ORIGINAL RESEARCH

Favorable Trend of Implantable Cardioverter-Defibrillator Service Life in a Large Single-Nation Population: Insights From 10-Year Analysis of the Italian Implantable Cardioverter-Defibrillator Registry

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***Background*—**Implantable cardioverter-defibrillators (ICDs) are widely employed for the prevention of sudden cardiac death. Despite technological improvements, patients often need to undergo generator replacement, which entails the risk of periprocedural complications. Our aim was to estimate the service life of ICDs over a 10-year interval and to assess the main causes of replacement on the basis of data from the National ICD Registry of the Italian Society of Arrhythmology and Cardiac Pacing (AIAC).

***Methods and Results*—**The registry includes data from over 400 hospitals in Italy. We included all patients who underwent device replacement from calendar years 2007 to 2016. The median service life of the ICDs and its trend over the years was estimated across the 3 types of devices (single-chamber, dual-chamber, cardiac resynchronization therapy defibrillator) and the indication to implantation. The causes of replacement were also analyzed. We included 29 158 records from 27 676 patients (80.9% men; mean age at device replacement 65.8±12.0 years). The median service life was 57.3 months (interquartile range 27.8 months). Over the years, service life showed an increasing trend. The majority of patients underwent elective replacement because of battery end of life, and over the years there was a significant reduction of replacement for recalls, erosion/infections, and cardiac resynchronization therapy upgrading.

***Conclusions*—**Our data from a large single-nation population showed that the trend of ICD service life, independently from ICD type, indication, and settings, significantly improved over time. Moreover, there was a striking reduction of interventions for upgrading and infection/erosion. This favorable trend has important clinical, organizational, and financial implications. **(*J Am Heart Assoc*. 2019;8:e012759. DOI: 10.1161/JAHA.119.012759.)**

Key Words: implantable cardioverter-defibrillator • longevity • registry

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) have become a landmark option for the prevention of sudden cardiac death in patients at risk for fatal ventricular arrhythmias.[1,2] Registries from clinical practice have confirmed in larger scale the efficacy of ICD therapy in the setting of both primary and secondary prevention.[3–5] The growing mismatch between the service life of the devices and patient survival is already a well-known issue.[6] Moreover, previous single-center and few-center studies have demonstrated highly variable ICD longevity according to device manufacturers.[7–11] Technology improvements, in particular on the front of battery longevity, have tried to solve the problem, but ICD and CRT-D service life may still be shorter than patients' average survival. This implies the need for generator replacement, which entails the risk of periprocedural complications (damage of the leads,

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Clinical Perspective

What Is New?

- This is the first article to analyze the trend of service life of implantable cardioverter-defibrillators/cardiac resynchronization therapy defibrillators over the years on a whole-nation basis.
- We showed an incremental trend of implantable cardioverter-defibrillator/cardiac resynchronization therapy defibrillator service life over the years in the whole population and in a subanalysis subdividing the population according to the type of device and the indications to first implantation.

What Are the Clinical Implications?

- The shown incremental trend in service life positively impacts the cost-effectiveness of implantable cardioverter-defibrillator/cardiac resynchronization defibrillator therapy, potentially allowing for better use of the resources saved.

bleeding, and infections) and negatively impacts the cost-efficacy of the devices.[12–16]

The aim of this study was to estimate over a 10-year interval the trend of service life of ICD and CRT-D generators, which also reflects device longevity, and to evaluate the main causes of replacement on the basis of data from the National ICD Registry of the Italian Society of Arrhythmology and Cardiac Pacing (AIAC), which regularly collects main technical and clinical information on all ICD and CRT-D implantations performed in the majority of Italian hospitals.

Materials and Methods

Because of the sensitive nature of the data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to the IRCAB Foundation at ircab.foundation@asuiud.sanita.fvg.it.

Patients gave informed consent to sensible data collection and its possible use, in anonymized form, for research purposes at the time of first implantation with an ICD/CRT-D. Our institutional review board has previously approved the research activities of the Italian National ICD Registry.

