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How to truly value implantable cardioverter-defibrillators technology: Up-front cost or daily cost?

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Background: We calculated the daily cost of implantable cardioverter-defibrillators (ICDs) based on their actual longevity to prove whether the up-front cost is a reliable parameter for the ICD purchasing-process.
Methods. Longevity of single chamber (SC), double chamber (DC), and biventricular (BiV) ICDs from Medtronic (MDT), Guidant (GDT), and St. Jude Medical (SJM) was measured in all the patients implanted in years 2000, 2001, 2002 who reached device replacement within December 31, 2009. The cost of each ICD (device + lead/s) was normalized for its own longevity. Data are expressed as median (25th–75th percentile).
Results: A total of 123/153 patients completed the study, 70 percent being alive 8 years after implantation. MDT devices had a superior longevity compared with GDT and SJM ($p < .001$). Fifty-eight percent of replaced ICDs had a service life at least 1 year shorter than the manufacturers' prediction. Longer-lasting devices had a significantly lower daily cost: €4.8 (4.6–5.7) versus €6.8 (6.2–9.2) and €6.9 (6.2–7.6) for SC ($p < .001$); €6.9 (6.8–7.7) versus €12.6 (11.8–13.3) and €13.4 (10.3–16.1) for DC; €8.5 (8.3–10.3) versus €15.4 (15.1–15.8) and €14.6 (14.1–14.9) for BiV ($p < .005$).
Conclusions: The true cost of ICD treatment is strictly dependent on device longevity, whereas device up-front cost is unreliable. This aspect should be valued in the technology purchasing process, and could set the basis for an outcome-based reimbursement system. Our observations may be the benchmark respectively for ICD longevity and daily ICD cost in future comparisons. Independent observations in the real-life scenario are needed to properly value newer technologic improvements.

Keywords: ICD longevity, ICD cost, ICD replacement

Implantable cardioverter-defibrillators (ICD) are a milestone in the prevention of sudden cardiac death in selected patients deemed at high risk for ventricular tachycardia/fibrillation (2;6;17;18;23). Only recently, comparative studies of device longevity among different manufacturers have demonstrated that enhanced battery technology significantly improve device longevity (3;15;22). This improvement is highly

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relevant for clinical practice, as it may enable: (i) stable and reliable capacitor charge time throughout the entire device service of life; (ii) less frequent capacitor reforming and routine device check; (iii) prolonged device longevity, meaning a decreased risk of replacement-related complications (3;10;13;14;15;22); (iv) matching of the patients' expected survival (decreased ICD replacements) (11). Overall, improved patients' comfort as well as economic benefits for the health systems are to be expected from these technologic enhancements. However, misleading perceptions of technologic improvements tend to highlight the up-front cost of devices instead of the value for the patients (7). Device longevity is mostly prized by the patients (24), yet it is largely unmet (3;10;11;15;22). Indeed, as far as a true clinical improvement is achieved, significant savings may be expected by newer technologies. We undertook the evaluation of ICD performance and of daily ICD cost in those patients from our former observation (3) to assess whether the manufacturers' predictions are reliable, and whether the up-front or the daily ICD cost is a useful economic indicator for the health systems. Owing to the long-term follow-up until device replacement, this is the first study in literature to report actual ICD longevity based on the real clinical data instead of projections or modeling, as in cost-effectiveness analysis.

METHODS

The economic evaluation reported in this study refers to the population described in our former observation (3). The follow-up was extended until all the surviving patients had their device replaced. All ICDs were replaced 30 to 60 days after the Elective Replacement Voltage had been reached, that is nearly at the end of service of life. No replacement occurred because of mid-life charge time prolongation.

ICD Longevity Computation

Briefly, we followed all the patients consecutively implanted with an ICD from January 1, 2000 to December 31, 2002 up to December 31, 2009. Single Chamber (SC), Dual Chamber (DC), and ICDs for cardiac resynchronization therapy (CRT-D) by Medtronic (MDT), Guidant Boston (GDT), and St. Jude Medical (SJM) were used in this study. Patients who underwent heart transplantation or died before battery replacement were excluded from the analysis of device longevity. Longevity was calculated up to the day of ICD replacement; multivariable comparison was carried out as previously reported (3). Device programming was standardized so that it played level among manufacturers, and designed to maximize longevity, as reported (3).

In the event the ICD activity (delivered shocks and pacing) was similar to the manufacturer's specifications, the actual ICD longevity was compared with that predicted by manufacturers to assess whether the device had met the expectations or not.

