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Implantable cardiac defibrillators in octogenarians

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ABSTRACT

OBJECTIVE Implantable cardiac defibrillators (ICD) implantation in the very elderly remains controversial. We aimed to describe the experience and outcome of patients over 80 years old implanted with an ICD in Belgium.

METHODS Data were extracted from the national QERMID-ICD registry. All implantations performed in octogenarians between February 2010 and March 2019 were analysed. Data on baseline patient characteristics, type of prevention, device configuration and all-cause mortality were available. To determine predictors of mortality, multivariable Cox proportional hazard regression modelling was performed.

RESULTS Nationwide, 704 primo ICD implantations were performed in octogenarians (median age 82, IQR 81-83 years; 83% male and 45% secondary prevention). During a mean follow-up of 3.1 ± 2.3 years, 249 (35%) patients died, of which 76 (11%) within the first year after implantation. In multivariable Cox regression analysis age (HR = 1.15, P = 0.004), oncological history (HR = 2.43, P = 0.027) and secondary prevention (HR = 2.23, P = 0.001) were independently associated with 1-year mortality. A better preserved left ventricular ejection fraction (LVEF) was associated with a better outcome (HR = 0.97, P = 0.002). Regarding overall mortality multivariable analysis withheld age, history of atrial fibrillation, centre volume and oncological history as significant predictors. Higher LVEF was again protective (HR = 0.99, P = 0.008).

CONCLUSIONS Primary ICD implantation in octogenarians is not often performed in Belgium. Among this population, 11% died within the first year after ICD implantation. Advanced age, oncological history, secondary prevention and a lower LVEF were associated with an increased one-year mortality. Age, low LVEF, atrial fibrillation, centre volume and oncological history were indicative of higher overall mortality.

Patients with heart failure with reduced ejection fraction (HFrEF) have an increased risk of sudden cardiac death (SCD). Clinical trials have shown convincingly that selected patients with HFrEF who received an implantable cardioverter-defibrillator (ICD) have a better survival in comparison with patients treated with anti-arrhythmic drugs only. This was first reported in 1996 in patients with previous myocardial infarction who had inducible ventricular arrhythmia during electrophysiological testing.[1,2] Later the MADIT-II trial showed that this benefit was preserved in ischemic heart disease (IHD) with a low left ventricular ejection fraction (LVEF), even when omitting electrophysiological testing for patient selection.[3] Subsequently, trials were conducted in patients with non-ischemic heart disease (NIHD) which showed no benefit in total mortality but did show a reduction in SCD due to arrythmias.[4,5]

Although current guidelines recommend implantation of an ICD in patients with HFrEF regardless of age,[6] evidence in the elderly is conflicting.

This might in part be due to their under-representation in clinical trials, especially regarding primary prevention indication. The average age in the landmark ICD trials ranged from 58 to 65 years.[7] This is in contrast with real world data, where a growing proportion of devices are implanted in elderly patients. Furthermore, up to 25% of all ICD's are implanted in secondary prevention, meaning that the patient survived a sudden cardiac arrest because of ventricular tachycardia (VT) or ventricular fibrillation (VF) or had symptomatic documented or inducible VT. In secondary prevention patients, the survival benefit of an ICD was most pronounced in patients with worse LVEF and lower NYHA class.[8] However, in elderly there was no reduction of all-cause death in patients > 75 year as the competing risk to die from non-arrhythmic causes is exponentially higher in comparison with the younger cohort.[9,10]

It has been suggested that with increasing age, the cost-effectiveness of ICD implantations might decrease.[11] One research group calculated that for an ICD to be cost-effective in the elderly (> 75 years), survival should be > 5 years after implantation.[12]

In view of this conflicting evidence, careful consideration of the risk of non-arrhythmic versus arrhythmic death is required when deciding to implant an ICD in the elderly patient, taken into account the biological age of the patient. This study describes the experience in Belgium of ICD implantation in patients over 80 years old and tries to identify predictors of (early) mortality in this cohort.

