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LEONOR GUERRA E VASCONCELOS MANSO PRETO

Comparison of "real life" longevity of implantable cardioverter-defibrillator from different manufacturers

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Comparison of "real life" longevity of implantable cardioverter-defibrillator from different manufacturers

Authors:

Leonor Guerra e Vasconcelos Manso Preto [1]

Diogo de Almeida Fernandes [2]

Pedro Alexandre Sousa [2]

Natália Sofia Cláudio António [1,2]

1. Faculty of Medicine, University of Coimbra (FMUC), Portugal[1]
2. Cardiology Service, Coimbra Hospital and University Center, Portugal[2]

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ABSTRACT

Background: The implantable cardioverter-defibrillator (ICD) is an indispensable tool in primary and secondary prevention of sudden cardiac death. Since these devices represent high costs for public health systems, it is crucial to assess their real word longevity. However, evidence regarding battery longevity of contemporary ICDs is scarce.

***Aims*:** To compare battery longevity and potential complications of ICDs from different manufacturers in a real-life setting. Additionally, we also attempt to determine factors that influence battery-life and contribute to earlier device replacement.

***Methods*:** This is a cross-sectional retrospective study of 373 consecutive patients undergoing ICD implantation at Coimbra Hospital and University Center, between 2010 and 2015. The study included ICDs from all manufacturers in the market: Abbott/St Jude, Biotronik, Boston/Guidant, Medtronic, Microport/Sorin. Main diagnosis, time to replacement, reason of replacement, number of device therapies (shocks and anti-tachycardia pacing) and percentage of pacing were retrieved. Survival analysis with Kaplan-Meier curves and Cox regression (with hazard ratio (HR)) was performed to compare battery longevity between the different manufacturers.

***Results*:** Mean age of the study population was 60.84 ± 11.84 years, and in the majority of patients the ICD was implanted in primary prevention (78.8%): mainly due to ischemic cardiomyopathy (55.4%). The mean ejection fraction of the overall population was 31.3 ± 11.01%. The distribution of implanted ICDs according to manufacturers was as follows: 23.2% ICDs from Medtronic, 22.9% from Boston/Guidant, 19.6% from Biotronik, 18.7% from Abbott/St Jude and 15.6% from Microport/Sorin.

During follow-up, there were 35 patients (9.4%) lost for follow-up. It was found that 107 patients (37.1%) died and 13 patients (3.8%) underwent heart transplantation before ICD battery end of life. Most patients did not need ICD therapies (72.2%). Of note, 14.2% of patients needed ventricular pacing, with a pacing percentage ranging from only 1 to 25% (n=41; 14.2%). Only 89 patients (26.3%) underwent device replacement during follow-up, including 69 (71.1%) due to battery exhaustion.

There were significant differences in battery longevity between manufacturers, with a mean longevity was 6.47 ± 1.71 years for Boston/Guidant, 7.87 ± 0.76 for Microport/Sorin, 6.93 ± 1.81 for Abbott/St Jude, 7.66 ± 2.15 for Medtronic and 7.87 ± 1.71 for Biotronik.

Patients with Medtronic or Biotronik ICDs had a hazard more than 5.5 times greater of being replaced earlier due to battery exhaustion (Medtronic HR 5.487, 95% CI 1.909-15.766, p 0.002; Biotronik HR 6.102, 95% CI 2.021-18.424, p 0.001) when compared to Microport/Sorin. These results remained consistent after adjustment for potential confounders (percentage of pacing, number of ICD shock, and ATP).

***Conclusions*:** Patients with Medtronic and Biotronik ICDs were more likely to have the ICD replaced earlier due to battery exhaustion, even after considering therapies and pacing needs. These data may have important implications for patients and hospital centers.