Economic Computations

In our center, the price of devices and leads is negotiated every 12 months, so the cost of implanted units and leads was not constant throughout the study period. We reported the ICD up-front cost of each unit implanted as comprehensive of device + lead/s + implantation tools. The daily cost of the ICD was then calculated based on the longevity of each unit.

Statistical Analysis

Continuous variables were expressed as mean and standard deviation or median and interquartile range (25th–75th percentile) when not normally distributed, while categorical data were expressed as absolute and relative frequency. Comparisons between groups were made by Kruskal-Wallis test.

All statistical tests were two-sided, and a p value $< .05$ was considered significant. A statistical software program SPSS 15.0 (SPSS Inc, Chicago, IL) was used for statistical analysis.

RESULTS

In the indicated period, 153 patients aged 64 $\pm$ 12 years received an ICD; their median follow-up was 7.7 years (range, 5.2–8.5 years); 107/153 (70 percent) patients were still alive after a median 8.3 years (range, 7.5–9.4 years). Patients' clinical characteristics (mean LVEF = 39 $\pm$ 16 percent, no coronary artery disease in 48 percent) may explain the median survival, and have been previously reported together with device features (3). In the 2 years elapsed since December 2007 up to December 31, 2009, 123/124 devices were replaced (a patient died before ICD replacement).

ICD Longevity

Overall, 123/153 (80 percent) patients from our initial cohort had their device replaced, enabling a meaningful comparison among manufacturers. It is confirmed that MDT ICDs had a significantly greater longevity (Table 1). In 111/123 patients, ICD activity was comparable to the specifications used to calculate predicted longevity as reported by manufacturers: 65/111 (58 percent) devices had a longevity at least 1 year shorter than predicted (Table 1). Only MINI III and Mini IV SC ICDs and Prizm AVT DC ICDs did not meet projections among GDT devices, whereas SJM uniformly failed to meet predicted longevity, Photon DR having the poorest longevity (3).

Among the 123 patients who had reached device replacement, 16 (7.6 percent) died within December 2009: 8 had a SC device, whereas 8 had a DC device. Among the eight patients who had undergone a SC device replacement, four died before the seventh year after the first device implantation, and four between the seventh and the eighth year. Among the eight patients who had undergone a DC device replacement, six died before the seventh year after the first device implantation, and two between the seventh and the

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Table 1. Longevity of 123 ICDs Replaced in the Follow-up Period

ICD longevity (years)	Single chamber ($n = 63$)	Double chamber ($n = 50$)	CRT-D ($n = 10$)	p
Medtronic (n = 23)	**7.4** (6.4–8.1)	**6.9** (6.4–7.2)	**6.3** (5.5–5.8)	.76[a]
Predicted[b]	*6.5–9.1*	*6.3–9*	*6.8*	
ICDs RETP	**0/10**	**0/5**	**0/4**	
Guidant (n = 43)	**4.9** (4–5.7)	**4.2** (3.8–4.6)	**3.9** (3.9–4)	.56[a]
Predicted[b]	*4.1–7.2*	*3.9–6.5*	*4.8*	
ICDs RETP	**6/18**	**14/18**	**0/2**	
St. Jude Medical (n = 57)	**4.7** (4.4–5)	**3.7** (3.1–4)	**3.7** (3.6–3.8)	.002[a]
Predicted[b]	*6.5*	*6.5*	*4.4*	
ICDs RETP	**25/28**	**20/24**	**0/2**	
P	<0.001[a]	<0.001[a]	0.19[a]	

[a]Kruskal-Wallis.
ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronization therapy; ICDs RETP, ICDs Replaced ≥ 1 year Earlier Than Predicted/total working according to manufacturers' specifications.
[b]Range is used where ICDs with different predicted longevity were used.

Table 2. Up-Front Cost of ICDs Used in the Study, According to Manufacturer and Implantation Year

Cost (€)	Single chamber ($n = 63$)	Double chamber ($n = 50$)	CRT-D ($n = 10$)	p
Medtronic (23)	12246 (10931–16006)	17918 (1661–18602)	20932 (17179–20932)	.003[a]
Guidant (43)	13428 (12865–13428)	19936 (18905–19936)	20962 (20962–20962)	<.001[a]
St. Jude Medical (57)	12353 (10957–12353)	18562 (16950–18562)	19775 (19775–19775)	<.001[a]
p	<.001[a]	.006[a]	.080[a]	
Year 2000 (35)	13428 (13428–15039)	19936 (16950–19936)	NA	<.001[a]
Year 2001 (39)	12353 (12353–12353)	18562 (18562–18562)	20932 (20932–20932)	<.001[a]
Year 2002 (49)	11467 (10957–12865)	16318 (15223–17142)	19775 (16890–20665)	<.001[a]
p	<.001[a]	.002[a]	.37[a]	

[a]Kruskal-Wallis.
NA, not available (no device implanted)

ninth year. All these sixteen replacements would have been prevented by the older 9-years lasting ICD. Only 35/107 (33 percent) of the surviving patients would have needed ICD replacement by December 31, 2009, when all the devices had been 9-years lasting.