METHODS

Data Source

The Quality Electronic Registration of Medical acts, Implants and Devices (QERMID) registry contains information on all ICD device and ICD lead related procedures performed in Belgium. Participation by implanting centres is mandatory for reimbursement purposes. A database was extracted from this registry containing coded information on the specific procedure and patient. A detailed description of the original registry and data processing can be found in the online supplement (Supplementary Appendix 1). The ethical committee of the University Hospitals of Leuven approved analyses on this nationwide database.

Study Population

All octogenarians implanted with a first ICD device between February 1, 2010 and February 27, 2019 were eligible for inclusion. We excluded non-Belgian patients and patients with an unknown residency because of missing data on their vital and socio-economic status.

Endpoints

The primary endpoints of early mortality (within one year after implantation) and overall mortality were obtained via the Crossroads Bank for Social Security of Belgium. As such, information on the vital status and thus endpoint adjudication is reliable.

Statistical Analysis

Descriptive statistics was performed for the cohort in general, for early mortality and total mortality. Continuous variables are presented as mean ± SD or median with interquartile range (IQR). Categorical variables are presented as number with percentage. After rejecting a normal distribution for age and LVEF using the Kolmogorov-Smirnov test, continuous variables were compared with a Mann-Whitney *U* test and categorical variables by a Chi square test. A Kaplan Meier survival curve was constructed. Cox proportional hazard regression modelling was performed to determine predictors of early and overall mortality. All variables with a *P*-value < 0.10 in univariable regression were included in the multivariable model. A hazard ratio (HR) greater than 1 indicates an increased mortality risk. Proportional hazard assumptions were assessed using Schoenfeld residuals and visual interpretation of the proportional hazard plots. Collinearity in the final model was assessed using a covariance matrix of the final model. The Harrell's C-index was calculated for the final model. Statistical analysis was performed using SPSS (IBM Statistics, version 27, IBM Corp. Armonk, NY, USA) and Stata (StataCorp LLC, Texas, US).

RESULTS

Baseline Characteristics

Nationwide, 704 primo ICD implantations were performed in octogenarians (median age 82, IQR 81-

83 years) between February 1, 2010 and February 27, 2019. This corresponds to less than 5% of all primo-implantations during the same timeframe. Baseline characteristics for this cohort as well as for patients with early and total mortality can be found in Table 1. Majority of recipients were male (83%) and had a history of IHD (66.9%). Primary *vs.* secondary prevention indications were almost balanced (54.7% in primary prevention *vs.* 45.3% in secondary prevention). The median LVEF of patients was 33% (IQR = 26%-45%) resulting in functional limitations according to the NYHA status. Around a quarter of patients (23.2%) received a cardiac resynchronization therapy (CRT) device. A history of atrial fibrillation (AF) was the most prevalent comorbidity (34.7%). Figure 1 illustrates the evolution of primo ICD implantations over time in octogenarians vs. non-octogenarians. There is an increase in ICD-implantation in non-octogenarians, in octogenarians there is no increase in ICD implantation in Belgium.

Mortality and Complications

During an average follow-up of 3.1 ± 2.3 years, 249 (35.1%) patients died (Figure 2). In total, 76 (11%) patients died within 1 year after implantation of

Table 1 Patient characteristics.

