Defibrillator exchange in the elderly

Henrike Andresen, MD,* Nikolaos Pagonas, MD,*† Marius Eisert, MD,† Daniel Patschan, MD,*†‡ Peter Nordbeck, MD,§ Ivo Buschmann, MD,*†‡ Benjamin Sasko, MD,*†¶ Oliver Ritter, MD*†‡

*From the *Department of Internal Medicine I, Klinikum Brandenburg, Brandenburg/Havel, Germany, †Brandenburg Medical School Theodor Fontane, Brandenburg/Havel, Germany, ‡Faculty of Health Sciences Brandenburg, Brandenburg/Havel, Germany, §Department of Internal Medicine I, University Hospital of Würzburg, Würzburg, Germany, and ¶Department of Internal Medicine IV–Cardiology, Knappschaftskrankenhaus Bottrop, Bottrop, Germany.*

BACKGROUND Implantable cardioverter-defibrillator (ICD) therapy in elderly patients is controversial because survival benefits might be attenuated by nonarrhythmic causes of death.

OBJECTIVE The purpose of this study was to investigate the outcome of septuagenarians and octogenarians after ICD generator exchange (GE).

METHODS A total of 506 patients undergoing elective GE were analyzed to determine the incidence of ICD shocks and/or survival after GE. Patients were divided into a septuagenarian group (age 70–79 years) and an octogenarian group (age ≥80 years). The primary endpoint was death from any cause. Secondary endpoints were survival after appropriate ICD shock and death without experiencing ICD shocks after GE ("prior death").

RESULTS The association of the ICD with all-cause mortality and arrhythmic death was determined for septuagenarians and octogenarians. Comparing both groups, similar left ventricular ejection fraction (35.6% ± 11.2% vs 32.4% ± 8.9%) and baseline prevalence of New York Heart Association functional class III or IV heart failure (17.1% vs 14.7%) were found. During the entire follow-up period of the study, 42.5% of patients in the septuagenarian group died compared to 79% in the octogenarian group ($P < .01$). Prior death was significantly more frequent in both age groups than were appropriate ICD shocks. Predictors of mortality were common in both groups and included advanced heart failure, peripheral arterial disease, and renal failure.

CONCLUSION In clinical practice, decision-making for ICD GE among the elderly should be considered carefully for individual patients.

KEYWORDS Generator exchange; Implantable cardioverter-defibrillator; Octogenarians; Quality of life; Septuagenarians

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Introduction

Implantable cardioverter-defibrillator (ICD) therapy represents one of the cornerstones for primary and secondary prevention of sudden cardiac death.[1] The majority of ICD recipients are older patients. In the recent ICD landmark trials, >40% of ICDs were implanted in individuals >70 years of age, but at the same time most controlled ICD trials defined age >80 years as an exclusion criterion.[2]

Following current recommendations, ICD implantations are "rarely appropriate" in nonagenarians (ie, individuals ≥90 years of age).[3] In general, a prognosis of 1-year survival is recommended as a criterion for ICD implantation. However, this primarily relates to malignant concomitant diseases and severe comorbidities, with less focus on patient age. In a constantly aging population, many individuals develop several comorbidities and are prone to die of conditions other than cardiac disease.[4] In these patients, ICD therapy decreases quality of life (QoL) or even prolongs end-of-life situations.[5] The risk (or benefit) of receiving ICD therapy ranges between 20% and 50% depending on the indication for primary or secondary prevention.[6–8] Patients who have not received shocks during the first battery life of an ICD have a 25% probability of adequate ICD therapies at 5-year follow-up after generator exchange (GE).[6] This has been shown to have a negative effect on QoL, but with the net effect of saving lives.[9] Systematic reviews as well as controlled trials found that approximately 20% of ICD patients suffer from significant psychological distress with anxiety and depression related to the ICD.[10,11]

In an elderly population, prognostic considerations may be less relevant than QoL and might require an adaptation of therapeutic goals. Accordingly, not replacing the ICD when battery depletion occurs could be a reasonable option.[12]

To improve QoL for patients in the late periods of life, clinicians have raised questions about device deactivation

Address reprint requests and correspondence: Dr Oliver Ritter, Klinik für Kardiologie, Medizinische Hochschule Brandenburg, Hochstraße 29, 14770 Brandenburg an der Havel, Germany. E-mail address: o.ritter@klinikum-brandenburg.de.