Keywords: implantable cardioverter-defibrillator, ICD longevity, battery, cardiac resynchronization therapy

ABBREVIATIONS

ATP - Adenosine triphosphate

BMI - Body mass index

CI - Confidence interval

CRT-D - Cardiac resynchronization therapy bi-ventricular ICD

DDD - Dual pacing, dual sensing, dual action ICD

HF - Heart failure

HR - Hazard ratios

ICD - Implantable cardioverter defibrillator

LVEF - Left ventricular ejection fraction

SCD - Sudden cardiac death

VDD - Ventricular pacing, dual sensing, dual action ICD

VF - Ventricular fibrillation

VT - Ventricular tachycardia

VVI - Ventricular pacing, ventricular sensing, inhibited; single chamber ICD

INTRODUCTION

The implantable cardioverter-defibrillator (ICD) is a device capable of continuously monitoring cardiac electrical activity which recognizes potentially fatal arrhythmias and prevents sudden death through antitachycardia pacing (ATPs) or shocks (cardioversion or defibrillation). As a result, the ICD has become an indispensable tool in the primary and secondary prevention of sudden cardiac death (SCD). The number of indications for an ICD has vastly increased, irrespective of being utilized in primary or secondary prevention, and its impact in cardiac morbidity and mortality is now universally recognized.[1,2] Main indications today include heart failure[3], hypertrophic cardiomyopathy[3], arrhythmogenic right ventricle cardiomyopathy[3,4] and channelopathies such as long QT syndrome[3,5] and Brugada syndrome.[3,6]

Despite all its proven benefits, this great technological advance in Medicine implies very high costs.[7] The implantation of an ICD is considered a lifelong therapy and since patient survival often exceeds device lifetime in most patients, necessity of device replacement is frequent. Therefore, two major aspects arise regarding the longevity of these products: the impact on patients' lives and the effective cost to public health systems.[8]

Also of note, implantation of these devices is an invasive procedure and is not devoid of complications. Lead dysfunction is a major concern in ICD patients, whether owing to manufacturing defects or random failures, which may result in inappropriate or ineffective shocks or lack of rhythm.[9] Among most common complications are the risk of developing local infection or active bleeding and inappropriate shocks which lead to a deterioration of patient's quality of life.

Since these devices represent high costs for public health systems, it is crucial to assess their longevity in real world. Most longevity data are provided by manufacturers and are performed under intensive but standardized laboratory measurements. Even though most manufacturers project the longevity of their ICDs at 5-9 years, data on ICD durability in clinical circumstances are scarce, especially regarding newer generation devices.[1,2] Recently there have been some studies published that have analyzed which factors can influence the lifespan of devices in clinical practice, including the manufacturer and type of device, but their results are inconsistent.[10,6] There are few studies conducted in this scientific area.

This study aims to assess longevity and potential complications of ICDs in a real-life setting. Additionally, we also attempt to compare longevity between different manufacturers and to determine factors that influence battery-life and contribute to earlier device replacement.

METHODS

Study design and Patient selection

We performed a retrospective study of 373 consecutive patients submitted to a first ICD implantation at Coimbra Hospital and University Center between 2010 and 2015, from a prospectively maintained database.

The inclusion criteria were:

1) age > 18 years old;
2) first ICD implantation procedure;
3) patients submitted to implantation of ICD alone (patients with cardiac resynchronization therapy devices were excluded);
4) ICDs from all manufacturers implanted in our hospital within the time period of this study were included: Abbott/St Jude, Biotronik, Boston/Guidant, Medtronic and Microport/Sorin.

This research project has been approved by the local Ethics Committee (Approval number 121/CES; OBS.SF.023-2022). The ethical principles ascertained in the Declaration of Helsinki were followed and respected.

Data Collection

Variables recorded were patient's age, gender, BMI and possible associated comorbidities. Hypertension, diabetes mellitus, dyslipidemia, atrial fibrillation (AF), and heart failure (HF) were considered relevant pathologies. The value of serum creatinine (to be able to estimate the glomerular filtration rate) and the left ventricular ejection fraction (LVEF) were also collected. Regarding the ICD implantation procedure, date of implantation was recorded as well as type of prevention (primary or secondary) and main diagnosis. Data regarding ICD characteristics, such as the manufacturer, device model, and type of ICD were also noted.

Follow-up data was retrieved from outpatient clinical and emergency department admissions records; and from device monitoring consultation. All ICD replacements were identified and their replacement date and reason (battery exhaustion, lead dysfunction, early extraction and upgrade to another type of device) were assessed. The average percentage of pacing (calculated as the average of atrial and ventricular pacing divided by 2) was ascertained and the number of shocks applied (appropriate and inappropriate) and ATP therapies were also surveyed. ICDs lost to follow-up were censored at the date of last follow-up. Device or pocket infection, heart transplant and mortality during follow up were also evaluated. Devices of patients who were transplanted or dead were censored at that respective date. All remaining

devices were censored at the date of the last database access. The date of last access of clinical follow up was March 05, 2022.