We included all patients from the Italian National ICD Registry who underwent device replacement of ICD/CRT-Ds from calendar years 2007 to 2016. In fact, complete and validated data are so far available in the Registry up to calendar year 2016 and we decided a priori to include a 10-year period. Along the entire period, the main indications to replacement were explored according to the European Patient-Implantable Cardioverter/Defibrillator Identification Card (EURID) form.[17–19]

The mean duration from implantation to replacement was calculated by subdividing the patients according to device characteristics (single-chamber ICD [ICD-VR], dual-chamber ICD [ICD-DR], or CRT-D), indications to implantation (primary or secondary prevention), and year of device replacement.

The Italian National ICD Registry is a centrally held database in which all participating centers (over 400 hospitals that perform about 95% of ICD/CRT-D implantations in Italy) voluntary provide clinical and technical data on every patient and device implanted.[17,19]

Data are reported in the registry using EURID implant forms and retrieved by mail after implantation, replacement, and explantation procedures. Validation of data is performed using a 2-step protocol: first, at the time of data entry, data are checked for formal consistency, and, then, at the time when the annual report is performed, data are evaluated for internal consistency. Of note, for internal policy the Italian National ICD registry does not publicly report data subdivided by device manufacturer.

The causes of replacement were grouped into 4 categories: (1) elective replacement for battery end of life; (2) system recall according to specific manufacturer advisory or system malfunction detected at the follow-up center; (3) upgrading to CRT device; and (4) system infection or pocket erosion.

For the analysis IBM SPSS Statistics version 20 and R version 3.5.2[20] powered by the rms package version 5.1-2[21] were employed. Data analysis included basic descriptive statistics, with categorical variables usually reported in frequencies (percentages) and absolute numbers, and continuous variables reported as mean±SD or median values and interquartile range (IQR), as appropriate. *P* values have been calculated, whenever appropriate, using ANOVA or Wilcoxon-Kruskal–Wallis test for continuous variables and Pearson chi-square test for categorical variables. The significance cutoff of *P* was fixed to 0.05. The mean expected temporal trends of device longevity were estimated using a generalized linear model with gamma distribution and log link function to account for the positive values, the skewness, and long tails in the distribution of devices' time of duration. To take into account the heteroskedasticity, 1000 bootstrap evaluations of the model, clustered at the subject level, were evaluated to estimate 95% CIs.[22]

Results

In the decade 2007–2016 the Italian ICD Registry collected 29 158 records (80.9% men; mean age 65.2±12.1 years) pertaining to 27 676 patients, who underwent ICD/CRT-D device replacement. Among these records, 18 814 (64.5%;

Table 1. Distribution of Patients Who Underwent ICD Replacement in the Period 2007–2016, According to the Type of Implanted Device and Indication to First ICD Implantation

	Primary Prevention	Secondary Prevention	Combined
ICD-VR	3797 (20.2)	3278 (31.7)	7075 (24.3)
ICD-DR	4733 (25.1)	3478 (33.6)	8211 (28.2)
CRT-D	10 284 (54.7)	3588 (34.7)	13 872 (47.5)
Combined	18 814 (100)	10 344 (100)	29 158 (100)

Data are expressed as count (percentage). CRT-D indicates cardiac resynchronization therapy defibrillator; ICD, implantable cardioverter-defibrillator; ICD-DR, dual-chamber implantable cardioverter-defibrillator; ICD-VR, single-chamber implantable cardioverter-defibrillator. $P<0.001$.

mean age at device replacement 66.2±11.5 years) had received their first ICD/CRT-D for primary prevention and 10 344 (35.5%; mean age at device replacement 64.1±13.1 years) for secondary prevention.

Table 1 shows the distribution of records according to the main clinical indication and the characteristics of the implanted device. Overall, the largest proportion of patients underwent implantation with a CRT-D (47.5%), but this distribution was strongly influenced by the larger subgroup of patients implanted for primary prevention. In fact, patients undergoing implantation for secondary prevention received the 3 ICD types (VR, DR, CRT-D) in substantially equally distributed percentages.

