

The economic impact of battery longevity in implantable cardioverter-defibrillators for cardiac resynchronization therapy: the hospital and healthcare system perspectives

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Aims

Patients receiving cardiac resynchronization therapy defibrillators (CRT-Ds) are likely to undergo one or more device replacements, mainly for battery depletion. We assessed the economic impact of battery depletion on the overall cost of CRT-D treatment from the perspectives of the healthcare system and the hospital. We also compared devices of different generations and from different manufacturers in terms of therapy cost.

Methods and results

We analysed data on 1792 CRT-Ds implanted in 1399 patients in 9 Italian centres. We calculated the replacement probability and the total therapy cost over 6 years, stratified by device generation and manufacturer. Public tariffs from diagnosis-related groups were used together with device prices and hospitalization costs. Generators were from 3 manufacturers: Boston Scientific (667, 37%), Medtronic (973, 54%), and St Jude Medical (152, 9%). The replacement probability at 6 years was 83 and 68% for earlier- and recent-generation devices, respectively. The need for replacement increased total therapy costs by more than 50% over the initial implantation cost for hospitals and by more than 30% for healthcare system. The improved longevity of recent-generation CRT-Ds reduced the therapy cost by ~6% in both perspectives. Among recent-generation CRT-Ds, the replacement probability of devices from different manufacturers ranged from 12 to 70%. Consequently, the maximum difference in therapy cost between manufacturers was 40% for hospitals and 19% for the healthcare system.

Conclusions

Differences in CRT-D longevity strongly affect the overall therapy cost. While the use of recent-generation devices has reduced the cost, significant differences exist among currently available systems.

Keywords

Battery • Cardiac resynchronization therapy • Cost analysis • Defibrillator • Device longevity

Introduction

Cardiac resynchronization therapy by means of defibrillators (CRT-Ds) is an established treatment for heart failure. Recently,

the survival rate in mildly symptomatic patients who received CRT-D was reported to be 82% at 7 years.¹ Since the average longevity of CRT-Ds implanted in the last 10 years ranges from 3.5 to 4.0 years,^{2–4} recipients of CRT-Ds are likely to undergo

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What's new?

- This study provides original data on the economic impact of cardiac resynchronization therapy defibrillator (CRT-D) battery longevity in a real-world cohort of patients.
- This analysis provides comparative evidence on the total cost of therapy delivered by CRT-D of different generations and from different manufacturers.

one or more device replacements for battery depletion.⁵ This mismatch between CRT-D longevity and patient survival was also confirmed by a recent study.⁶

We recently measured the rate of replacement for battery depletion in a population of consecutive patients who had undergone implantation of CRT-D devices from different manufacturers⁷ and identified possible determinants of early depletion. Our analysis revealed differences in longevity among devices from different manufacturers and of different generations.

The replacement of implantable cardiac devices has both a clinical and economic impact. From a clinical standpoint, device replacement increases the risk of complications.⁸

From an economic perspective, the need for replacement increases the total costs of therapy, not only on account of the additional procedures, but also owing to the management of replacement-related complications. Indeed, a model-based study has demonstrated that the longevity of cardioverter-defibrillators has an important effect on the long-term cost of device therapy.⁹ To date, however, no published studies have provided evidence on the economic impact of CRT-D battery longevity in a real-world cohort of patients.

The aim of the present study was to assess the economic impact of replacement for battery depletion on the overall cost of CRT-D from the perspectives of the hospital and the healthcare system. We also compared the total cost of therapy delivered by CRT-Ds from different manufacturers and of different generations.

