, does not apply to the risk for complciations.[12, 22] Aside from age, indications for ICD implantations are a continuous matter of debate. New trials have led to discussions on ICD benefit in populations included in the guideline. [23] For example the DANISH trial illustrated that in the non-ischemic cardiomyopathy population an ICD for primary prevention did not reduce all-cause mortality. [8]

Considering the drawbacks stated above, patient preferences should be considered when deciding for (continuation of) therapy. These considerations are particularly important at the of time of ICD generator replacements. With increasing battery longevity, patients will be around 10 years older at the moment of pulse-generator exchange compared to the moment of the initial ICD implantation.[24] Substantial clinical and personal changes are likely to have taken place in such a timeframe, rendering this moment favourable for the re-evaluation and possibly reconsideration of ICD therapy.[10] Patients remaining free from tachytherapy by their ICD in the period of their follow-up, may experience ICD benefit differently

from peers who did receive tachytherapy. Furthermore, with every pulse-generator exchanges the risk of a pocket infection increases, a potentially lethal complication requiring a high risk extraction procedure and systemic antibiotic treatment.[25] Only 46% of Dutch centres invited patients to the out-patient clinic as a standard part of care prior to pulse generator exchange procedures. Additionally, there are to date no recommendations or tools for the evaluation of patients at risk of non-benefit or to support the decision making regarding the ICD pulse generator replacement.

ICD nurses and Shared decision making

Shared decision making with decision aids facilitating patient counselling and taking into consideration patient preferences, can help choose the most suitable individual treatment. In the absence of guideline dictated selection criteria and structured framework for the counselling of ICD patients, shared decision making tools can provide an outcome in the future. Moreover, the recently updated European Society of Cardiology guideline on cardiac pacing and cardiac resynchronization therapy emphasizes the need for patient-centred care and shared decision making.[26] Most ICD centres employed a specialized ICD nurse (96%). These nurses were involved in all aspects of the ICD patient care and follow-up, allowing them to build up sustainable relationships with patients and gain insight on patient preferences. Recently, we have developed a Dutch web-based decision aid. The decision aid is aimed to improve patient knowledge and involvement and provide insight in patient preferences to both the caregiver and the patient. This will facilitate shared decision making in the consultation room. Currently, the decision aid is being evaluated in the setting of a multi-centre randomized controlled trial. Participating centres have chosen their ICD nurses as the primary caregiver to hand out decision aids to patients and discuss the results during follow-up out-patient clinic visits.

Study limitations

The study has a small sample size. However, suitable representatives with a clear oversight over their local clinical practice were selected from all Dutch ICD implanting centres. The study is limited to the Netherlands and thereby can potentially introduce bias reflecting the geographical and cultural practice. The interviews were conducted with only one device cardiologist per centre. This could have introduced reporting bias. Sample error cannot be excluded. However, the questions were answered independently with a high level of congruence

between the different centres. In addition, the questions were tailored to the collection of data aimed to evaluate current clinical practice in Dutch ICD centres and thereby answer our research question. We therefore believe the findings of this study reflect the Dutch clinical practice at the time it was conducted.

Implications for practice

- An increasing proportion of ICD patients are of old age.
- Continuing ICD therapy is not a life-time commitment and can be re-evaluated periodically, preferably at time for pulse-generator replacement.
- Patient preferences and social and cognitive wellbeing are important to consider when making a shared decision.
- Decision aids facilitate shared decision making and can help clarify patient preferences.
- Current design of ICD pulse generators and leads impedes downgrades to a pacemaker.

Conclusion

An increasing proportion of ICD patients are of older age. A structured framework for the care and evaluation of older patients is absent in most hospitals in the Netherlands. Shared decision making and the implementation of a decision aid can potentially help improve decision making and management of ICD patients. Such decision aids are aimed to improve patient knowledge and involvement and subsequently decrease decisional conflict.

Disclosures

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TABLES

Table 1. Demographic details of participants.

Responses	**n = 24**
Female respondents, n (%)	3 (13)
Age, mean (SD)	48.5 (6.5)
Years of experience as cardiologist, median (IQR)	14.5 (11-18)
ICD implantations per year (per center), median (IQR)	180 (128-365)

ICD = Implantable cardioverter-defibrillator, IQR = interquartile range

Table 2. Key findings.

Responses	**n = 24**
ICD Nurse involved in patient counselling and follow-up, n (%)	23 (96)
Pre-procedural assessment and counselling of patients at out-patient clinic, n (%)	20 (83)
Pre-procedural information and patient education, n (%)	22 (92)
Patient education on end-of-life issues included in pre-procedural counselling	
• In all patients, n (%)	8 (33)
• In older patients or/and significant comorbidity, n (%)	6 (25)
• Not included, n (%)	10 (42)
Social and cognitive wellbeing evaluation	
• Using standardised tools (when indicated), n (%)	2 (8)
• Solely based on 'clinical impression', n (%)	21 (88)
• None, n (%)	2 (8)
Evaluation when patient is up for pulse-generator exchange due to battery depletion	
• None / based on administrative clinical parameters, n (%)	6 (25)
• Personal discussions with patient at outpatient clinic	
◦ Only in patients selected on old age or increased comorbidity based on clinical parameters, n (%)	7 (29)
◦ All patients, n (%)	11 (46)
One or more downgrades or ICD-deactivations performed in past 5 years, n (%)	24 (100)

ICD = Implantable cardioverter-defibrillator