Table 2 shows the distribution of records according to the underlying heart disease and device characteristics. Overall, the majority of patients had ischemic cardiomyopathy and the second most represented cause was nonischemic cardiomyopathy. Conversely, nonischemic cardiomyopathy was preponderant in the subgroup of patients implanted with a CRT-D. As expected, patients undergoing implantation for an idiopathic, purely arrhythmic disease were more represented in the subgroup of patients implanted with an ICD-VR.

The median service life of the replaced devices was 57.3 months (IQR 27.8 months). In detail, in those undergoing implantation for primary prevention, the median service life was 56.8 months (IQR 27.0 months), whereas in those undergoing implantation for secondary prevention, the median service life was 58.0 months (IQR 29.4 months) ($P<0.001$). The service life of CRT-D devices was significantly lower than the service life of ICD-VR and ICD-DR devices, independently from the indication to ICD implantation (Figure 1).

Over the years, device service life showed an increasing trend that remains evident among the 3 types of ICDs and among the 2 main indications to implantation. In particular, the median service life of the ICD replaced in 2007 was 45.8 months (IQR 28.6 months), whereas the median service life of the devices replaced in 2016 was 68.1 months (IQR 27.7 months; $P<0.001$), with a net increase of 22.3 months (relative increase 48.7%). According to ICD types, the net increase of longevity was, respectively, 32.6 months (relative increase 59%) in ICD-VR–treated patients, 28.7 months (relative increase 59.4%) in ICD-DR–treated patients, and 25.1 months (relative increase 68.9%) in the CRT-D group (Figures 2 and 3, Table S1).

The main replacement causes are summarized in Table 3. The majority of devices were replaced because of battery end of life, in particular in CRT-Ds (over 91% for both primary and secondary prevention). The proportion of replacements/explantations for recalls and infections/erosion was low and marginal. Conversely, the proportion of replacements for device CRT upgrading was important, in the range of ≈10%, but was obviously limited to ICD-VR and ICD-DR systems.

Table 2. Demographic Characteristics of the Population and Distribution of Patients According to Underlying Heart Disease and Device Characteristics

	ICD-VR	ICD-DR	CRT-D	Combined
Age, y	61.3±14.4	64.3±12.6	67.7±9.7	65.2±12.1
Men	5814 (82.2)	6849 (83.4)	10 916 (78.7)	23 579 (80.9)
Ischemic cardiomyopathy	3797 (53.7)	4447 (54.2)	5836 (42.1)	14 080 (48.3)
Nonischemic cardiomyopathy	2157 (30.5)	2612 (31.8)	7393 (53.3)	12 162 (41.7)
Hypertrophic cardiomyopathy	185 (2.6)	296 (3.6)	80 (0.6)	561 (1.9)
Arrhythmogenic ventricular cardiomyopathy	125 (1.8)	118 (1.4)	30 (0.2)	273 (0.9)
Other cardiomyopathies	241 (3.4)	304 (3.7)	284 (2.0)	829 (2.8)
Valvular heart disease	114 (1.6)	121 (1.5)	249 (1.8)	484 (1.7)
Long QT syndrome	60 (0.8)	74 (0.9)	0 (0.0)	134 (0.5)
Idiopathic arrhythmias	396 (5.6)	239 (2.9)	0 (0.0)	635 (2.2)

Data are expressed as mean±SD or count (percentage), as appropriate. CRT-D indicates cardiac resynchronization therapy defibrillator; ICD-DR, dual-chamber implantable cardioverter-defibrillator; ICD-VR, single-chamber implantable cardioverter-defibrillator.