Data analysis

Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations if normally distributed, or medians and interquartile ranges for variables with skewed distributions. Normal distribution was verified through the Kolmogorov-Smirnov test or skewness and kurtosis (maximum tolerated interval of -1 to 1). Bivariate analysis was performed by using $\chi 2$ test for categorical variables and t test for independent variables for continuous variables. Kaplan-Meier survival curves were used for survival analysis with log-rank testing for longevity comparison. Only manufacturers with more than 20 devices were included in this analysis. Hazard ratios (HR), confidence intervals (95% CI), and p-values were calculated with the use of Cox proportional-hazards models, with adjustment for confounding variables. All reported p values are two-tailed with a values inferior to 0.05 indicating statistical significance. Analysis was performed with the use of IBM® SPSS® 26.

RESULTS

Patients' characteristics

This study included 315 men (84.5%) and 58 women (15.5%), with a mean age of 60.84 ± 11.84 years (range 20 to 86 years).

Of these patients many had associated comorbidities such as HF (71.6%) with a mean left ventricular ejection fraction (LVEF) of 31.3% ± 11.01, and AF (41.8%, of these 31.6% had paroxysmal, 68,4% persistent or permanent AF). Metabolic syndrome was also present among these patients with a high prevalence of diabetes (45.5%), hypertension (79.6%), dyslipidemia (84.1%) and obesity (64.9% of patients with a BMI > 25 kg/m2); mean BMI of 27.31). The mean glomerular filtration rate was 77.98 ± 26.17 ml/min/1.73 m² (range from 6.54 to 130.12).

The majority of patients (78.8%) underwent device implantation in primary prevention and only 21.1% in secondary prevention. Among the indications for ICD implantation, ischemic cardiomyopathy ranked first (55.4%), followed by non-ischemic dilated cardiomyopathy (24%) and hypertrophic cardiomyopathy (10.5%). Other causes that led to ICD implantation in this population were Brugada syndrome (n=9, 2.4%), arrhythmogenic right ventricular dysplasia (n=9, 2.4%), idiopathic ventricular fibrillation (VF) or sustained ventricular tachycardia (VT) (n=16, 4.3%), Long QT syndrome (0.3%), non-compaction myocardiopathy (n=0.3%), non-specific congenital heart pathology (0.3%) (Table 1).

Table 1 - Baseline characteristics of the patients

Gender (Male) %	84.5
Age (mean + SD) years	60.84 ± 11.84
BMI (mean + SD) age/cm²	27.31 ± 4.41
Primary prevention	294 (78,8%)
Heart failure	267 (71.6%)
Atrial fibrillation	80 (41.8%)
Diabetes	135 (45.5%)
Hypertension	283 (79.6%)
Dyslipidemia	270 (84.1%)
Ejection fraction (mean + SD) %	31.30 ± 11.01
Glomerular filtration rate (mean + SD) mL/min	77.98 ± 26.17

BMI, body mass index; SD, standard desviation

Characterization of implanted ICD

The study comprises devices from all manufacturers in the market: Abbott/St Jude in 67 patients (18.7%), Biotronik in 70 patients (19.6%), Boston/Guidant in 82 patients (22.9%), Medtronic in 83 patients (23.2%) and Microport/Sorin in 56 patients (15.6%). It was not possible to determine the manufacturer in 15 patients. Single and dual chamber ICDs were considered for the study, with the majority of patients receiving a single chamber ICD (N=299, 83.5%). In 52 patients a DDD-ICD was implanted and the remaining 7 patients received a VDD-ICD. (Table 2)

Table 2 - Manufacturers and pacing modes ICD shown in alphabetical order

Manufacturer	VVI	VDD	DDD	Total
Abbott/St Jude	63	0	4	67
Biotronik	56	7	7	70
Boston/Guidant	67	0	15	82
Medtronic	66	0	17	83
Microport/Sorin	47	0	9	56
Total	**299**	**7**	**52**	**358**

ICD, implantable cardioverter defibrillator; VVI, single-chamber ICD; DDD, dual-chamber ICD

Follow up outcomes

Mean follow-up time was 6.6 ± 3.1 years. There were 35 patients (9.4%) lost for follow-up. It was found that 107 patients (37.1%) died and 13 patients (3.8%) underwent heart transplantation before ICD battery end of life.