Methods

Patient population and study design

Data on all patients who had received a CRT-D system according to international recommendations were prospectively collected in the hospital databases of nine Italian implanting centres. At the time of implantation, all patients provided written informed consent to data storage and analysis. As previously described,⁷ data on all consecutive CRT-D systems implanted from January 2008 to March 2010 were retrieved for analysis. All patients underwent implantation of a CRT-D by means of standard techniques and, after implantation, returned for regular clinic visits every 6 months. For the aim of the previously published analysis,⁷ patients were analysed from implantation to the first event resulting in surgical intervention for device replacement. For the present economic analysis, the study database was further searched for all device replacements, not only the first one, performed in the study population from implantation to the end of the observation period in March 2014. Data on CRT-Ds manufactured by Biotronik and Sorin (156 devices implanted in 122 patients) were excluded from the analysis owing to the small sample size (<8% of all devices). To estimate the probability of replacement for battery depletion, for each generator we measured the time from implantation to the surgical intervention for device replacement. Cases

were censored at the time of patient death or the last outpatient follow-up visit, or in the event of device removal for reasons other than battery depletion. Baseline data included the date of implantation and the manufacturer and model of the device. As previously described,⁷ devices were stratified by manufacturer and device generation. Defibrillators from each manufacturer were divided into recent and earlier generations. We identified as recent generation the most recent device families released onto the market (for the most part after 2007), and as earlier generation all devices belonging to previous device families.

Cost input and economic analysis

The economic analysis was performed from both the hospital and the healthcare system perspectives. Concerning the hospital perspective, device prices and hospitalization costs were considered. In the analysis, every procedure performed by the hospitals was regarded as an expenditure from the hospital's budget—even though these procedures are reimbursed through the diagnosis-related group (DRG) system. A weighted average price of devices was obtained from information on tenders and was then used for the economic analysis; the prices of the first implant and the replacement device were assumed to be equal. Minimum and maximum prices were also used to assess the entire possible range of results. With regard to hospital costs (including procedure and hospital stay), a proxy of the costs was taken from the published literature⁹ since this information was not available from the hospitals. All costs and tariffs were inflated to €2015 as recommended by the health economics literature.¹⁰ Inflated costs and tariffs are reported in *Table 1*. Regarding the healthcare system perspective, the implantation procedures were matched with their corresponding DRG tariffs, DRG 515 (Cardiac defibrillator implant without cardiac catheterization) being used for first implantation and DRG 551 [Permanent cardiac pacemaker implant with major cardiovascular diagnosis or automatic defibrillator (AICD) lead or generator] for replacement. The tariffs of the procedure were assigned at the time of event occurrence (*Table 1*). The economic analysis adopted the same methodology for both perspectives. First, the proportion of devices replaced for battery depletion over 6 years was calculated and stratified according to manufacturer, generation, and manufacturer plus generation. Second, on the basis of the probability of battery depletion, the cumulative expenditure per patient for replacement and total therapy was calculated yearly over 6 years and compared among device generations and manufacturers. Finally, the overall economic burden of replacement for battery depletion and overall cost of CRT-D were calculated at the participating hospitals over the observation period. We also estimated the potential saving that could be obtained in the observed cohort over 6 years if only recent- and earlier-generation devices from the manufacturer associated with the greatest longevity were adopted.

Statistical analysis

Kaplan–Meier analyses were performed to determine device longevity and to calculate the annual rate of device replacement. Log-rank test was applied to evaluate differences in longevity. A *P*-value of <0.05 was considered significant. All statistical analyses were performed by means of STATA software, release 13 (StataCorp. 2015. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

Results

Study population, devices in analysis, and probability of replacement

From January 2008 to March 2010, a total of 1726 heart failure patients received a CRT-D at the 9 study centres and were included in

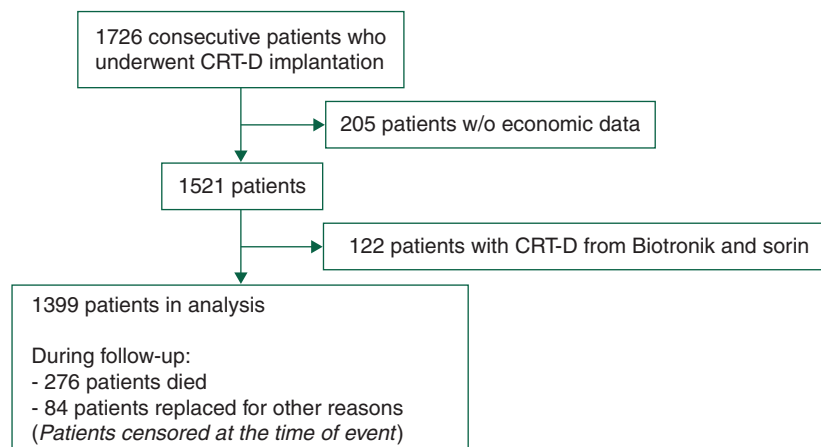
Table 1 Cost input data: hospital and healthcare system perspectives (€2015)