Characteristics	All *n* = 704	< 1 yr *n* = 76	> 1 yr *n* = 173
Age in years (range)	82.0 (81.0-83.0)	82.0 (81.0-84.0)	81.0 (80.0-83.0)
Male	585 (83.1%)	67 (88.2%)	144 (83.2%)
EF in % (range)	33.0 (26.0-45.0)	30.0 (25.0-40.0)	33.0 (27.0-45.0)
NYHA class			
I	54 (7.7%)	6 (7.9%)	11 (6.4%)
II	476 (67.6%)	50 (65.8%)	114 (65.9%)
III-IV	174 (24.7%)	20 (26.3%)	48 (27.8%)
Comorbidities			
Diabetes	83 (11.8%)	10 (13.2%)	20 (11.6%)
COPD	51 (7.2%)	8 (10.5%)	11 (6.4%)
CVA/TIA	40 (5.7%)	3 (3.9%)	10 (5.8%)
Oncologic	34 (4.8%)	7 (9.2%)	10 (5.8%)
Renal failure	116 (16.5%)	14 (18.4%)	24 (13.9%)
Atrial fibrillation	244 (34.7%)	30 (39.5%)	59 (34.1%)
LBBB	183 (26.0%)	18 (24.7%)	30 (17.3%)
Upgrade from pacemaker	80 (11.4%)	11 (14.5%)	13 (7.5%)
Prevention			
Primary	385 (54.7%)	30 (39.5%)	83 (48.0%)
Secondary	319 (45.3%)	46 (60.5%)	90 (52.0%)
Indication			
Ischemic	471 (66.9%)	51 (67.1%)	125 (72.3%)
Non-ischemic	233 (33.1%)	25 (32.9%)	48 (27.7%)
Type of device			
VVI/DDD	541 (76.8%)	63 (82.9%)	135 (78.0%)
CRT-D	163 (23.2%)	13 (17.1%)	38 (22.0%)
QRS duration			
< 120 ms	458 (65.0%)	49 (64.5%)	123 (71.1%)
120-150 ms	67 (10.0%)	11 (14.5%)	5 (2.9%)
> 150 ms	179 (25.0%)	16 (21.0%)	45 (26.0%)

Data are presented as *n* (%) unless other indicated. COPD: chronic obstructive pulmonary disease; CRT-D: cardiac resynchronization therapy defibrillators; CVA: cerebrovascular accident; TIA: Transient ischemic attack.

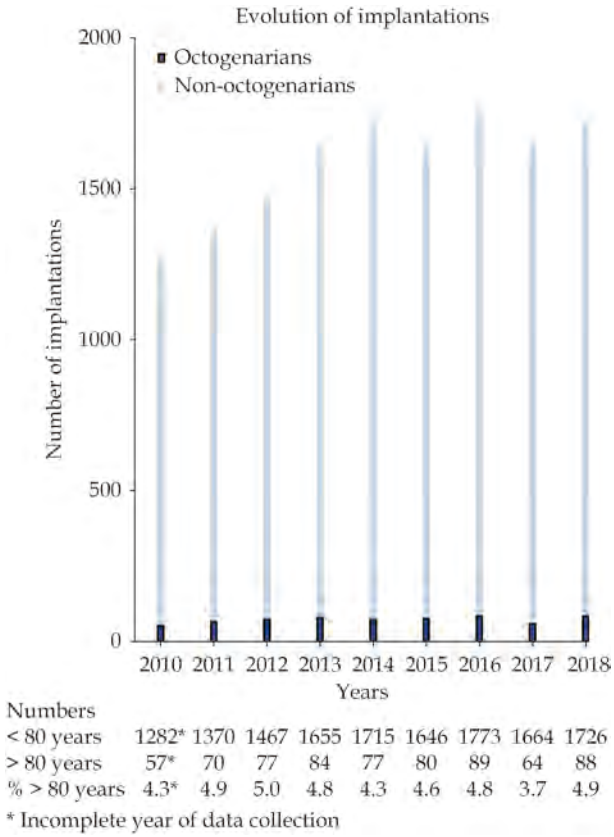

Figure 1 Evolution over time of primo ICD implantations. ICD: implantable cardioverter-defibrillator.