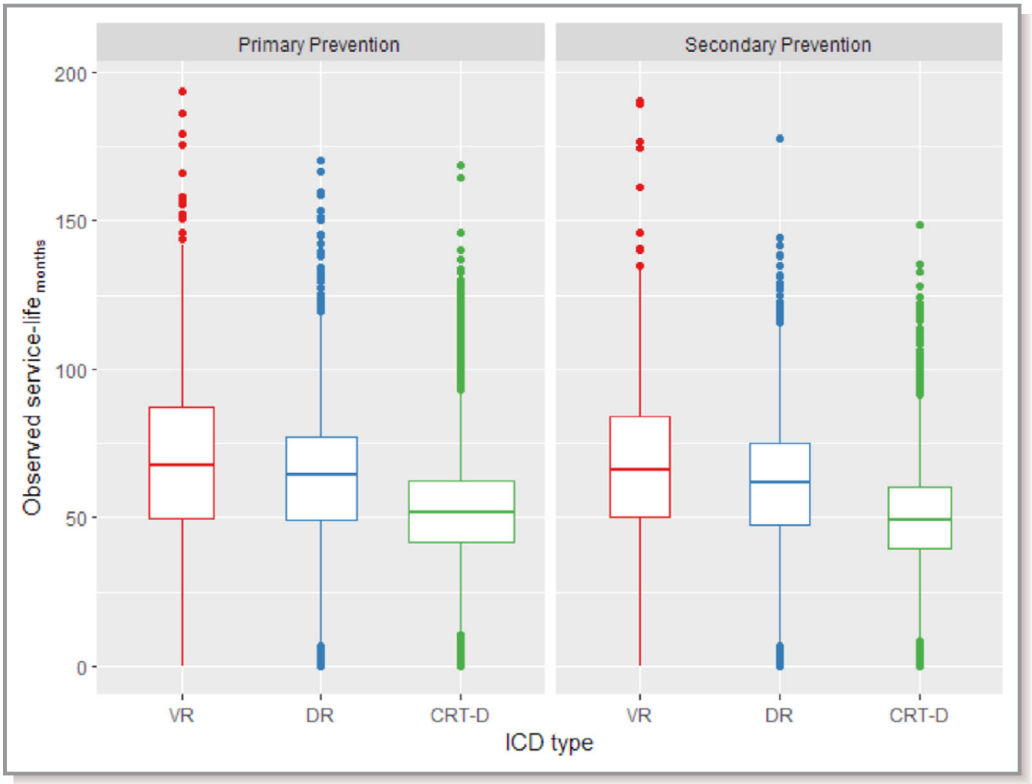

Figure 1. Distribution of service life (months) of implantable cardioverter-defibrillator (ICD)/cardiac resynchronization therapy defibrillator (CRT-D) devices according to ICD indication and device characteristics. Box borders represent the first and third quartiles of the distribution, the segment inside the box represents the median value of the distribution, the vertical lines above and below the box extend up to 1.5 times the interquartile range (IQR; ie, the height of the box), and observations that exceed 1.5 times the IQR are considered outliers and are drawn as singular dots. Boxes are drawn with widths proportional to the square roots of the number of observations in the groups. In detail, the median service life was: primary prevention: ICD–single-chamber device (VR) 67.5 months (IQR 37.6 months), ICD–dual-chamber device (DR) 64.6 months (IQR 28.0 months), and CRT-D 51.9 months (IQR 20.5 months); secondary prevention: ICD-VR 66.2 months (IQR 33.6 months), ICD-DR 61.9 months (IQR 27.2 months), and CRT-D 49.1 months (IQR 20.8 months).

Over the years there was a significant ($P<0.001$) reduction in replacement for recalls, erosion/infections, and upgrading, and, consequently, a relative increase in replacements for battery end of life (Table 4).

Discussion

Data from our large single-nation population, including more than 29 000 replacements, showed that ICD service life, independently from ICD type, indication, and settings, significantly improved over a 10-year period and that the causes of replacement evolved with a striking reduction of interventions for CRT upgrading and infection/erosion in favor of interventions for battery end of life. The relative increase in device longevity across the years was particularly evident for CRT-D, a subset of high-cost and more sophisticated devices with high technological evolution.

The importance of increasing the longevity of ICDs appears obvious both in the setting of purely electric diseases, clinical conditions where patient survival may be similar to the normal population, and in the cohort of patients with left ventricular dysfunction and heart failure, because long-term outcome of these patients has been recently improved with new pharmacologic agents and appropriate clinical management. Extension of device longevity may reduce the mismatch that was demonstrated in the past between patient survival and ICD/CRT-D service life.[16] An increase of device longevity could be obtained by improved device technology (both hardware and software) and battery chemistry and determines both clinical and economic benefit, with an important impact on reducing procedural complications and long-term cost of ICD therapy.[13–15]