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KEY FINDINGS

- During follow-up of 4 years after implantable cardioverter-defibrillator (ICD) exchange due to battery depletion, mortality was high in older patients: 42% in the septuagenarian group and 79% in the octogenarian group.
- Prior death was significantly more frequent than appropriate ICD therapy in these patients, and the effect was more pronounced in the octogenarian group.
- Predictors of mortality were advanced heart failure, peripheral artery disease, and renal failure.
- Complication rates and inappropriate therapies were similar to those reported in other trials despite the advanced age of these patient cohorts.

or exchange,[12–14] yet only a minority of patients have discussed these options with their physician[15] and no reliable data on patients' wishes are available.

Despite the increasing numbers of ICD exchanges in elderly patients, only a few reports are available on further follow-up in an elderly patient population with regard to survival, concomitant diseases, mode of death, and QoL. Therefore, we assessed survival, mode of death, necessity of ICD therapy, psychological distress, and comorbidities in the follow-up period after ICD exchange in septuagenarians and octogenarians.

Methods

This study was an investigator-initiated retrospective, observational, bicenter cohort study of 506 patients with previous ICD implantations. After providing written informed consent, patients with a minimum age of 70 years were enrolled if GE had been performed. Patients were screened at GE surgery and underwent follow-up at their institution during regular device follow-up.

Patients were questioned about heart failure symptoms, comorbidities, medications, depression, anxiety, QoL, and hypothetical deactivation of ICD function at the time of GE. Patients also were assessed for ejection fraction (EF), previous ICD therapies, indication for first ICD implantation, and presumable mode of death, if applicable.

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) standard, and was approved by the local ethics committee.

Study population

Inclusion criteria were any reason for ICD implantations (including cardiac resynchronization therapy–defibrillator devices), regardless of ischemic or dilated cardiomyopathy or channelopathy and GE. Patients with both primary or secondary prevention indication ICDs were included. We included only patients in whom their previous ICD had been implanted for at least 1 year. In all patients, implantation was performed according to ICD guidelines at the indicated time. Enrollment started in October 2013 (University Hospital Würzburg) and 2015 (University Hospital Brandenburg). The administrative censoring date was 2020. Exclusion criteria were dementia or any other state of absent legal competence. Baseline patients characteristics are listed Table 1.

Endpoints

The primary endpoint was death from any cause. Secondary endpoints were survival after appropriate ICD therapy and death without experiencing ICD shocks after GE (stated as "prior death"). Appropriate ICD shock for ventricular tachycardia (VT) or ventricular fibrillation (VF) was defined as delivery of shock therapy in the respective tachycardia zone, which was programmed individually for each patient. In general, the VT zone was programmed at >180 bpm and the VF zone >220 bpm. Programming was not standardized but was determined individually in each patient at the discretion of the treating physician to prevent early (and painful) ICD shocks.

Mode of death

Mode of death was assigned according to the physician's discretion. Device interrogation was performed physically in case of inpatient settings or per telemedicine in outpatient settings. Arrhythmic death was assigned if device interrogation revealed an arrhythmia that could not be terminated.

Table 1 Baseline patient data

	Age group (y)		
	70–79	≥80	*P* value
Demographic data			
No.	399	107	
Age (y)	74.4	82.3	.001
Female (%)	41	44	.4
NYHA functional class	2.3	2.7	.1
Years since implantation	7,3	9,5	<.05
Primary prevention (%)	61	65	.3
Secondary prevention (%)	39	35	.3
No. of previous ICDs	1.3	1.5	.1
Patients with previous shocks (%)	29	30	.4
Patients with ischemic cardiomyopathy (%)	78	82	.4
Clinical data			
Atrial fibrillation (%)	23	32	<.01
PAD (%)	17	28	<.05
Previous stroke (%)	11	21	<.05
Neurological disorders (%)	12	19	<.05
Advanced kidney disease (%)	7	27	<.001
Diabetes (%)	27	26	.3
Hypertension (%)	63	61	.4
COPD (%)	18	16	.4

Patients were considered as having kidney disease if glomerular filtration rate was <30 mL/min/1.73 m^2.

COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; PAD = peripheral artery disease.

Statistical analysis

The primary endpoint was survival after elective GE. The incidence of the primary endpoint, stratified by age group, was estimated by Kaplan-Meier curves. The log-rank test was used to calculate *P* values, and hazard ratios (HRs) and confidence intervals (CIs) were generated from a multivariate Cox proportional hazards model. Clinically important predictors of outcome were used in a multivariate Fine and Gray model for competing risk analysis (appropriate ICD shock or prior death), using nonarrhythmic mortality as a competing risk and appropriate ICD shock as an endpoint. Cumulative incidence curves were used to display appropriate ICD shock or prior death separated by age group. Standardized self-report questionnaires were used for psychometric assessments, that is, Hospital Anxiety and Depression Scale (HADS) subscales for anxiety and depression assessment. Data analysis was conducted using SPSS Version 20 (IBM, Germany) and R software Version 3.4.0 (R Core Team, Vienna, Austria; http://www.r-project.org).