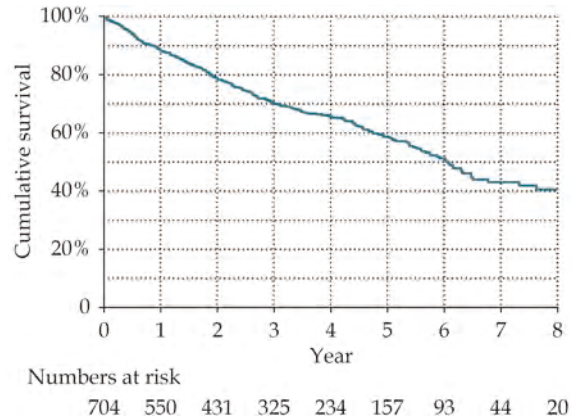

Figure 2 Kaplan-Meier survival curve. Survival curve of the overall cohort of octogenarians.

which 8 patients died within the first month. The cumulative mortality rates at 1-year, 3-years and 5-years, were 11.7%, 30.0% and 41.3%, respectively. There were no implantation-procedure related deaths reported. Acute complications were relatively rare in this cohort of older patients with 692 procedures being performed with no complications (98.3%). Overall, 14 complications were reported in 12 procedures. The most reported complications reported were significant hematoma (n = 4) and pneumothorax (n = 3). Venous perforation sustained total AV-block, sustained VT, ventricular perforations, pericardial effusion, tamponade and ventricular lead dislocation were each reported one time. Two patients had two acute complications in the same procedure. One patient suffered ventricular perforation and cardiac tamponade and one patient developed sustained AV-block while also having a pericardial effusion.

Regarding early mortality, increasing age was associated with a higher early mortality with a HR of 1.15 per year > 80 (95% CI: 1.05-1.27; P = 0.004). Better LVEF was predictive of better early survival with a HR of 0.97 (95% CI: 0.95-0.99; P = 0.002). ICD implantation in secondary prevention (history of ventricular arrhythmia or survivor of sudden cardiac death) was associated with higher early mortality (HR = 2.23; 95%CI: 1.39-3.58; P = 0.001). A history of oncological disease was associated with increased risk of early mortality with a HR of 2.43 (95%CI: 1.11-5.31; P = 0.027) (Table 2). The Harrell's C-index for the final model was 0.658.

Regarding overall mortality, increasing age was again associated with worse survival (HR = 1.06; 95% CI: 1.001-1.13; P = 0.048), while having a better LVEF was an indicator for better survival (HR = 0.99; 95% CI: 0.98-0.997; P = 0.008). A previous oncological history was also indicative for higher total mortality (HR = 1.78; 95% CI: 1.08-2.93; P = 0.023). A history of atrial fibrillation was shown to be pro-

Table 2 Multivariate Cox regression analysis of early (< 1 yr) mortality.

Variables	HR	95% CI	*P*-value
Age, yrs	1.15	1.05-1.27	0.004
LVEF, %	0.97	0.95-0.99	0.002
Oncological history	2.43	1.11-5.31	0.027
Secondary prevention	2.23	1.39-3.58	0.001

LVEF: left ventricular ejection fraction.

gnostic for total mortality (HR = 1.46; 95% CI: 1.12-1.90; P = 0.005). Implantation in a low volume operating centre showed higher overall mortality (HR = 1.35; 95% CI: 1.04-1.75; P = 0.023) (Table 3). The Harrell's C-index for the final model was 0.603.

CRT-D was not withheld as an independent predictor of survival in our cohort. Short term mortality in patients with a CRT-D in our cohort was 8.0% at 1 year and 23.9% at 3 years, while it was respectively 11.3% and 24.9% in patients with a VVI/DDD-ICD and a narrow QRS and 14.9% and 31.9% in patients with a VVI/DDD-ICD and a QRS > 150 ms. Kaplan-Meier analysis with log-rank test did not show a significant difference in mortality (P = 0.214).

