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Impact of extending device longevity on the long-term costs of implantable cardioverter-defibrillator therapy: a modelling study with a 15-year time horizon

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Aims To determine the long-term costs of extending device longevity in four patient populations requiring a single-chamber implantable cardioverter-defibrillator (ICD) or requiring cardiac resynchronization therapy with defibrillation (CRT-D) device over a 15-year time window.

Methods and results We considered patient populations with an accepted indication for a single-chamber ICD for prevention of sudden cardiac death in the context of preserved (Population A) or impaired (Population B) left ventricular function; or with indication for a CRT-D device in the context of heart failure in New York Heart Association class II (Population C) or III (Population D). Expected patient survival and a cost analysis, including the cost of complications, was undertaken from a hospital perspective. Extended device longevity of 5 vs. 9 years for ICDs (Populations A and B); 4 vs. 7 years for CRT-Ds (Populations C and D) were considered. Over a 15-year time horizon, total, yearly, and *per diem* savings, per patient, from extending ICD longevity to 9 years were €10 926.91, €728.46, and €1.99 for Population A, and €7661.32, €510.75, and €1.40 for Population B. Total, yearly, and *per diem* savings from extending CRT-D longevity to 7 years were €13 630.38, €908.69, and €2.49 for Population C, and €10 968.29, €731.22, and €2.00 for Population D. Avoidance of a generator replacement amounted up to 46.6–62.5% of the saving.

Conclusion Extending device longevity has an important effect on the long-term cost of device therapy, both for ICD and CRT-D. This has important implications for device choice.

Keywords Budget • Cardiac resynchronization therapy • Cost • Cost analysis • Device longevity • Economics • Implantable cardioverter-defibrillator • Primary prevention • Sudden death

Introduction

Implantable cardioverter-defibrillator (ICD) therapy is the only clinically effective treatment for the primary and secondary prevention of sudden cardiac death (SCD) due to ventricular tachycardia or fibrillation.[1–4] Cardiac resynchronization therapy with defibrillation (CRT-D) devices is effective in improving patient outcomes in the setting of severe, moderate, as well as mild heart failure.[5,6] In this light, consensus guidelines now include specific evidence-based recommendations for the implantation of ICDs or CRT-D devices for a widening spectrum of patient populations. Consequently, a rise in device implantations has been observed worldwide, notably in North America and Europe. This increasing trend has important implications for the affordability of device therapy in some healthcare systems.[7,8]

The cost of device therapy is not only attributable to the cost of the initial implantation, but also to the cost of device replacements and associated complications.[9–12] Arguably, current technology has

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What's new?

- A rise in implantable cardioverter-defibrillators (ICDs) implantations has been observed worldwide, with important implications for the affordability of device therapy.
- Since the cost of device therapy is not only attributable to the cost of the initial implantation, but also to the cost of device replacements and associated complications improved device longevity may reduce the long-term costs of ICDs, However, the economic implications of extending longevity have not been assessed.
- In this modelling study, based on a 15-year time window, we showed that extending device longevity has an important impact in reducing long-term costs of device therapy, with substantial daily savings in favour of devices with extended longevity, in the range of 29–34%, depending on the clinical scenario.

improved device longevity, but the economic implications of extending longevity have not been assessed. In this model-based cost analysis,[13] we sought to determine the cost-impact of extending device longevity in different clinical scenarios requiring treatment with ICD or CRT-D devices.

Methods

The Longevity Model

The Longevity Model is an Excel®-supported tool for calculating the costs associated with ICD and CRT-D device therapy, according to varying device longevities (ranging from 4 to 15 years since the first implant) in a 'real-world' clinical practice setting. Inputs into the model include the costs of complications related to initial implantation and replacement of devices, which permit calculation of the frequency-weighted costs of treatment. The Longevity Model assumes that, other patients' characteristics being equal, the longer the device longevity, the lower the number of device replacements that patients will face during their lifetime.

Patient populations

The Longevity Model was applied to four different, typical, patient populations:

- *Population A*: Patients with conditions with a SCD risk and preserved left ventricular (LV) systolic function (e.g. hypertrophic cardiomyopathy, Brugada syndrome, long QT syndrome);
- *Population B*: Patients with conditions with a SCD risk and impaired LV function due to ischaemic or non-ischaemic cardiomyopathy;
- *Population C*: Patients with impaired LV function, mild heart failure [New York Heart Association (NYHA) class II], and a wide QRS;
- *Population D*: Patients with impaired LV function, moderate heart failure (NYHA III), and a wide QRS.