Results

Patient characteristics

Among 506 elderly patients who underwent ICD GE, 399 were between 70–79 years of age, and 107 patients were ≥80 years at the time of battery exchange. Left ventricular EF was 32% in the age group 70–79 years (septuagenarians) and 33.7% in the age group ≥80 years (octogenarians). Average New York Heart Association functional classification was 2.3 in the younger group and 2.7 in the older group. Septuagenarians received 6 medications on average and had 6 comorbidities; octogenarians received 8 medications on average and had 8 comorbidities. In the septuagenarian group 41% of patients were female vs 44% in the octogenarian group. Septuagenarians had a statistical average of 1.3 prior ICD GEs with 7.3 years since initial implantation, and octogenarians had 1.5 prior GEs with an average of 9.5 years since initial ICD implantation. Median follow-up was 4.3 years in both groups. Baseline characteristics are listed in Table 1. In the septuagenarian group 61% of ICDs were implanted for primary prevention; in the octogenarian group 65% had an indication for primary prevention for the first implantation. Octogenarian patients were more likely to exhibit atrial fibrillation, peripheral artery disease, previous stroke, neurological disorders, and reduced kidney function compared to septuagenarian patients. Hypertension, chronic lung disease, and diabetes were similar across both age groups.

Mortality

Over mean follow-up of 4.3 years, older patients (octogenarians) had a higher all-cause mortality. During the entire follow-up period of the study, 42.5% patients (168/399) in the septuagenarian group died compared with 79% (85/107) in the octogenarian group ($P < .01$). Kaplan-Meier estimates of the time to the primary endpoint of death from any cause are shown in Figure 1A.

Deaths increased with older age after both primary and secondary prevention implantations. Statistically significant ($P < .05$) predictors of mortality were common to both groups and included advanced heart failure, peripheral arterial disease, and renal failure (glomerular filtration rate <30 mL/min/1.73 m^2) (Table 2). Death after appropriate shock during previous battery lifetimes was highest in the octogenarian group (Figure 1B). However, there was no predictive value of appropriate shocks during earlier battery cycles. Adjusted HR for death per year was 1.08 (95% CI 0.98–1.44; $P = .17$) for septuagenarians and 1.04 (95% CI 0.94–1.59; $P = .08$) for octogenarians.

We also assessed survival after appropriate shock in the current ICD lifetime (Figure 1B). After a survived appropriate shock, 80% of patients in the septuagenarian group were alive after 6 months. The 1-, 2-, and 3-year survival rates were 78%, 68%, and 62%, respectively. In the octogenarian group, 78% of patients were alive after 6 months, with 1-, 2-, and 3-year survival rates of 68%, 43%, and 41%, respectively. Comparing prior death vs appropriate ICD shock, we found that prior death was significantly more frequent in both age groups than was appropriate therapy (Figures 1C and 1D, and Supplemental Table 1).

Modes of death

A total of 252 deaths were included in the analysis. During median follow-up of 4.3 years [interquartile range 2.7–5.4 years], 168 patients in the septuagenarian group after ICD GE died vs 85 patients in the octogenarian group. Heart failure death and non–cardiac death were the most common modes of death for both groups. Sudden (arrhythmic) death accounted for 5% of all deaths in the septuagenarian group and 7% of all deaths in the octogenarian group. Arrhythmic death was defined as death during VT/VF episodes recorded in the ICD memory. Causes of antiarrhythmic death were pneumonia/chronic obstructive pulmonary disease, sepsis, stroke/intracranial bleeding, terminal heart failure, terminal kidney failure, progressive neurological disorders, and acute myocardial infarction (Figure 2). The most significant differences with regard to mode of death between the 2 age groups were terminal heart failure (43% in septuagenarians vs 29% in octogenarians; $P < .05$) and increase in stroke/intracranial bleeding in the same group (5% vs 17%; $P < .05$).

ICD use following previous ICD shocks

In the septuagenarian group, 29% had an appropriate ICD shock for VT or VF during previous generator lifetimes; 71% had no former ICD shocks. In the octogenarian group, 30% had earlier ICD shocks; 70% had no previous shocks.