DISCUSSION

Ageism in Landmark Trials

The median age in the global population is steadily rising. Today, approximately 142 million people on this planet are 80 years or older and the World Health Organisation predicts this number will triple by 2050.[13] As older people tend to have more comorbidities, we stand before a major healthcare challenge in the coming years. Currently, 50% of ICD-implantations in the United States are performed in patients over 70 years old.[14] In 2002, a Medicare database study on underutilization of ICD-therapy, predicted that 28% of all potential ICD recipients are over 79 years old.[15] However, the actual implantation rate is much lower. Although ICD-implantation is the cornerstone in the prevention of SCD in patients with a history of reduced systolic function despite optimal medical therapy and in patients with a history of ventricular arrhythmia, convincing evidence of its value in elderly patients is lacking. This is partly because inclusion of the very elderly patients in the landmark ICD trials was low (Table 4). The MADIT-II trial showed that in patients who had a previous myocardial infarction with a remaining systolic ejection fraction (EF) < 30% both the older (> 70 years) and younger (< 70 years) benefited from ICD-therapy.[9] The Danish study however did not show a benefit in all-cause mortality in patients with non-ischemic systolic heart failure. Subgroup analysis implied an age-dependant association, with mortality benefit only in younger patients.[4] In this study there was a decreasing mortality-benefit of the ICD with age, with an optimal age cut off at < 70 years. The incidence of non-sudden cardiac death (heart failure, non-cardiovascular causes) in older patients with systolic heart fail-

Table 3 Multivariate Cox regression analysis of total mortality.

Variables	HR	95% CI	*P*-value
Age, yrs	1.06	1.001-1.13	0.048
LVEF, %	0.99	0.98-0.997	0.008
AF	1.46	1.12-1.90	0.005
Oncological history	1.78	1.08-2.93	0.023
Low volume center	1.35	1.04-1.75	0.023

AF: atrial fibrillation; LVEF: left ventricular ejection fraction.

Table 4 Comparison of trials regarding predictors for survival in the elderly.

Variable	Alba, *et al.*[31]	Koplan, *et al.*[32]	Ertel, *et al.*[33]	Mezu, *et al.*[34]
Time of publication	2013	2006	2010	2011
Type of study	Meta-analysis	Retrospective cohort study	Retrospective cohort study	Retrospective cohort study
Patient population	ICD-patients; heart failure	ICD-patients; > 80 yrs	ICD-patients; > 80 yrs	ICD-patients; > 80 yrs; heart failure
Total number of patients	257,692	107	225	99
Predictors of mortality	age, renal function, COPD, diabetes, PAD, LVEF, ICD intervention	LVEF, renal function	LVEF, no beta-blocker treatment	Age, GFR

COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; ICD: implantable cardiac defibrillators; LVEF: left ventricular ejection fraction; PAD: peripheral arterial disease;

ure was twice as high as in patients < 70 years with the incidence of SCD not differing significantly between the two groups. The DEFINITE trial also reported no reduction in total mortality in NIHD, independent of age, but found a reduction in arrhythmic mortality.[16] This result was found in both younger and older patients. The SCD-HeFT trial showed a reduction in mortality in patients with reduced systolic function caused by IHD or NIHD with ICD compared to Amiodarone and placebo.[17] However, this finding was not significant in patients > 65 years. A meta-analysis performed in 2015, pooling data from MADIT-I, MUSTT, MADIT-II, DEFINITE and SCD-HeFT, showed a lower survival benefit of ICD therapy with increasing age.[7,8] A higher incidence of death in the elderly is also seen in other populations: a Spanish study found a mortality rate of 24.4% during follow-up in patients over 75 years old, while younger patients only had a 12.4% mortality rate during follow-up.[18] Moreover, there might be a higher complication rate during procedure in the elderly with a higher chance of pneumothorax, lead dislodgement and cardiac perforation, though this evidence is conflicting.[19,20,21] One could postulate that the risk of inappropriate shocks might be higher in the elderly because of the higher incidence of atrial fibrillation and flutter in that age group. However, studies have shown a higher rate of inappropriate shocks in young patients due to sinus tachycardia with a similar rate of appropriate shocks in all age groups.[22,23]