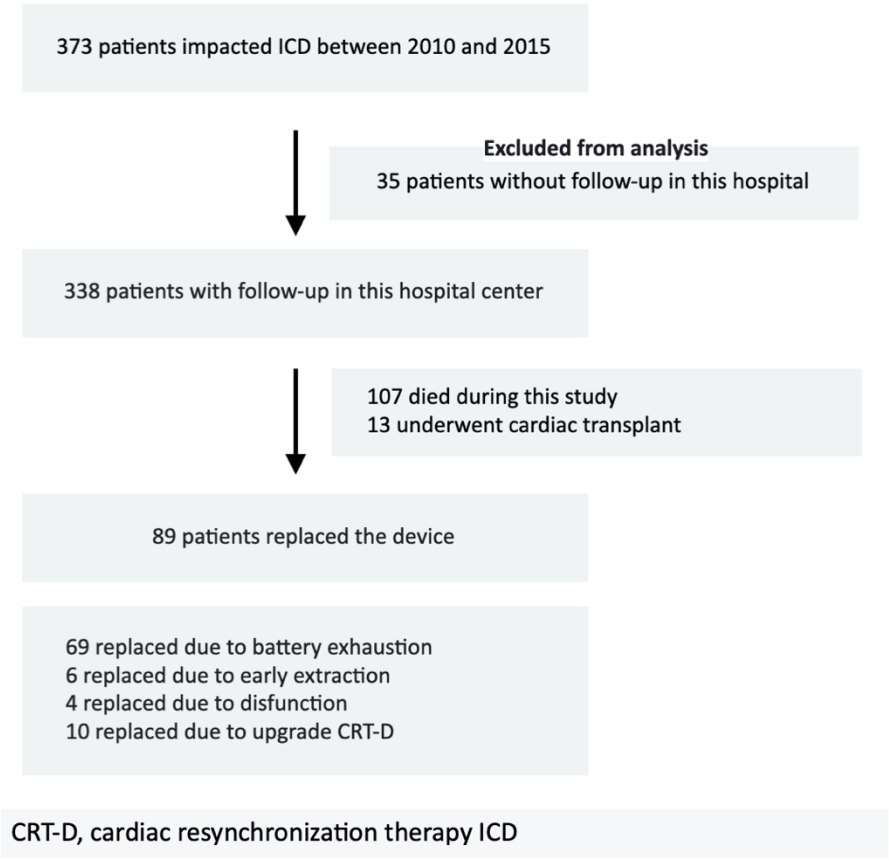
Regarding complications associated with the surgical procedure, there were 21 device infections recorded (6.2%). Early extraction (n=6; 1.8%), device dysfunction (n=4; 1.2%), and upgrade to CRT-D (n=10; 3.0%) were also documented. It was not possible to determine the reason for device replacement in one patient.

Regarding ICD therapies during follow up, patients most frequently did not require any shock or ATPs (n=228; 65.7%).

Of note, only 28.3% of patients needed pacing, with most ranging from 1 to 25% (49.4%).

Only 89 patients (26.3%) underwent device replacement during follow-up, including 69 (71.1%) due to battery exhaustion (Figure 1).