Cost		Cost per unit, €2015	
Hospital perspective			
CRT-D average price		€16 290 (from €14 971 to €17 248)	
CRT-D cost of procedure and hospitalization—first implant		€6174	
CRT-D cost of procedure and hospitalization—replacement		€1852	
Healthcare system perspective			
Healthcare system perspective	Year	First CRT-D implant ^a	CRT-D replacement ^b
Tariff per DRG, €2015	2008	€25 346	€13 516
	2009	€23 593	€13 322
	2010	€23 271	€13 140
	2011	€21 639	€12 103
	2012	€20 986	€11 738
	2013	€16 689	€9450
	2014	€16 590	€9393

Source: (1) Accordo Interregionale per la Compensazione della Mobilità Sanitaria, <http://www.regioni.it/> date last accessed 21 March 2016; (2) Ref. ⁹.

^aDRG 515—Cardiac defibrillator implant without cardiac catheterization.

^bDRG 551—Permanent cardiac pacemaker implant with major cardiovascular diagnosis or automatic defibrillator (AICD) or generator.

**Figure 1** Diagram of the study: number of cases in analysis.

the main analysis. The present analysis was performed on a subset of 1399 patients who met criteria for the economic analysis and who were followed up until March 2014 (Figure 1). The initial procedure was a *de novo* implantation in 857 (61%) patients, a replacement of a previous CRT-D system in 406 (29%) patients, and an upgrade from a previous dual-chamber ICD or CRT-D in the remaining 136 (10%) patients.

During a median follow-up of 45 months, 276 (20%) patients died and were therefore censored from the analysis. During the observation period, a total of 1792 implantation procedures were performed in the study population: 842 (47%) *de novo* implantations and 950 replacements (53%). Details of the devices implanted are summarized in Table 2. The generators were from 3 manufacturers: 667 (37%) from Boston Scientific, 973 (54%)

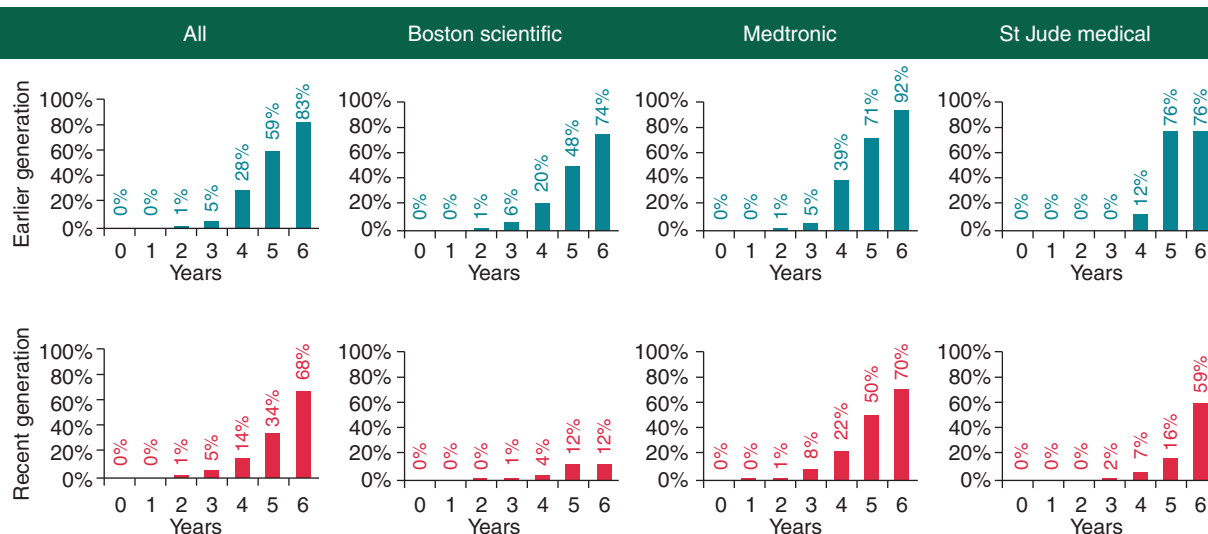
from Medtronic, and 152 (9%) from St Jude Medical. They belonged to defibrillator families released onto the market from 2003 to 2010. Earlier-generation devices (released before 2007) and recent-generation devices (released since 2007) numbered 571 and 1221, respectively. The probability of replacement for battery depletion was calculated up to 6 years by device generation, by manufacturer, and by generation and manufacturer together. Cumulative probabilities of replacement are shown in Figure 2.