During follow-up, the rates of appropriate ICD shocks in septuagenarians with (n = 115) and without (n = 284) former appropriate ICD shocks were 41% and 19% (adjusted HR 1.89; 95%T CI 1.21–2.21; $P < .001$), respectively. In the octogenarian group, rates of ICD shocks with (n = 32) and without (n = 75) former appropriate ICD shocks were 22% and 17% (adjusted HR 1.75; 95% CI 1.11–2.31; $P < .01$),

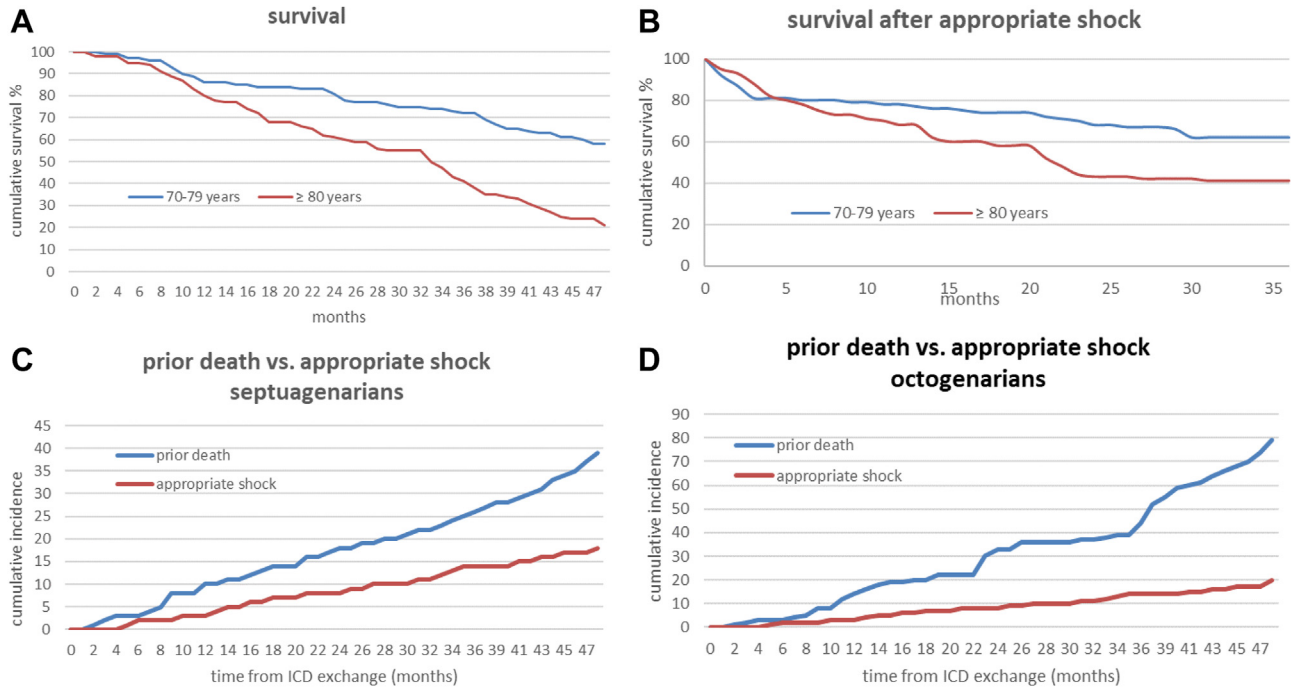

Figure 1 **A:** Unadjusted survival of the septuagenarian group *(blue line)* and the octogenarian group *(orange line).* There is an unadjusted 37% difference in survival between the 2 age groups. **B:** Unadjusted survival of the septuagenarian group *(blue line)* and the octogenarian group *(orange line)* after the first implantable cardioverter-defibrillator (ICD) shock after generator exchange. There is a 20% decrease in survival in the first 6 months after an appropriate ICD shock. **C:** Cumulative incidence of first appropriate ICD therapy and prior death after ICD exchange in the septuagenarian group. **D:** Cumulative incidence of first appropriate ICD therapy and prior death after ICD exchange in the octogenarian group.

Table 2 Multivariate cox regression analysis for predictors of total mortality in septuagenarians and octogenarians

	HR	95% CI	*P* value
Septuagenarians			
Female	0.97	0.68–1.43	.97
NYHA **functional class** III–IV	1.57	1.23–2.01	.01
Previous shock	1.08	0.98–1.44	.17
Atrial fibrillation	1.26	0.86–1.91	.08
PAD	2.13	1.52–3.11	.001
Previous stroke	1.13	0.75–2.98	.053
Neurological disorders	1.41	1.01–1.96	.05
Advanced kidney disease	1.76	1.29–2.37	.001
Diabetes	1.23	0.91–1.91	.079
Hypertension	1.16	0.81–1.87	.247
COPD	1.29	0.91–1.89	.131
Ischemic cardiomyopathy	1.03	0.78–1.58	.113
Secondary prevention	1.06	0.69–1.64	.79
Octogenarians			
Female	0.99	0.61–1.48	.097
NYHA **functional class** III–IV	1.61	1.13–2.31	.01
Previous shock	1.04	0.94–1.59	.08
Atrial fibrillation	1.21	0.88–1.97	.08
PAD	2.18	1.49–2.19	.001
Previous stroke	1.17	0.65–2.18	.053
Neurological disorders	1.41	1.07–1.83	.05
Advanced kidney disease	1.91	1.31–2.45	.001
Diabetes	1.13	0.81–1.73	.079
Hypertension	1.21	0.77–1.65	.247
COPD	1.12	0.79–1.87	.131
Ischemic cardiomyopathy	1.07	0.82–1.61	.13
Secondary prevention	1.02	0.72–1.58	.89