In our experience, the observed reduction of interventions for device system CRT upgrading could be explained by improvements in the initial choice of ICD type, which was probably induced by evidence that periprocedural morbidity is higher in patients who undergo an upgrade compared with patients who undergo replacement of the generator.[23]

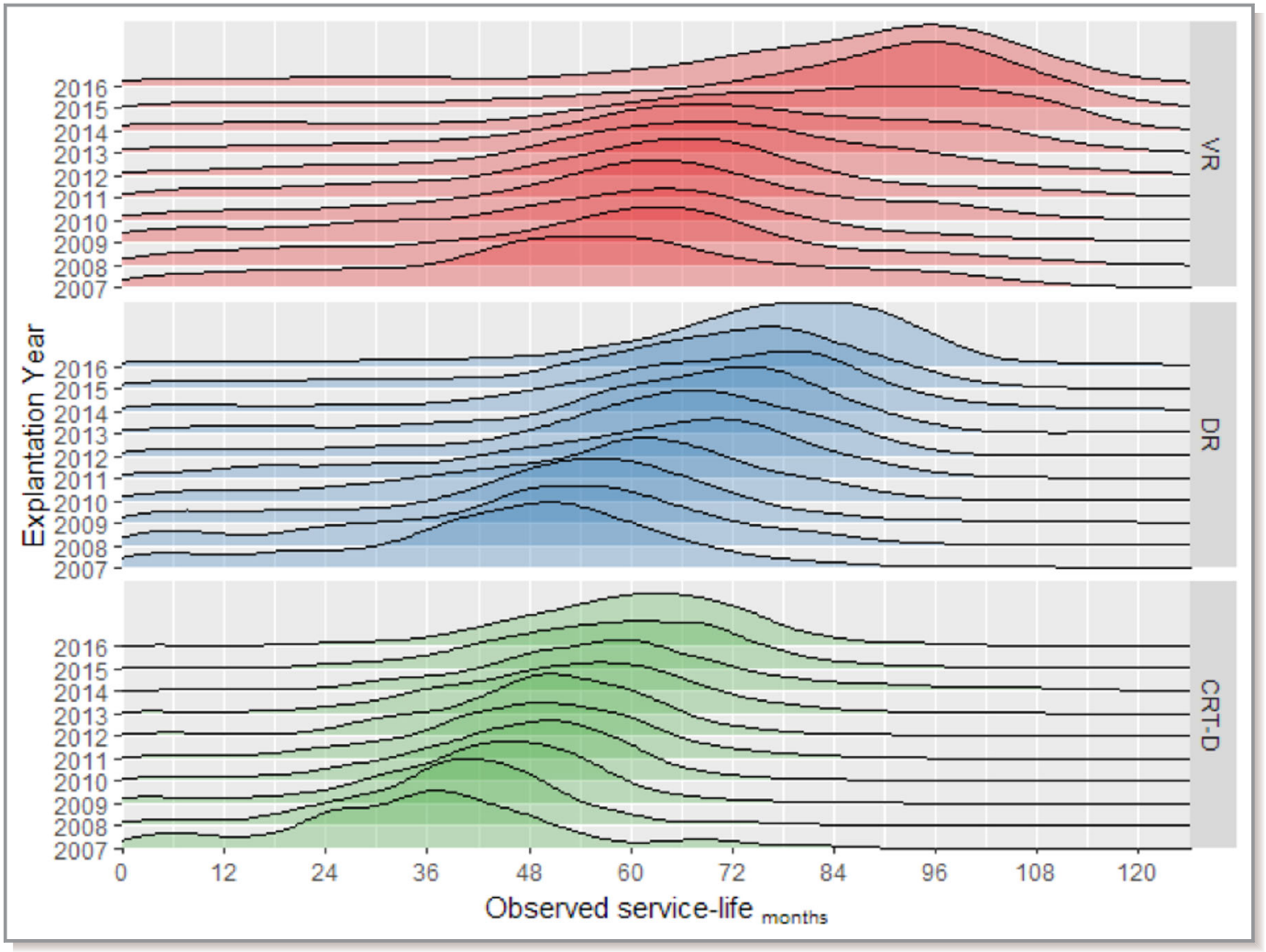

Figure 2. Trends of the implantable cardioverter-defibrillator (ICD) service life distributions across the years according to ICD type. CRT-D indicates cardiac resynchronization therapy defibrillator; DR, dual-chamber device; VR, single-chamber device.