According to guidelines, Populations A and B may satisfy primary prevention indications for single-chamber ICD therapy, while Populations C and D may satisfy prevention indications for CRT-D, provided that appropriate criteria are satisfied. The annual survival probability over a time horizon of 15 years from the initial implant was derived from published studies.[14–20] Whenever expected survival probabilities at long-term could not be retrieved from literature, they were estimated via extrapolation of available data following a computational approach[21] (see Supplementary material online, *Table S1*).

Resource consumption and associated costs

A cost analysis was undertaken from a hospital perspective. From this perspective, only healthcare resources provided by hospital quantified and costed, based on consensus of experts. Inputs included the cost of devices, procedures (first implant and replacement), follow-up (two visits per year for every year following implant, except the year of replacement, when three visits were deemed necessary), and post-implant (or replacement) management of complications, such as infections and lead malfunction/dislodgement (see Supplementary material online, *Tables S2* and *S3*). The management of infection after the first implant or replacements was split into two stages: acute and sub-acute. During the acute stage, patients were assumed to be hospitalized for 15 days in intensive care unit, whereas during the sub-acute stage the hospitalization continued in cardiology ward for 5 days. An average of 2 days was assumed for the management of lead malfunction/dislodgement after the first implant or replacement. Device costs were assessed on the basis of mean hospital prices across European countries. As far as the other healthcare resources are concerned, costs were defined by a consensus of experts, taking into account published literature.[22,23] Additional costs, including those attributable to medications and other healthcare services, were included in the daily hospital costs. The frequency of complications for the base case estimates, as well as the range for the probability of re-implant procedure after infection, was derived from published studies[11,23–25] and from experts' consensus.

All costs were expressed in Euro (€) 2012. Unlike drugs, devices are expected to exert their effect for more than 1 year after the first implant or replacement; hence, it is necessary to consider a wider span of time for cost analysis (15 years in our analysis). Therefore, as recommended by reference literature on the economic evaluation of healthcare programmes, costs were discounted using a 3% annual real social rate.[13,26]

Cost analysis

Cost analysis is a partial model of economic evaluation of healthcare programmes that compares two or more healthcare technologies solely in terms of cost, not clinical effectiveness.[13] For replacement, a straight-line depreciation approach was adopted[13] and equivalent shares of the full cost of replacement (including device, procedure, follow-up, and complications) for each year of useful life of device were calculated. Devices were assumed to be replaced 'like with like' (i.e. to be replaced with another device of the same type and with the same longevity as the previous one).

Cost analysis compared the cost of devices (overall cost in 15 years, yearly, and daily cost) as well as device longevity, from 4 to 15 years since the first implant. As in previous studies,[27–30] we assessed the impact of extending device longevity by comparing different mean longevities for specific device types: 5 vs. 9 years for ICDs (Populations A and B); 4 vs. 7 years for CRT-Ds (Populations

C and D). The model considered that during a 15-year time horizon, in the absence of any complication, ICDs with longevities of 5 and 9 years were associated with two and one replacements from the first implant (on Years 5 and 10; on Year 9, respectively). cardiac resynchronization therapy with defibrillations with longevities of 4 and 7 years were assumed to require replacements three and two times after the first implant (on Years 4, 8, and 12; on Years 7 and 14, respectively). The difference in yearly and daily cost between devices with different longevity was calculated. To account for leap year, daily costs were determined by dividing the yearly cost by 365.24.[31]

Statistical analysis

All the healthcare resource consumption, frequencies and unit costs for device, first implant and replacement procedure, complications management, as well as patients' expected survival, defined according to literature and expert consensus, were reported as base case estimates with 95% confidence intervals (95% CI) (see Supplementary material online, *Tables S2* and *S3*). In accordance with the recommendations from the international literature on the economic evaluation of healthcare programmes,[21,32] an appropriate statistical distribution was given to each variable (gamma distribution for total costs and volume of healthcare resources; normal distribution for unit costs; beta distribution for probabilities) and a coefficient of variation was applied to the base case estimate to obtain the appropriate standard error (SE) for the parameter distribution. For the probability of re-implantation after lead malfunction/dislodgement, the SE was calculated assuming a sample of 1000 patients. The percentile method was used to calculate the 95% CI for the base case estimates.[21,33] No hypothesis testing was undertaken.