CI = confidence interval; HR = hazard ratio; other abbreviations as in Table 1.

respectively. The results were similar if we looked at primary or secondary indications (Table 3 and Figure 3A).

Statistically significant ($P < .05$) predictors of appropriate ICD shocks were previous ICD shocks during earlier battery life times, advanced heart failure, peripheral artery disease, and advanced kidney disease in both septuagenarians and octogenarians. Predictors of prior death (before an ICD shock occurred) were advanced New York Heart Association functional class III–IV, peripheral arterial disease, and advanced kidney disease, which were common to both age groups (Supplemental Table 1).

Previous ICD criteria

Reasons for first ICD implantation were either secondary prophylaxis or an indication for primary prophylaxis due to heart failure with reduced EF or European Society of Cardiology guideline recommendations for channelopathies or cardiomyopathies. In the septuagenarian group, 87% of patients still met the original ICD criteria at the time point of exchange; in the octogenarian group, 82% of patients still met the criteria (Figure 3B). The reason for not meeting the criteria was improvement of EF in both age groups. However, in the patients who received a new ICD generator, fluctuations in EF occurred during the observation period. Therefore, the improvement was expected to not be persistent. In septuagenarian group 33% of patients who met the previous criteria during exchange had an appropriate shock during follow-up vs 20% in the octogenarian group. Among patients who did not meet previous criteria, 9% in the septuagenarian

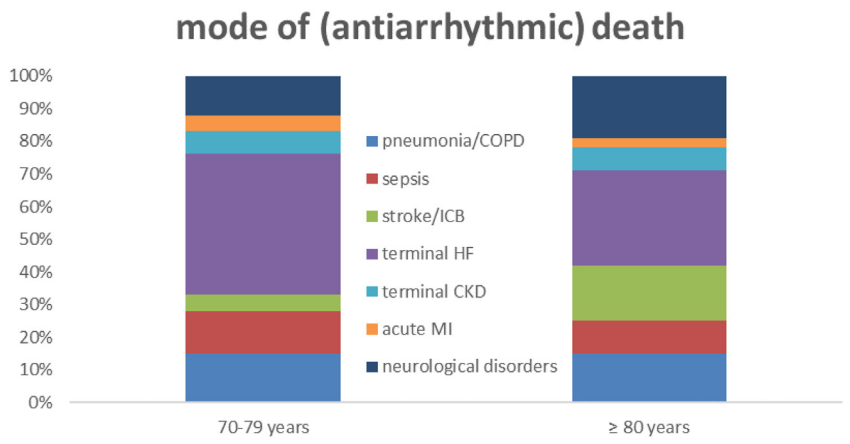

Figure 2 Modes of antiarrhythmic death separated by age group. Terminal heart failure (HF) was the leading mode of death in both age groups. The prevalence of neurological disorders increased in the octogenarian group. CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; ICB = intracranial bleeding; MI = myocardial infarction.

group had an appropriate shock during follow-up and 11% in the octogenarian group. There was no significant difference in the number of patients who received shocks with regard to the persistence of previous ICD indications.

Patient views

In the septuagenarian group, 17% had depression, 24% had anxiety, 26% had concerns related to ICD shocks and technical problems, and 29% described a low perceived control in life. One-third of patients (34%) received at least 1 shock prior ICD GE and their experience was significantly correlated with a higher perception of symptoms (eg, anxiety) compared to patients who did experience any shock in the past (24% vs 10%, respectively; $P < .01$).

In the octogenarian group, 23% reported symptoms of depression, 19% had anxiety, 22% complained of concerns related to the ICD, and 33% mentioned a low perceived control in life; 30% had received at least 1 shock prior to ICD GE. Again, this correlated with a higher percentage of symptoms (eg, anxiety) compared to those without any incidence of shock (19% vs 9%, respectively; $P < .01$) (Tables 4 and 5).

When asked the hypothetical question to decide for or against GE in case of a future study contribution at the time of battery depletion of the ICD, most participants in the septuagenarian group stated that they would like to renew the ICD even if no shock therapy had been necessary (92%), 3% declined GE, and 5% had no opinion. In the octogenarian group, 61% voted for exchange, 9% declined GE, and 30% had no opinion (Figure 4).