The actuarial probability of battery depletion at 6 years was 83 and 68% for earlier- and recent-generation devices, respectively (log-rank test, $P < 0.001$). Among recent-generation CRT-Ds, the probability of replacement ranged from 12 to 70% according to the manufacturer (overall log-rank test, $P < 0.001$).

Table 2 Devices in analysis

Manufacturers	N	Battery depletion, n (%)	Replaced for other reasons, n (%)	Generation	N (%)	Device families
Boston Scientific	667	109 (16)	25 (4)	Earlier generation	291 (44)	Renewal Livian
Medtronic	973	237 (24)	49 (5)	Recent generation	376 (56)	Cognis
				Earlier generation	242 (25)	InSync III Marquis InSync Sentry InSync Maximo Concerto
St Jude Medical	152	24 (16)	10 (6)	Recent generation	731 (75)	Consulta, Maximo II Protecta
				Earlier generation	38 (25)	Atlas Epic Promote
				Recent generation	114 (75)	

For the purpose of the analysis: earlier generation (before 2007) and recent generation (after 2007).

**Figure 2** Cumulative probability of replacement based on Kaplan–Meier analysis.

Economic impact of battery longevity: the hospital perspective

With regard to the hospital perspective, the cost of a first CRT-D implantation was €24 156 (range: €22 700–25 214). The cumulative cost of replacement was calculated by considering the probability of battery depletion, stratified by device manufacturer and by generation (Figure 3). Over 6 years, the total cost of therapy per patient was €39 514 (range: €36 938–41 384) for earlier-generation devices (with replacement costs generating a 64% increase over the initial implant cost) and €36 638 (range: €34 273–38 356) for recent-generation devices (with replacement costs generating a 52% increase over the initial implant cost). The use of recent-generation CRT-Ds was associated with a mean reduction of

€2875 (7%) in the total cost of therapy in comparison with earlier-generation devices. The reduction ranged from €1419 (4%) to €7111 (17%), when the variability in device prices was taken into account. Among recent-generation CRT-Ds from different manufacturers, the total cost of therapy per patient ranged from €26 417 (range: €24 796–27 594) to €37 041 (range: €34 647–38 780), with replacement costs varying from 9 to 53% of the initial cost. The maximum difference in therapy cost among recent-generation CRT-Ds from different manufacturers presented a mean value of €10 624 (40% of the minimum cost) and ranged from €7052 (27%) to €13 984 (53%), when the variability in device prices was taken into account.

On considering the hospital perspective, the overall mean cost of CRT-D was €30.5 million (range: €28.5–31.8 million). Specifically,