ICD Cost

The up-front ICD cost, comprehensive of lead(s) and implanting tools, is reported in Table 2. It changed during the study owing to periodic re-negotiation, so that consistent cost reduction was observed along that time (Table 2). The up-front cost of ICDs showed marked differences in the median device cost, SC devices being cheaper than DC or CRT-D devices. The up-front cost was divided for device longevity to calculate the cost/day of treatment of replaced ICDs (Table 3): it appears that SC devices are cheaper than more technologically complex ICDs, and that significant difference exists among manufacturers owing to a superior longevity (Tables 1 and 3).

DISCUSSION

ICD Longevity

The extended follow-up (2 years) from our former report (3) enabled us to calculate the net longevity advantage among manufacturers, as 123/124 devices were replaced (one death). Other numerically consistent observations from European centers have recently reported results similar to ours (15;22); in particular MDT device longevity in the report of Schaer et al. (22) is nearly the same. Notably, longevity of GDT and SJM devices also matched other North American (11;12) and European experiences (15;22).

The main observation in our study is that in an ICD population without severe co-morbidities approximately 70 percent of patients survive up to 8 years; hence, the device longevity should match the patients', as reported by Hauser (11). On the contrary, 58 percent of devices matching the manufacturers' working specifications had a longevity shorter than predicted by at least 1 year. A 9-years ICD longevity would have saved 88/123 (71 percent) replacements that occurred in our patients before December 31,

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Table 3. Cost per Service Life of 123 ICDs up to Replacement

ICD cost/day (€)	Single chamber (n = 63)	Double chamber (n = 50)	CRT-D (n = 10)	*p*
Medtronic (n = 23)	4.8 (4.6–5.7)	6.9 (6.8–7.7)	8.5 (8.3–10.3)	.004[a]
Guidant (n = 43)	6.8 (6.2–9.2)	12.6 (11.8–13.3)	15.4 (15.1–15.8)	<.001[a]
St. Jude Medical (n = 57)	6.9 (6.2–7.6)	13.4 (10.3–16.1)	14.6 (14.1–14.9)	<.001[a]
p	<.001[a]	.001[a]	.10[a]	

[a]Kruskal Wallis.

2009. In this perspective, the true cost of device therapy is not its up-front cost, but the ultimate cost at device replacement on a daily basis: this highlights the pivotal role of device longevity.

ICD Cost

In a landmark study, Camm et al. (7) argued against the evaluation of ICD therapy cost as it is usually computed in cost-effectiveness analysis, because of several debatable assumptions that heavily hinder their applicability to the clinical scenario. The calculation of cost/life-year saved along an inconsistent follow-up compared with patients survivorship, and the mismatch of ICD longevity are among the most debatable issues (7) in cost-effectiveness studies. We followed their concept in carrying out this analysis.

Our evaluation of ICD cost has not to be viewed as a comparison of manufacturers: rather, it should be interpreted as a novel approach to value Device therapy (the ICD in this setting), and to purchase health technologies. The actual cost of a therapy is the basis to carry out cost effectiveness calculations, upon which therapeutic interventions are valued by national health systems, insurance companies, and medical associations. Most cost-effectiveness studies made the assumption of a given Device service life, usually 5 or 6 years (17–19). Indeed, most ICDs (the Device in this specific setting) hardly met a 5-year longevity in the three European observational studies published so far (3;15;22), as well as in Hauser's reports (11;12): only 26 percent of Devices were in service 5 years after implantation (12). Moreover, Schaer et al. (22) reported that 5 years after implant 10 percent of Devices failed to meet the projected service of life, meaning that cost-effectiveness studies (1;16;21) do not reflect the real-life scenario. Our data are in agreement, showing that the manufacturers' predictions were not met in 58 percent of cases by at least 1 year longevity, and meaning that the interplay between power source and housekeeping current drain led to an unpredictable outcome on longevity in some Device releases (Table 1).