Table 3 Predictors of appropriate ICD therapy

	HR	95% CI	*P* value
Septuagenarians			
NYHA functional class III–IV	1.49	1.17–2.09	.01
PAD	2.02	1.51–3.01	.01
Previous shocks	1.89	1.21–2.21	.001
Previous stroke	1.21	0.69–2.34	.06
Neurological disorders	1.39	0.97–1.91	.06
Advanced kidney disease	1.79	0.89–2.41	.001
Diabetes	1.13	0.81–1.85	.07
Secondary prevention	1.19	0.79–1.82	.07
Octogenarians			
NYHA funcional class III–IV	1.32	1.07–2.12	.01
PAD	2.21	1.56–2.91	.01
Previous shocks	1.75	1.11–2.31	.01
Previous stroke	1.34	0.71–2.09	.07
Neurological disorders	1.42	0.87–1.85	.08
Advanced kidney disease	1.57	0.79–2.22	.001
Diabetes	1.09	0.68–1.76	.06
Secondary prevention	1.23	0.72–1.78	.06

Independent multivariable Fine and Gray models for prediction of appropriate implantable cardioverter-defibrillator (ICD) therapy in septuagenarians and octogenarians. Predictors for appropriate ICD therapy with $P < .1$ are listed. Nonsignificant predictors ($P > .1$) were female gender, ejection fraction <35%, persistence of previous ICD criteria, atrial fibrillation, hypertension, chronic obstructive pulmonary disease, and ischemic cardiomyopathy in both groups.

Abbreviations as in Tables 1 and 2.

Complications due to GE and inappropriate ICD therapy

Pocket hematomas attributable to device replacement requiring reoperation occurred in 12 patients (3.1%) in the septuagenarian group and 2 patients (1.9%) in the octogenarian group. A major complication requiring clinical interventions was hospital-acquired pneumonia (3 patients [0.75%] in the septuagenarian group and 2 patients [2%] in the octogenarian group). We observed no pocket infections and no deaths related to GE. No lead complications related to GE occurred in our patients.

In the septuagenarian group, inappropriate ICD shocks occurred in 9% of patients before ICD exchange and 7% of patients after ICD exchange. In the octogenarian group, inappropriate ICD shocks occurred in 7% of patients before ICD exchange and 8% of patients after ICD exchange.

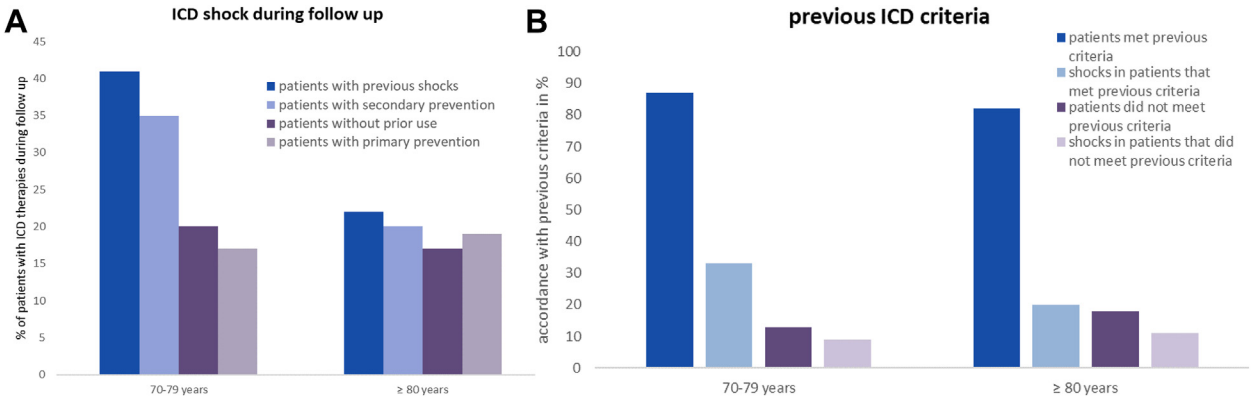

Figure 3 **A:** Implantable cardioverter-defibrillator (ICD) use after previous therapies during earlier generator lifetimes. The number of patients in the septuagenarian group with secondary prevention indication or previous ICD shocks who received an ICD shock during follow-up compared to the octogenarian group. **B:** Assessment for relevance of prior ICD criteria. Most patients still met the previous criteria from the first ICD implantation at the time of ICD generator exchange. Nevertheless, patients who did not meet the previous criteria experienced appropriate ICD shocks during follow-up.