Conversely, in our registry, the reduction of explantations for erosion/infections could be justified by the improvement of surgical techniques and equipment, as well as by a more diffuse and increasing expertise across the implanting centers. ICD or CRT-D replacement for system recalls could also have been reduced by large implementation after the year 2012 of remote monitoring, which allows a stricter follow-up permitting postponement of replacement.[24–27] The reduction of the number of replacements has important clinical implications related to a potential decrease in the risk of complications and specifically of device system infections that any replacement may imply according to a series of risk factors.[28,29]

The service life of ICDs is determined by a multiplicity of factors and is difficult predict a priori. Therefore, data from "real-world" registries can be particularly helpful as they have already been shown to accurately describe the actual impact of ICD therapy on ordinary populations.[3,4] In the past years, several studies on ICD longevity have been published, with most being single-center or multicenter studies collecting data from <50 participating centers.[8–10,30,31]

With respect to previously published data, it must be noted that proper comparison of device service life between different studies is difficult to obtain because of inhomogeneity of patients included and data presentation. Thijssen et al[30] reported longevity as a mean value of 5.0±0.1 years and included 4673 patients who underwent implantation with an ICD from calendar year 1996 to calendar year 2011. Analyzing data from a population of 3436 patients from calendar year 1994 to calendar year 2004, von Gunten et al[9] showed that 69.8% of ICDs were still operative after 5 years. Zanon et al[31] estimated a median service life of 5.9 years (IQR 2.0 years) in ICD-VR and ICD-DR and of 4.9 years (IQR 1.7 years) in CRT-D explanted from March 2013 to May 2015. Conversely, Manolis et al[8] assessed ICD service life over a 20-year period among 685 patients, with the majority of them