Sensitivity analyses

Sensitivity analysis allows for uncertainty in economic evaluation of healthcare programmes.[13,26,32] A one-way sensitivity analysis, in which variables were changed one at a time by replacing the base case estimate with the lower and the upper limit of range or 95% CI while keeping the other ones at their baseline levels,[13,26,32] was carried out concerning: cost of devices; cost of procedures for the first implant and following replacements; cost and frequency of follow-up visits; cost of complications (incidence, resource consumption, and related unit costs, as well as probability of re-implant after lead malfunction/dislodgement).

The impact of discounting on the results of cost analysis was also tested by replacing the 3% base case social discount rate with 0 and 5%, as suggested by international literature on the economic evaluation of healthcare programmes.[13,26] Changes in the base case findings due to increasing or reducing the base case expected survival probability were also explored. The results of one-way sensitivity analyses were plotted on Tornado charts. For the purposes of illustration, the *y*- and *x*-axes of Tornado charts crossed at the base case daily saving.

Results

Base case analysis of implantable cardioverter-defibrillator

As shown in *Table 1*, the cost per day for an ICD in Population A (conditions with a SCD risk and preserved LV systolic function) was, per patient, €5.80 for a device longevity of 5 years and €3.80 for a longevity of 9 years, which correspond to a yearly cost of €2117.00

Table 1 **Base case analysis for Population A—patients with conditions with a SCD risk and preserved LV systolic function (cost in €2012)**

Cost item	5 years longevity (%)	9 years longevity (%)	Savings 9 vs. 5 years longevity (%)
First implant			
Device cost	€10 000.00 (31.5)	€10 000.00 (48.0)	–
Procedure cost	€5000.00 (15.7)	€5000.00 (24.0)	–
Complications cost	€397.00 (1.3)	€397.00 (1.9)	–
Follow-up	€636.16 (2.0)	€636.16 (3.1)	–
First replacement			
Device cost	€6893.22 (21.7)	€3712.57 (17.8)	€3126.65 (29.1)
Procedure cost	€1378.64 (4.3)	€742.51 (3.6)	€636.13 (5.8)
Complications cost	€608.14 (1.9)	€327.53 (1.6)	€280.61 (2.6)[a]
Follow-up	€22.98 (0.1)	€12.38 (0.1)	€10.60 (0.1)
Second replacement			
Device cost	€5279.62 (16.6)	–	€5279.62 (48.3)
Procedure cost	€1055.92 (3.3)	–	€1055.92 (9.7)
Complications cost	€465.78 (1.5)	–	€465.78 (4.3)[a]
Follow-up	€17.60 (0.1)	–	€17.60 (0.2)
Total cost	€31 755.06 (100.0)	€20 828.15 (100.0)	€10 926.91 (100.0)
Yearly cost	€2117.00	€1388.54	€728.46
Daily cost	€5.80	€3.80	€1.99

[a]These saving are primarily due to the lower cumulative rate of complications in favour of 9 years longevity ICD (5.23 vs. 8.71%).

and €1388.54, respectively. This amounts to a relative saving of 34% over the 15-year time horizon. The effect of any extension in device longevity compared with a standard longevity is shown in *Figure 1* (upper panel). Over a 15-year time horizon, the main cost-driver for devices with a 5-year and a 9-year longevity was attributable to the cost of the device for the first implant (31.5 and 48%, respectively). Clinical follow-up after implantation contributed least to the total cost of therapy after the initial implantation or replacement (0.1% of the total cost). Total, yearly, and *per diem* savings from extending ICD longevity to 9 years were €10 926.91, €728.46, and €1.99, respectively (*Table 1*). Avoidance of a generator replacement accounted for 62.5% of the saving.

The lower cumulative rate of complications in favour of 9 years longevity ICD (5.23 vs. 8.71%) mainly explains 6.9% of the saving.