Discussion

Implantation of an ICD is an established therapy for prevention of sudden cardiac death.[16–24] In an aging population with an increasing number of ICD implantations, the number of elderly patients considered for ICD GE due to battery discharge is continuously increasing.[25] However, data supporting the clinical effectiveness of the ICD in patients at older ages are inconsistent.[19,26–32] The few elderly patients selected for admission into large randomized clinical trials are not representative of the real-world elderly population. We hypothesize that the assumption of persistent ICD benefit in the elderly population is questionable, as any advantage of the device with regard to arrhythmic death may be attenuated by a higher total nonarrhythmic mortality rate.[33] Therefore, we assessed the outcomes of 506 patients with age >70 years after ICD GE.

The key findings of this study were as follows. (1) Mortality increases with age in ICD patients. (2) Prior death is significantly more frequent than appropriate ICD shocks and was more pronounced in the octogenarian group. (3) Predictors of mortality were advanced heart failure, peripheral artery disease, and renal failure. (4) Complication rates and inappropriate therapies were similar to those reported in other trials despite the advanced age of these patient cohorts.

In our analysis, we found that mortality over follow-up of 4.3 years was 42% in the septuagenarian group and 79% in the octogenarian group. We also observed that the majority of patients died without experiencing ICD shocks. These data highlight that the benefits of ICD therapy likely diminish over time. For most individuals in our cohort, the proportional risk of arrhythmic death decreased over time because of an age-related increase in competing risks of nonarrhythmic death. ICDs are able to prevent only arrhythmic causes of death; therefore, it is likely that the benefit associated with ICD therapy vanishes over time, leading to a very low rate of ICD use in this patient population.

Other trials showed similar 1-year mortality rates in geriatric ICD patients, ranging from 10%–30% depending on comorbidities[34] and >50% in octogenarians.[35] After appropriate ICD therapy (from the new ICD, after GE), survival was approximately 80% in both age groups after 6 months in our trial. Although overall mortality was high in our patients, persistent survival after an ICD shock suggests that there is a subset of patients who benefit from ICD GE and subsequent ICD therapy in terms of prognosis. Of note, in that specific elderly population the pure lifesaving effect of the ICD may be outweighed by a low QoL.

We observed terminal heart failure as a leading mode of death in both patient groups, although neurological disorders were increased in the older patient group. Predictors of death were advanced renal failure, peripheral artery disease, and secondary prevention as indication for the first implantation.

Table 4 Percentage of patients who suffered from psychological distress

Age group (y)	70–79	≥80
Anxiety	23/10*	19/9*
Depression	17/16	23/22
Low perceived control in life	29/19*	33/30
Technical concerns	26/24	22/20

Values are given as % patients with prior implantable cardioverter-defibrillator shocks/% patients without prior shocks.
*P <.05 for differences in groups with and without shocks.

Table 5 Multivariate cox regression analysis for predictors of anxiety or depression

	HR	95% CI	P value
Anxiety			
Age 70–79 y	1.16	0.78–2.11	.13
Age >80 y	1.08	0.88–1.34	.17
Previous shock	1.82	0.81–2.16	.05
Depression			
Age 70–79 y	1.13	0.74–2.18	.06
Age >80 y	1.31	1.03–1.97	.07
Previous shock	1.91	1.29–2.37	.01

Abbreviations as in Table 2.

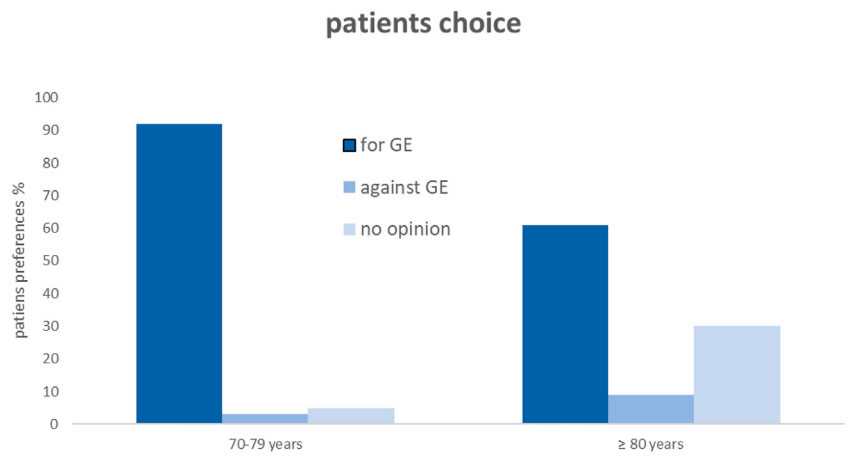

Figure 4 Patient views on generator exchange (GE). Most patients preferred implantable cardioverter-defibrillator GE after being asked the hypothetical question whether GE exchange should take place in case of battery depletion. The number of patients with no clear opinion increased in the octogenarian group.