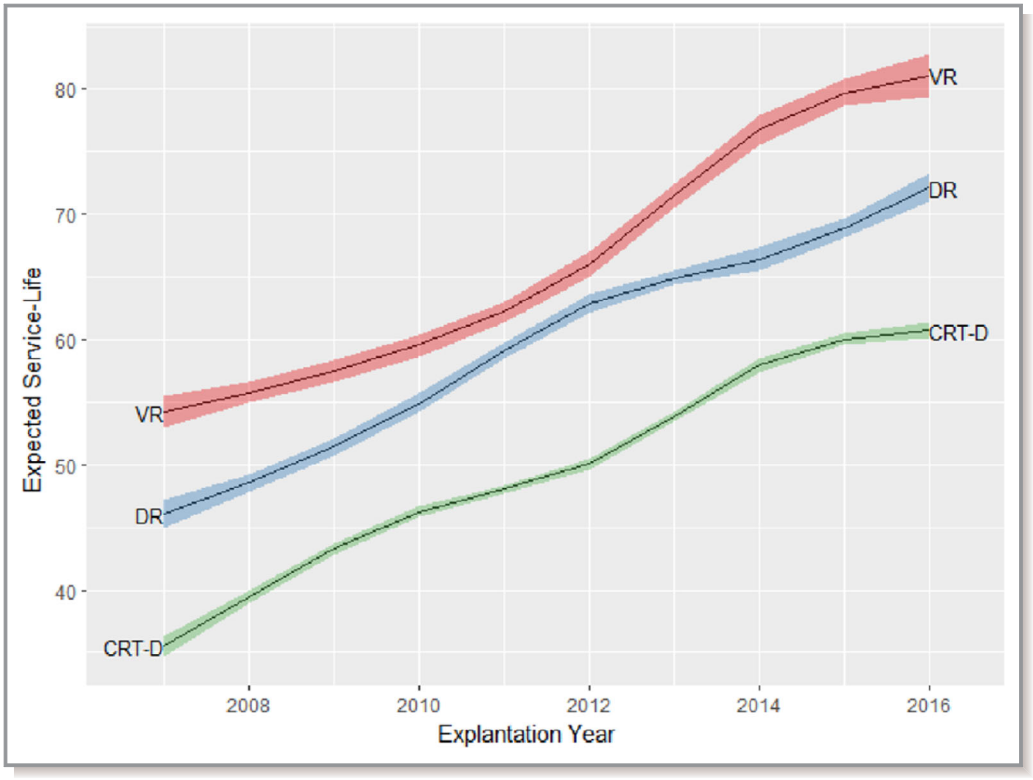

Figure 3. Model fitted by implantable cardioverter-defibrillator (ICD) type: trend of the expected service life (in months) as modeled by the years. Vertical bars represent the original data. Shadows represent the 95% CI for the drawn lines. CRT-D indicates cardiac resynchronization therapy defibrillator; DR, dual-chamber device; VR, single-chamber device.

undergoing implantation with an ICD for secondary prevention; they estimated a mean service life of 58.3±18.7 months. In another single-center study, the mean longevity of 1665 devices implanted in 1272 patients between calendar year 1998 and calendar year 2010 ranged from 5.2 to 5.7 years according to different manufacturers.[10] Device type and percentage of pacing, but not pacing output and ICD shocks, had an influence on battery longevity.[10]

Data from the literature confirm our finding that longevity of CRT-D is shorter than that of ICD-VR and ICD-DR, which can be intuitively explained by the higher percentage of pacing, especially left ventricular pacing, and by device complexity.[13,16,31]

In addition, battery end of life is the most frequent cause of device replacement interventions in previous studies.[9,30,31] Only Thjissen et al[30] found higher percentages of substitution for erosion/infections and recalls, but their population included patients who underwent implantation with an ICD from calendar year 1996.

The trend toward a prolongation of service life over the years among all ICD types has been highlighted in previous

Table 3. Causes of Replacement According to Device Characteristics and Indication to Implantation

	Primary Prevention			Secondary Prevention			
	ICD-VR	ICD-DR	CRT-D	ICD-VR	ICD-DR	CRT-D	Combined
Battery end of life	2650 (69.8)	3502 (74.0)	9470 (92.1)	2297 (70.1)	2602 (74.8)	3302 (92.0)	23 823 (81.7)
Recall/system malfunction	35 (0.9)	59 (1.2)	120 (1.2)	53 (1.6)	51 (1.5)	36 (1.0)	354 (1.2)
CRT upgrading	781 (20.6)	824 (17.4)	0 (0.0)	702 (21.4)	565 (16.2)	0 (0.0)	2872 (9.8)
Infection/erosion	46 (1.2)	80 (1.7)	182 (1.8)	38 (1.2)	66 (1.9)	73 (2.0)	485 (1.6)
Not available	285 (7.5)	268 (5.7)	512 (5.0)	188 (5.7)	194 (5.6)	177 (4.9)	1624 (5.6)

Data are expressed as count (percentage). All comparisons were significant at the $P<0.001$ level. CRT indicates cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; ICD-DR, dual-chamber implantable cardioverter-defibrillator; ICD-VR, single-chamber implantable cardioverter-defibrillator.

Table 4. Causes of Replacement Before and From Calendar Year 2012

	Explantation Before Calendar Year 2012	Explantation From Calendar Year 2012
Battery end of life	9424 (72.4)	13 602 (84.2)
CRT upgrading	2141 (16.5)	1528 (9.5)
Infection/erosion	288 (2.2)	197 (1.2)
Recall/system malfunction	163 (1.3)	191 (1.2)
Not available	997 (7.7)	627 (3.9)

Data are expressed as count (percentage). CRT indicates cardiac resynchronization therapy. $P<0.001$.

studies and is attributable to technology improvements.[9,30] The long-term effects of up-to-date ICD technology and programming should be evaluated in the future and compared with the longevity predicted by industry models.[32]

Since the cost of ICD therapy is typically characterized by the upfront cost of the device, at implant or replacement,[33] the positive trend in service life that emerges in our analysis has important implications for the organization of care and for the financial resources spent on ICD therapy. The population in Western countries is becoming older[34] and the lengthening of ICD service life may allow distribution of the saved resources to a wider patient population.