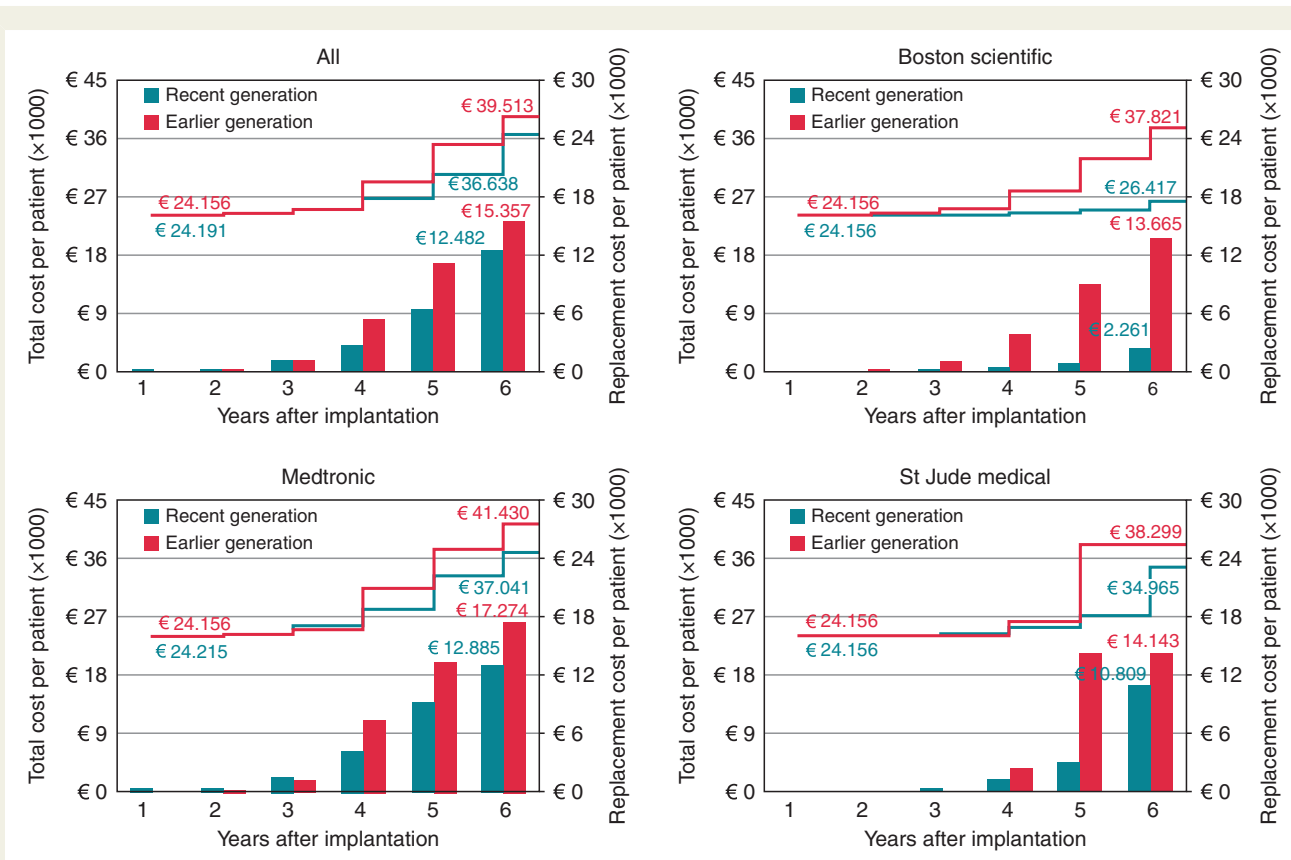


Figure 3 Cumulative expenditure per patient for replacement due to battery depletion: hospital perspective. Lines represent the total cost of therapy; bars represent the cost of replacement.

€23.6 million (range: €22–25 million) was spent on first implantations and €6.8 million (range: €6.3–7.2 million) on replacements for battery depletion.

Considering the yearly probability of replacement due to battery depletion, and assuming that only those early- and recent-generation CRT-Ds with the greatest longevity would be implanted in the 1399 patients in analysis, 14% (range: 7–20%) of the total expenditure could be avoided over 6 years. This expenditure reduction corresponds to the costs of implanting CRT-Ds in 282 (range: 146–412) new patients with heart failure requiring CRT.

Economic impact of battery longevity: the Italian healthcare system perspective

Based on public DRG tariffs, the cost of a first CRT-D implantation was €24 321. The cumulative cost of replacement based on the actuarial probability of battery depletion is reported in *Figure 4*. Over 6 years, the total cost of therapy per patient was €33 413 for earlier-generation devices (with replacement costs generating a 37% increase over the initial implantation cost). The total cost for recent-generation devices was €31 274 (with replacement costs accounting for 29% of the initial implantation cost); thus, the total cost of recent-generation CRT-Ds was 6% lower than that of earlier-generation devices. Among recent-generation CRT-Ds from different manufacturers, the total cost of therapy over 6 years

ranged from €25 579 (with replacement costs generating only a 5% increase over the initial cost) to €31 536 (with replacement costs generating a 23% increase over the initial cost). Therefore, the maximum difference in the cost of therapy was 19% among recent-generation CRT-Ds.