Figure 1 - Flow chart of patients and ICDs



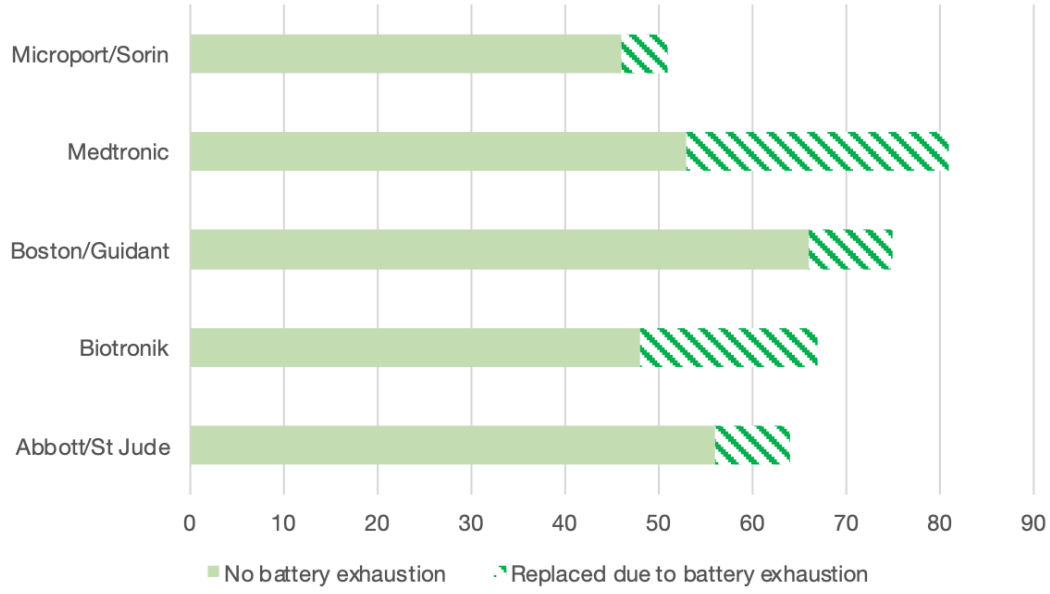
CRT-D, cardiac resynchronization therapy ICD

Comparison of ICD longevity between manufacturers

For ICD longevity comparison between manufacturers, we excluded patients who died or underwent heart transplantation before ICD battery end of life and patients who underwent ICD replacement for other reasons than battery exhaustion. For this analysis our study sample comprised 338 patients.

In this subgroup population, there were 19 replacements due to battery exhaustion from Biotronik (28.4%), 9 from Boston/Guidant (12.0%), 28 from Medtronic (34.6%), 5 from Microport/Sorin (9.80%) and 8 from Abbott/St Jude (12.5%). Figure 2 represents device replacements by manufacturers through a bar graph. All transplant patients, patients who died before the end of the generator's life and those who underwent extractions due to complications were excluded.

Figure 2 - Bar graph showing number of devices replaced by manufacturer.

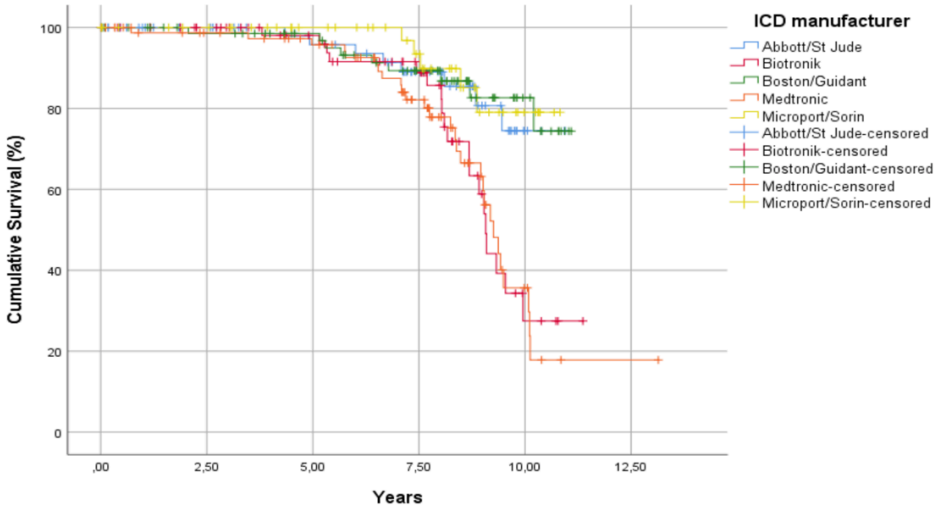


The mean battery longevity was 6.47 ± 1.71 years for Boston/Guidant, 7.87 ± 0.76 for Microport/Sorin, 6.93 ± 1.81 for Abbott/St Jude, 7.66 ± 2.15 for Medtronic and 7.87 ± 1.71 for Biotronik.