Ischemic cardiomyopathy and secondary prevention were not significant predictors.

ICD registries have shown that the majority of ICDs are implanted in patients >60 years of age, and >40% of new ICDs are implanted in patients >70 years of age. The average battery lifetime of ICDs currently is between 4 and 8 years, so patients face ICD GE for battery discharge after that period of time. In parallel, health conditions usually deteriorate during that period, with progression of congestive heart failure , pulmonary or kidney disease, or frailty-related disorders. Data from Medicare patients from the National Cardiovascular Data Registry show that 1-year mortality was 22% for ICD patients with frailty, and subsequent observational studies found that patients with a predicted 1-year mortality risk of 20% did not benefit from an ICDs.[34,36] A meta-analysis by Santangeli et al[37] reported on pooled data from the DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation), SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial), and MADIT (Multicenter Automatic Defibrillator Implantation Trial) studies but was unable to demonstrate a significant survival benefit of the ICD in the elderly. A different meta-analysis pooled individual patient data from all 3 secondary prevention trials comparing ICD to amiodarone (AVID [Antiarrhythmics Versus Implantable Defibrillators], CIDS [Canadian Implantable Defibrillator Study], and CASH [Cardiac Arrest Study–Hamburg]) and concluded that ICD therapy did not seem to offer a survival benefit in secondary prevention patients ≥75 years of age.[32]

Recent findings from the EU-CERT-ICD (EUropean Comparative Effectiveness Research to Assess the Use of Primary ProphylacTic Implantable Cardioverter-Defibrillators) Registry showed that younger patients <75 years benefit from ICD implantation, whereas older patients ≥75 years did not benefit from ICD implantation.[38] In the DANISH (DANish Randomized, Controlled, Multicenter Study to Assess the Efficacy of Implantable Cardioverter Defibrillator in Patients With Non-ischemic Systolic Heart Failure on Mortality) trial, patients with dilated cardiomyopathy <68 years benefited from ICD implantation, whereas older patients ≥68 years did not benefit.[39] These results show that, in line with our observations, ICD battery renewal in older patients does not necessarily improve prognosis in terms of survival.

An important additional aspect when considering ICD replacement in the elderly is QoL, which may change drastically with advancing age. There is little but inconsistent QoL data on the use of ICDs in elderly patients, which is a paradox because QoL often is a critical factor in clinical decision-making in the elderly.[40-42] Shared decision-making processes may help to determine the solution for individual patients[43,44] but is hampered by the lack of data from randomized trials.

In general, although older patients with ICDs exhibit decreased physical functioning, a higher frequency of comorbidities, and worsening of symptoms that negatively impact on QoL, younger patients with ICDs tend to experience increased psychological distress, anxiety, and depression.[11,40-42] Patient perceptions of ICD deactivation are heterogeneous, and most felt that the decision should be the physician's responsibility.[45]

In our patients, we observed consistently that >20% of patients reported symptoms of depression, anxiety, or ICD-related concerns, regardless of the age group. The number of patients increased after they had received appropriate ICD shocks. Important in this context is that complication rates and rates of inappropriate ICD therapy were similar in other trials of younger patients.[46]

Consequently, the absolute benefit of ICDs in a typical, elderly, community-based, well-treated population with heart failure might be small. These observations highlight the need to offer ICD therapy to the patient cohort that most likely will benefit, specifically, to those who remain at high risk for sudden death despite additional therapy and those who are able and willing to balance prolonged survival and QoL with regard to advancing comorbidities. Predictors of mortality were advanced heart failure, advanced kidney disease, and peripheral artery disease. Mortality was higher in

octogenarians compared to septuagenarians. Of note, mortality of older patients was similar to an age-matched general population irrespective of delivery of ICD therapy.[47]

Study limitations

This study was based on patients from only 2 centers and was not prospective or randomized. Further, this study was not designed to develop a score for prediction of ICD use in an elderly population.

Conclusion

Older patients with ICDs have a high incidence of nonarrhythmic death. In this patient group, the ICD does not afford the same survival benefit as that seen in younger patients. High mortality rates in a geriatric population and nonarrhythmic deaths counteract the protective effects of ICDs. Therefore, clinical decision-making for ICD GE among elderly patients should be considered carefully for individual patients until randomized trials provide a more solid basis for clinical decision-making.

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Ethics Statement: The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) standard, and was approved by the local ethics committee.

Appendix
Supplementary Data

Supplementary data associated with this article can be found in the online version at 10.1016/j.hroo.2023.05.001.

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