The Italian healthcare system spent €27.7 million to provide CRT-D therapy for the 1399 patients at the participating hospitals over the observation period. Overall, the cost of first implantation was €23.7 million, while that of replacement for battery depletion was €4 million.

Considering the yearly probability of replacement due to battery depletion, and assuming that only those early- and recent-generation CRT-Ds with the greatest longevity would be implanted in the 1399 patients in analysis, up to 9% of the total expenditure could be avoided over 6 years. This expenditure reduction corresponds to the costs of implanting CRT-Ds in ~161 new patients with heart failure requiring CRT.

Discussion

The present economic analysis, which was carried out in a cohort of 1399 patients who had undergone implantation of CRT-Ds from different manufacturers, revealed that device replacement for battery depletion was a significant cost driver. Indeed, over 6 years, the need for replacement increased therapy costs by more than 50%

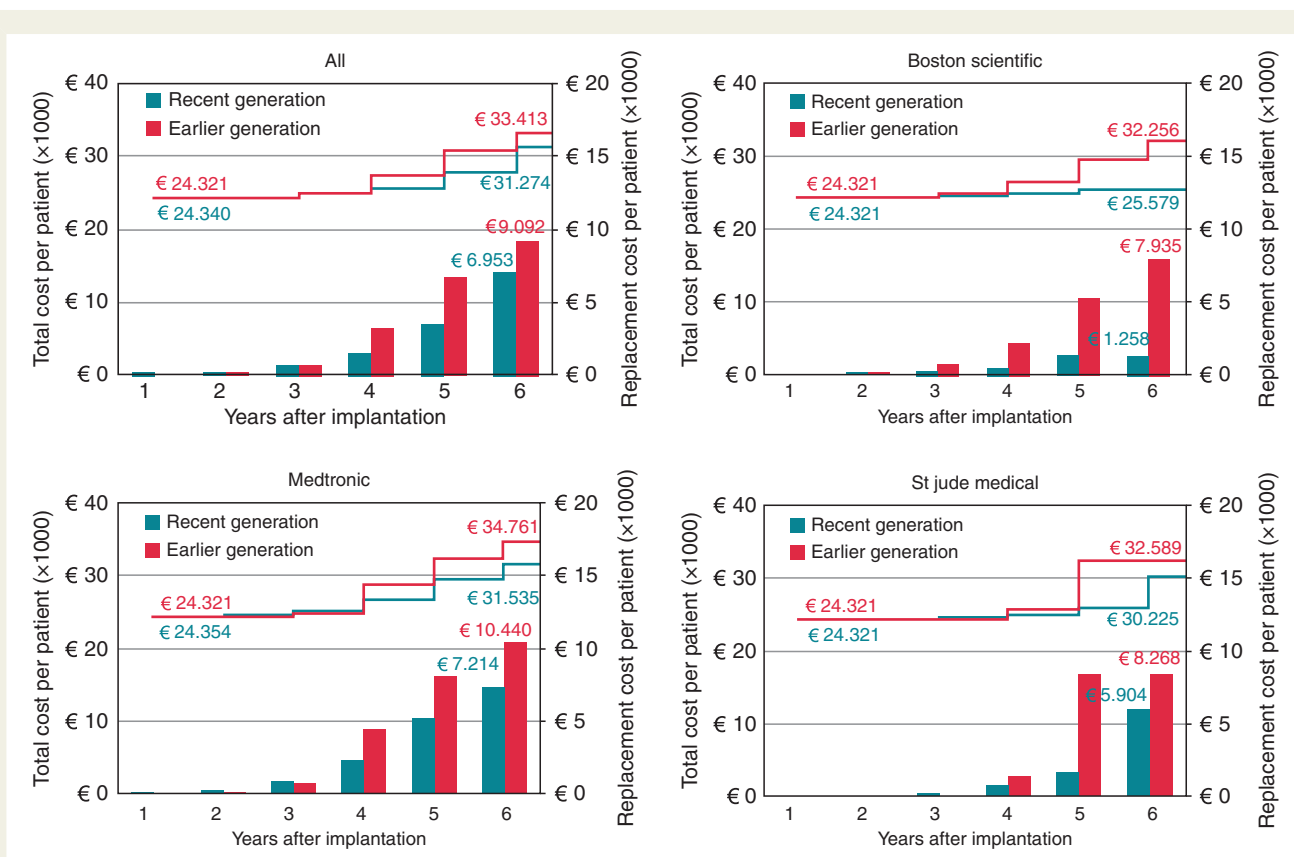


Figure 4 Cumulative expenditure per patient for replacement due to battery depletion: healthcare system perspective. Lines represent the total cost of therapy; bars represent the cost of replacement.

over the initial implantation cost for hospitals, and by more than 30% for the healthcare system. Nonetheless, the improved longevity of recent-generation CRT-Ds reduced the cost of therapy by ~6%. Moreover, differences in the cost of therapy (up to almost 40% for hospitals and 20% for the healthcare system) emerged among currently available CRT-D systems from different manufacturers.

In our previously published analysis,⁷ we provided real-world longevity data on currently available CRT-D devices and identified the possible determinants of early battery depletion; this revealed that longevity varied among devices from different manufacturers and of different generations.

Device replacement constitutes a cost for the health system, which in Italy reimburses hospitals through the DRG system. From the hospital perspective, expenditure comprises the costs of the device, the procedure, and hospitalization. Thus, we assumed that, in both perspectives, the total cost of therapy per patient would be constituted not only by the cost of the initial implantation but also by the replacement cost, weighted according to the probability of battery depletion.