Figure 3 shows statistically significant differences in survival between manufacturers (p-log rank < 0.001). Patients with Medtronic or Biotronik ICDs had a hazard more than 5.5 times greater of being replaced earlier due to battery exhaustion (Medtronic HR 5.487, 95% CI 1.909-15.766, p 0.002; Biotronik HR 6.102, 95% CI 2.021-18.424, p 0.001) when compared to Microport/Sorin. These results remained consistent after adjustment for potential confounders (percentage of pacing, number of ICD shock, and ATP).

Table 3 shows the comparison of 5 and 10-year battery longevity between manufacturers.

Figure 3 - Kaplan-Meier curves of cumulative survival rates for Abbott/St Jude, Biotronik, Boston/Guidant, Medtronic and Microport/Sorin



No. at risk						
Abbott/St Jude	64	53	45	31	4	0
Biotronik	67	58	46	33	4	0
Boston/Guidant	75	66	56	41	11	0
Medtronic	81	70	63	41	7	1
Microport/Sorin	51	46	37	27	6	0

Table 3 - Comparison of devices longevity

Manufacturer	5-year longevity (%)	10-year longevity (%)
Abbott/St Jude	95.7%	74.5%
Biotronik	98.00%	27.50%
Boston/Guidant	98.50%	82.60%
Medtronic	95.70%	35.70%
Microport/Sorin	95.70%	79.00%

DISCUSSION

In this study, we analyzed the longevity of ICD devices from five major manufacturers: Abbott/St Jude, Biotronik, Boston/Guidant, Medtronic and Microport/Sorin.

There are few articles published in the literature comparing the battery longevity of ICD devices from different manufacturers. Since there is a constant trend of upgrading of the battery technologies employed, the first devices created by these manufacturers naturally do not have the same characteristics as those currently marketed.[11] Many of the models analyzed in previous studies at the time of their publication have already been discontinued. This makes scientific information about the current longevity of devices from different manufacturers even scarcer.[12] It is paramount to have information about the newer devices because only then will it be possible to make an ICD choice with the best cost-benefit ratio. As a result, we consider that an update of studies in the literature on this topic was lacking.

Device manufacturers regularly publish product performance reports that set supplier-specific limits on the performance of their devices. Unfortunately, the longevity is often overestimated and does not reflect the real-world paradigm.[1,13,14]

Our results showed that in current clinical practice the actual longevity of ICD systems is about 6.5 years. In our population there was a statistically significant lower longevity in ICDs from Medtronic and Biotronik. These results are inconsistent with previous studies comparing older devices. Some published studies indicate that the Medtronic manufacturer is more likely to be replaced sooner.[8] Nevertheless, it is also worth noting that other studies have shown superior battery longevity of Medtronic devices.[1,2,11,15] In these articles the longevity of Medtronic devices averaged from 5.8 to 7.6 years, followed by Boston and St Jude (5-5.4 and 5-5.8 years, respectively).[1]

Additionally, our study has the advantage of taking into consideration parameters known to affect battery lifetime, including ICD therapies (ATP and shocks) and pacing percentage. This allows for a more correct interpretation of the results since overall longevity is adjusted for confounding factors. To the best of our knowledge there is only a single previous study that underwent a similar task of comparing battery longevity among device manufacturers and concluded as well that high ventricular pacing load was one of the main determinants of earlier battery depletion.[16]

It is clear that a shorter battery life increases the financial burden. These costs encompass not only the implanting procedure itself, but also the cost of managing the patient perioperatively (clinic visits, anesthetics, antibiotics) and possible complications. These can occur either at implantation or at replacement with a new implant.

Limitations

We can recognize several limitations to the present study. First, this is single-center retrospective study of a relatively small number of participants. The retrospective nature of the study made the follow-up of all patients impossible. Some patients were excluded from the study because they were not followed-up in our hospital. Nevertheless, different ICD models of the same brand were analyzed. Different models have different intrinsic characteristics and may affect the longevity of these devices as well.

Prospective multicenter studies are needed to confirm these results.

CONCLUSION

In conclusion, this study shows significant discrepancies in the battery longevity of ICDs from different manufacturers. Abbott/St Jude, Microport/Sorin and Boston/Guidant were the manufacturers that showed the most favorable longevity profile. These results have important clinical implications for both patients and hospitals. It is important to reinforce that the longevity of cardioverter-defibrillators is a crucial parameter for the patients' quality of life. Therefore, data regarding this parameter should be regularly updated in order to make the best possible choice.

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