Study Limitations

The trend of service life that we found could be explained by the characteristics of our "real-world" analyses, which includes the device replacements collected in a whole nation. It is plausible that a significant percentage of our patients received less device optimization if compared with patients enrolled in prospective studies and performed in selected centers. In particular, the Italian ICD registry did not consider the impact on service life of large-scale implementation of up-to-date device programming, including long detection strategies and shock-avoiding device settings.[35–37] In addition, the effects on device longevity of the different pacing programming, percentage of atrial and ventricular pacing during the follow-up, and number and type of ICD interventions (shock and/or ATP) were not analyzed in our study because this information is not included in the queries of the Italian ICD registry. Finally, we did not consider the ICD and CRT-D service life according to the specific manufacturer because this type of analysis was not planned among the activities of the Italian ICD registry and could have been distorted by important technological inhomogeneities across a 10-year period. Similarly, other large and official ICD registries have not included vendor analysis in their reports.[38,39]

Conclusions

The 10-year analysis from 2007 to 2016 of the National Italian ICD Registry showed that around 29 000 patients underwent ICD and CRT-D replacement and that the trend of ICD service life, independently from ICD type, indication, and settings, significantly improved over time. Moreover, the causes of replacement evolved over the 10-year period with a striking reduction of interventions required for CRT upgrading and infection/erosion in favor of battery end of life. The positive trend that emerged has important and favorable clinical, organizational, and financial implications.

Disclosures

Dr Boriani reports small speakers' fees from Biotronik, Boehringer Ingelheim, Boston Scientific, and Medtronic. Dr Ricci reports minor consultancy fees by Medtronic, Boston Scientific, and Dompé. Dr Landolina reports modest speakers' fees and modest advisory board grants from Boston Scientific, LivaNova, and Medtronic. The remaining authors have no disclosures to report.

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SUPPLEMENTAL MATERIAL

Table S1. Service life of the devices (months) subdivided per year of replacement and according to the ICD type and ICD indications.

Year of Explantation	ICD-VR	ICD-DR	CRT-D	Primary Prevention	Secondary Prevention	Combined
2007	55.0	48.3	36.4	42.2	48.7	45.8
	IQR 29.7	IQR 21.6	IQR 19.3	IQR 28.1	IQR 27.9	IQR 28.6
2008	59.2	50.9	40.1	43.8	49.1	46.6
	IQR 30.4	IQR 25.2	IQR 15.5	IQR 24.1	IQR 27.1	IQR 25.7
2009	57.9	53.7	44.1	47.2	51.4	48.7
	IQR 32.4	IQR 22.0	IQR 16.6	IQR 21.2	IQR 24.6	IQR 23.3
2010	62.2	58.4	47.7	51.6	56.0	52.9
	IQR 26.2	IQR 26.2	IQR 17.9	IQR 22.6	IQR 24.7	IQR 23.7
2011	64.1	63.2	48.8	53.7	57.4	54.7
	IQR 26.9	IQR 27.2	IQR 17.9	IQR 24.6	IQR 27.4	IQR 25.6
2012	68.1	65.6	50.7	56.8	58.2	57.2
	IQR 28.3	IQR 21.8	IQR 16.8	IQR 22.15	IQR 26.7	IQR 23.5
2013	71.6	68.4	53.9	59.7	63.7	60.6
	IQR 31.6	IQR 21.4	IQR 19.8	IQR 24.8	IQR 27.8	IQR 25.6
2014	80.8	71.3	58.3	63.1	66.9	64.2
	IQR 35.7	IQR 24.7	IQR 20.6	IQR 28.1	IQR 31.3	IQR 29.3
2015	89.8	70.6	59.2	64.8	67.3	65.4
	IQR 27.6	IQR 24.3	IQR 20.4	IQR 27.0	IQR 30.8	IQR 27.7
2016	87.6	77.0	61.5	67.2	70.7	68.1
	IQR 30.2	IQR 22.1	IQR 19.0	IQR 27.2	IQR 28.3	IQR 27.7
p for trend	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Data are expressed as median value with interquartile range (IQR).