The Belgian Experience *vs.* Previous Trials

ESC guidelines recommend ICD therapy in selected patients regardless of age if the patient has an expected survival of > 1 year in reasonable health.[6] Elderly patients have a higher chance to die from a non-arrhythmic cause, cardiac or non-cardiac, which makes careful patient selection necessary. In Belgium, over a 9-year period only 704 patients aged 80 years or older received their first ICD, comprising less than 5% of all primo-implantations. Taken into account the higher incidence of arrhythmia or systolic dysfunction in the elderly, this demonstrates a restrictive approach regarding implantation in the elderly in contrast to other publications showing an implantation rate of 12.0%-37.9% in > 75 years old.[15,20,22,24] In view of the nature of this analysis based on a dataset of implanted patients we cannot compare the patients that did get an ICD with those that didn't. This selection was left to the clinical judgement of the implanting physician. Selected patients had a guideline based ICD indication and an expected survival of at least one year. They were typically male patients with a reduced LVEF and had only slight physical limitation corresponding with NYHA Class II symptoms. ICDs were most often implanted in patients with ICMP and in secondary prevention. Our study reports a 1-year mortality of 11% in octogenarians, which is lower than in other publications in comparison with other studies and consistent with a stringent patient selection. A 1-year mortality of 32% was reported in the highest age quartile (79.25 ± 4.44 years) in an American study regarding veterans with HFrEF and ICD,[25] while another study reported a 1-year mortality of 22% in patients over 75 years old.[26] An ever higher 50% 1-year mortality rate is reported in ICD generator replacement in octogenarians.[27] The strict patient selection could be related to the specific reimbursement system in Belgium. Yearly, every centre is attributed a fixed closed budget for ICDs. This envelope is mainly based on the number of ICD implantations and cardiac surgical procedures in the previous years. The excess ICDs implanted outside this envelope need to be financed by the implanting centre itself. To monitor implant practice centres are compared and can be penalised based on different criteria: the number of complications (infections, necessity of pleural or pericardial drainage); 30-day, 1-year and 3-year mortality; the ratio primary vs. secondary indications; battery longevity at replacement; the use of CRT in depressed systolic function < 30% and QRS-duration ≥ 150 ms; and the age and comorbidity of the patients implanted. To assess comorbidity the risk-score developed by Goldenberg, *et al.* based on NYHA class > 2, age > 70 years, atrial fibrillation, QRS ≥ 120 ms and kidney function is used.[28,29] Patients scoring ≥ 3/5 are considered at high risk of (non-arrhythmic) mortality. We hypothesise that both the financial responsibility over a closed budget and the awareness of the value of clinical risk scores to predict usefulness of an ICD contribute to the selective clinical practice in Belgium.

Predictors of Mortality in the Elderly

Over 10% of all patients with heart failure receiv-

ing an ICD in the United States is considered as frail. Frailty is related with a higher one year mortality rate than other chronic comorbid conditions (chronic obstructive pulmonary disease (COPD), CVA and diabetes).[30] A meta-analysis by Alba, *et al*.[31] withheld a higher mortality with increasing age, decreased renal function, COPD, peripheral vascular disease, decreased LVEF and shocks during follow-up. A study including 107 ICD implanted octogenarians also showed an increased mortality if LVEF was below 30% or if kidney function decreased to an eGFR < 60 mL/min per 1.72 m^2.[32] A multicentre trial in 2010 included 225 ICD-implantations in octogenarians from 1990 to 2006 and found a higher incidence of mortality in patients with LVEF < 20% and patients who did not have any betablocker use.[33] A 2011 study including 99 patients with LV-dysfunction (LVEF < 35%) showed age and renal dysfunction as independent predictors of mortality.[34] These findings are in line with the risk factors identified in our study. Predictors for early mortality in our population were increasing age, worse LVEF and secondary prevention indication. There was a tendency for male patients to have higher early mortality, however this was statistically not significant presumably because of the underrepresentation of female patients in our cohort. Although patients with a history of malignancy were either cured, being treated with curative intent or had slow progressing carcinoma, an oncological history was also predictive for early mortality. Regarding total mortality, patients with a history of atrial fibrillation were found to have decreased survival. Patients who received their ICD in a low volume implantation centre had higher overall mortality. Since this effect was not seen in early mortality, we presume that the cause is not implantation related. High volume centres typically have specialized heart failure and telecardiologic programs and were located in overall more wealthy and healthy regions, which might be a possible reason patients treated in high volume centres have better survival. Other studies also showed a decreased renal function as an independent predictor of mortality which was not confirmed in our study. However, in our database, there was no standardised cut-off value for renal failure which poses significant bias for analysis.