As expected, device longevity often proved to be shorter than the survival of patients currently receiving CRT-D. Consequently, frequent surgical procedures for generator replacement were required, as previously reported.^{5,11} To investigate the impact of innovation on healthcare expenditure, we calculated the total cost per patient over 6 years and compared this between device

generations. Similarly, we compared recent-generation CRT-Ds from different manufacturers in order to assess the variability in costs among currently available options in clinical practice.

The total per-patient cost of therapy after 6 years was significantly higher than the initial cost. The cost of replacement increased expenditure by 50–60% for hospitals and by 30–40% in the perspective of the healthcare system. The higher impact on hospitals was due to the lower value of the DRG tariff adopted for replacement despite comparable costs for first implantation and replacement in the hospital perspective.

Thanks to improved battery technology and the availability of specific algorithms for automatic pacing output adjustment,⁷ recent-generation CRT-Ds displayed better longevity; consequently, therapy costs were ~6% lower over 6 years. The differences that emerged among currently available CRT-D systems from different manufacturers were greater. Indeed, the probability of replacement ranged from 12 to 70% over 6-year follow-up, and the resulting differences in the cost of therapy were 40% for the hospitals and 19% for the healthcare system. These differences are in line with previous findings by Boriani et al.⁹ These authors calculated a relative saving of 30–35% for hospitals over a 15-year time horizon, on extending CRT-D lifespan from 5 to 10 years—the minimum and maximum longevities of devices in the present analysis.^{7,12}

In the present study, the unit costs changed over time, as well as among device generations and manufacturers. To account for

this variability, all costs and tariffs were corrected for the effect of inflation,¹⁰ and the average price in the study centres during the observation period was used for the analysis. In the hospital perspective, minimum and maximum values were used to take into account the possible impact of price variability on the results. Specifically, on attributing a higher unit price to novel devices, the cost of therapy by means of recent-generation CRT-Ds was calculated to be 4% lower than that of earlier-generation CRT-Ds; however, on hypothesizing a decline in the unit price of novel devices, the cost saving rose to 17%. Similarly, the maximum difference in therapy cost among CRT-Ds from different manufacturers ranged from 27%, with longer-lasting CRT-Ds costing the most, to 53% with longer-lasting CRT-Ds costing the least.