New technologies enabling increased Device longevity will improve cost-effectiveness, as this latter is sensitive to variations in device longevity (1;16;21). Indeed, in the analysis reported by Sanders et al. (21) and by Al-Khatib et al. (1), extension of Device longevity from 5 to 7 years and up to 10 years yielded a substantial improvement of cost-effectiveness estimates. Moreover, this is a rough approximation, as extended longevity would also suggest lengthening the time between follow-up visits, matching of device/patient longevity with a decreased replacement rate (11), and decreasing surgical complications and lead extractions (10;13;14). All are synergic to decrease health system expenditures, as reported in literature (3;11). An increased longevity represents also a still unmet patients' need (24). In our study the Device up-front cost was of limited meaning, owing to considerable differences in service of life. Indeed, in a chronic disease model managed by a long-term therapy such as the ICD, the long-term expenditures are more relevant than the up-front cost: Ramachandra (20) has clearly pinpointed the danger of a short Device longevity for the health system expenditures in term of number of device replacements, and has claimed the need for longer-lasting devices. In fact, in our study, 8 percent of patients died within 1–3 years from device replacement. Moreover, 10/16 (63 percent) of ICD replacements in patients with an overall survival < 9 years would have been saved by a 7-year lasting ICD (median MDT longevity), and completely avoided by the old devices lasting 9 years. Such a Device longevity would have saved 67 percent of replacements along the follow-up period. Indeed, nearly 70 percent of patients survived at least 8 years in our study, reinforcing the need of 10-years lasting Devices to match patients' life expectancy, as claimed by Hauser et al. (11). Madit II patients had a survival rate as 65 percent at 5 years and 45 percent at 8 years (8), meaning that an increased Device longevity around 7–9 years (3;22) would save a huge number of replacements also in an older and sicker population compared with ours. It appears that the up-front cost, that is the indicator usually guiding the purchasing process in tenders, has neither clinical nor economic reliability in a chronic disease model where therapy needs to be delivered for many years. On the contrary, an approach based on the patients' life expectancy might save valuable resources. A new concept should lead the purchasing process of medical therapies: focusing on the value for the patient (19). Truly relevant technologic improvements capable to target the pivotal clinical needs dramatically decrease costs, and benefit the health systems. This concept is emerging as "linking the costs to the benefits" for the proper economic evaluation of health technologies (9). Such an approach could also lead to a system where reimbursement occurs based on outcome (the quality

of care delivered to the patients), not on a fee-for-service basis.

It is generally believed that device discounting through suppliers competition plays a key role to decrease therapy cost. Indeed, ICD prices have been discounted 35 percent compared with 2002; nonetheless the daily cost would be €4.4, €6.2, and €9.2, respectively, for SC, DC, and CRT-D devices, when longevity around 5 years were awaited (11;12). These costs are quite comparable to those devices in our study (Table 3) whose median longevity was 7 years, that is, reliable technology equals a 35 percent discount. Nowadays, a 7-years lasting SC device would then cost €2.9 daily. Economic saving beyond price discounting is achieved by an improved technology: as recommended by Schaer et al. (22) device technology needs to be improved for the patients' sake and for making care affordable by the health systems.

Independent observations will be strongly needed in the future to confirm that the clinical needs (24) are ultimately met by the technologic improvements, as product performance reports by the industry may prove inaccurate compared with the real clinical scenarios (22). Indeed, 58 percent of ICDs had a shorter-than-expected service of life when working as per the manufacturer's recommendations in our study (Table 1), this being a negative drawback in a chronic disease model.

CONCLUSION

ICD cost is strongly dependent on device longevity. Technologies enabling 10-years ICD longevity are long-awaited and would dramatically decrease health systems' expenditures. Device up-front cost is an unreliable indicator for the ICD purchasing process. Indeed, a patient-focused approach matching the proper technology to the patients' clinical needs would allow significant savings to the health systems. The performance of these old ICD units should be regarded as benchmark respectively of ICD longevity and daily cost for future technical developments.

Study Limitations

Our study is not a cost-effectiveness evaluation, and does not provide an evaluation of overall ICD therapy cost, as the cost of the surgical procedure at implantation and of device follow-up was not evaluated. This latter would have been unpractical, as devices exhibiting a relevant increase of capacitor charge time toward the plateau phase at the lower battery voltage before replacement needed frequent device checks, depending on battery reliability and on the physician's confidence with this stage of battery depletion. Indeed, these costs are nowadays obviated by newer batteries enabling a stable charge time throughout the entire device service of life. In the forthcoming future, remote ICD monitoring could minimize ambulatory battery check at no compromise for patient safety toward the end of service life (5), probably increasing Device cost-effectiveness and decreasing the overall expenditure from a social perspective (4;5).

Although our analysis relates to outdated devices, we believe that it represents a benchmark for longevity, because the trend toward device downsizing and increasing, although energy-demanding, diagnostic and telemonitoring capabilities may result in an unpredictable longevity compared with old releases.

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CONFLICT OF INTEREST

All authors report they have no potential conflicts of interest.

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