Advanced Care Planning

It is unclear if the low implantation rate in Belgium is a good thing, since it should be comorbidity rather than age by itself that should be important in the shared clinical decision-making process. Firstly, the patient must be aware that an ICD only protects him/her from life-threatening arrythmia and not from other causes of (cardiovascular) death nor from progressive heart failure. Secondly, in this process it is important to discuss the possibility of ICD deactivation. While the device might have been implanted during a time when the patient was fit and without significant comorbidity, physical or cognitive decline can be swift. An analysis of 125 explanted ICDs after death showed that 31% of patients received a shock in the final 24 hours of their life which is painful for the patient and distressing for family members.[35] Moreover, 52% of all patients had an active DNR at time of death. Therefore, it is necessary to discuss the possibility of ICD deactivation in an elderly ICD patient with declining health, whether it be physically or mentally. In 100 deceased patients with an ICD, only 27 family members reported having a discussion about ICD deactivation, which in most cases was done only a few days before their death.[36] It is also reported that a lot of physicians are uncomfortable talking with their patient about ICD deactivation.[37] Since patients nearing end of life are not always primarily seen by their cardiologist, but by their general practitioner, geriatrician or oncologist, they should also have the conversational skills and awareness to talk to their patient about device deactivation.

In elderly patients with reduced ejection fraction despite medication and a wide QRS complex in left bundle branch block morphology CRT-P should be considered as an alternative to CRT-D. Studies have shown a positive effect on reverse ventricular remodelling and improved NYHA functional class in all age groups.[38] The latest ESC guidelines on cardiac pacing and cardiac resynchronization therapy suggest to consider age and comorbidities that could compete with sudden arrhythmic death and recommend shared decision-making between patient and cardiologist in the decision between CRT-P and CRT-D.[39]

Limitations

This study is not without its limitations. This cohort study has been designed without possibility to obtain a control group. Therefore, we cannot discuss the characteristics of the elderly patients that were either considered for an ICD, but not deemed fit due to comorbidity, or were not considered for implantation, but should have been. Since all data was extracted from the QERMID database, we rely on the faultlessness of the data input. While mortality is verified in the registry, causes of death are not known, nor did we have data on the number of appropriate shocks or inappropriate shocks in this population. While the registry contains nationwide data from multiple implantation centres, the population was predominantly white and male which may limit its generalizability. Further studies are required to better understand additional risk factors pertaining to early mortality after ICD implantation.

Conclusions

In Belgium, the number of primo ICD implantations in octogenarians is limited. Of these selected very elderly patients, only 11% died within the first year after ICD implantation. Advanced age, lower LVEF and an oncological history were significant predictors for short- as well as long-term mortality. Further research is necessary to risk stratify the elderly patients and warrant the cost-effectiveness of ICD therapy in this group.

Conflicts of interest

RW is supported as postdoctoral clinical researcher by the Fund for Scientific Research-Flanders (FWO-Vlaanderen). RW reports research funding from Abbott, Biotronik, Boston Scientific, Medtronic; speakers and consultancy fees from Medtronic, Boston Scientific, Biotronik, Abbott.

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