In the cohort analysed, expenditure over the period of observation was almost €30 million for the hospitals and the health-care system, and a considerable part of this expenditure was attributable to replacement for battery depletion. We observed that the improved performance of contemporary devices reduced the long-term cost of therapy. This should prompt the early adoption of novel solutions, not only because of the possible enhancement in clinical efficacy, but also in order to save resources. In addition, since the effectiveness of contemporary devices may be considered largely equivalent, device longevity, and therefore the actual cost of therapy, should be regarded as the main criterion for selection. This is emphasized by the extent of the differences among devices from different manufacturers that we observed in a real-life setting. However, the evaluation of existing technology is difficult. Indeed, projection on battery longevity provided by the industry is based on intensive laboratory testing under controlled conditions and might be different from device longevity in real life. Other information comes from product performance reports and is based on the analysis of returned devices. Concerns have been recently raised about their accuracy,¹³ and information are available only long after the launch of a new device model. Nonetheless, although published results may not fully apply to newer devices, specific battery characteristics, i.e. cell capacity,¹⁴ lithium manganese dioxide chemistry,⁷ or algorithms for the optimization of pacing output¹⁵ were shown to improve longevity and should therefore be considered at the time of device selection.

In the perspective of the single patient, the implantation of a long-lasting device means a lower probability of undergoing additional surgery for replacement¹² and, consequently, fewer complications.^{8,16} From the community standpoint, greater device longevity reduces the cost of therapy and, owing to budget constraints on public spending on health, increases access to care. This was evident in our study, in which the adoption of long-lasting devices could have freed resources, thereby enabling a large number of new patients requiring CRT to be treated.

Limitations

Some limitations of this study should be noted. Firstly, regional differences among tariffs were not considered in analysis. Secondly, patients were censored from the analysis in the event of device removal for reasons other than depletion, and the analysis did not include the effects of complications related to replacement. In the

model developed by Boriani *et al.*,⁹ complications accounted for 1–2% of the cost of first implantation and up to 6% of the cost of replacement. Our results could therefore slightly underestimate the economic burden of CRT-D replacements. Thirdly, the costs of hospital stays and procedures were taken from the literature rather than being directly collected. Fourthly, we defined device longevity as the time from implantation to the surgical intervention for device replacement and thus not to the day of the detection of elective replacement indicator. However, the results should have not been affected by any bias as this was done for all devices in analysis. Finally, although the majority of devices in the present analysis are still available today, newer devices have been released and our results may not apply to these.

Conclusions

Device replacement for battery depletion proved to be a significant cost driver in a large cohort of patients treated with CRT-D over 6 years. The improved longevity of recent-generation CRT-Ds reduced the cost of therapy. Moreover, differences emerged among currently available CRT-D systems from different manufacturers. Longevity should be regarded as a crucial criterion for selecting CRT-D devices.

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Conflict of interest: This was an independent study. M.L. has a speakers' bureau appointment with Medtronic and Boston Scientific and an advisory board relationship with St Jude Medical and Medtronic. M.G. has an advisory board relationship with Boston Scientific.

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Epicardial ventricular tachycardia successfully ablated from the left atrium in a case with a prior mitral valve repair

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A 59-year-old woman with a history of mitral valve repair (MVR), with an annuloplasty band due to severe mitral regurgitation, underwent electrophysiological testing of ventricular tachycardia (VT) exhibiting a right bundle branch block and right inferior axis QRS morphology. The ventricular activation recorded within the coronary sinus (CS) during the VT was the earliest at the posterior aspect and preceded the QRS onset by 73 ms. The earliest ventricular activation in the left ventricle (LV) during the VT was 34 ms later than that within the CS. Further mapping was performed along the mitral annulus (MA) in the left atrium (LA) through a transeptal approach, and the earliest ventricular activation preceding the QRS onset by 141 ms was recorded from the LA above the posterior MA. A single irrigated radiofrequency application at this site eliminated the VT. Post-procedural enhanced cardiac computed tomography demonstrated that the LA at the successful ablation site was in direct contact with the epicardial LV base. Such a strange anatomy was likely to have resulted from a structural remodelling after the MVR. This report illustrated a successful catheter ablation of an epicardial VT occurring after mitral valvular surgery by delivering a radiofrequency application from the LA.

The full-length version of this report can be viewed at: <http://www.escardio.org/Guidelines-&-Education/E-learning/Clinical-cases/Electrophysiology/EP-Case-Reports>.