As shown in *Table 2*, the cost per day for an ICD in Population B (patients with conditions with a SCD risk and impaired LV function due to ischaemic or non-ischaemic cardiomyopathy) was, per patient, €4.80 for a device longevity of 5 years and €3.40 for a longevity of 9 years, which correspond to a yearly cost of €1753.74 and €1242.99, respectively. This amounts to a relative saving of 29% over a 15-year time horizon. The effect of any extension in device longevity compared with a standard longevity is shown in *Figure 1* (lower panel). Over a 15-year time horizon, the main cost-driver for devices with a 5-year and a 9-year longevity was attributable to the cost of the device for the first implant (38.0 and 53.6% of the total cost, respectively). As for Population A, clinical follow-up after implantation contributed least to the total cost of therapy after the initial implantation or replacement (0.04% of the total cost). Total, yearly, and *per diem* savings from extending ICD longevity to 9 years were €7661.32, €510.75, and €1.40, respectively (*Table 2*). Avoidance of a generator replacement accounted for 51.4% of the saving.

The lower cumulative rate of complications in favour of 9 years longevity ICD (3.88 vs. 6.40%) relates to 6.8% of the saving.

Base case analysis of cardiac resynchronization therapy with defibrillation

The results of base case analysis for Population C (mild heart failure with NYHA II and wide QRS are shown in *Table 3*. The cost per day for a CRT-D device in Population C (mild heart failure with in NYHA

% Saving ICD cost Population A		Extended longevity											
		4	5	6	7	8	9	10	11	12	13	14	15
Standard longevity	4	0%	16%	27%	34%	40%	45%	48%	51%	53%	55%	56%	57%
	5	−18%	0%	13%	22%	29%	34%	39%	42%	45%	47%	48%	50%
	6	−37%	−15%	0%	10%	18%	24%	29%	33%	36%	39%	40%	42%
	7	−52%	−28%	−11%	0%	9%	16%	22%	26%	29%	32%	34%	35%
	8	−66%	−40%	−21%	−9%	0%	8%	14%	19%	23%	25%	28%	29%
	9	−81%	−52%	−32%	−19%	−9%	0%	7%	12%	16%	19%	21%	23%
	10	−93%	−63%	−42%	−28%	−17%	−7%	0%	5%	10%	13%	16%	18%
	11	– 105%	−73%	−50%	−35%	−23%	−13%	-6%	0%	4%	8%	11%	13%
	12	– 114%	−81%	−57%	−41%	−29%	−19%	−11%	-5%	0%	4%	6%	9%
	13	– 122%	−88%	−63%	−47%	−34%	−23%	−15%	-9%	-4%	0%	3%	5%
	14	– 129%	−93%	−68%	−51%	−38%	−27%	−18%	−12%	-7%	-3%	0%	2%
	15	– 135%	−98%	−72%	−55%	−41%	−30%	−21%	−15%	−10%	-6%	−2%	0%

% Saving ICD cost Population B		Extended longevity											
		4	5	6	7	8	9	10	11	12	13	14	15
Standard longevity	4	0%	14%	24%	30%	35%	39%	42%	44%	46%	47%	47%	48%
	5	−16%	0%	12%	18%	24%	29%	33%	35%	37%	38%	39%	40%
	6	−32%	−13%	0%	7%	14%	20%	24%	26%	28%	30%	31%	32%
	7	−42%	−22%	−8%	0%	7%	13%	18%	21%	23%	24%	25%	26%
	8	−53%	−32%	−16%	−8%	0%	7%	11%	14%	17%	18%	20%	21%
	9	−64%	−41%	−24%	−15%	−7%	0%	5%	8%	11%	13%	14%	15%
	10	−72%	−48%	−31%	−21%	−13%	−5%	0%	4%	6%	8%	10%	11%
	11	−79%	−54%	−36%	−26%	−17%	−9%	−4%	0%	3%	5%	6%	7%
	12	−84%	−58%	−40%	−29%	−20%	−12%	−7%	−3%	0%	2%	3%	4%
	13	−88%	−62%	−43%	−32%	−23%	−15%	−9%	−5%	−2%	0%	1%	3%
	14	113%	107%	103%	100%	97%	95%	94%	92%	92%	91%	0%	1%
	15	−92%	−66%	−46%	−36%	−26%	−18%	−12%	−8%	−5%	−3%	−1%	0%

Figure 1 Impact of extending device longevity on cost of ICD therapy in a 15-year time horizon. The yellow part highlights the relative saving in ICD cost attainable by any extension in device longevity in comparison with a previous standard longevity as a reference, for Population A, patients with conditions with a SCD risk and preserved LV systolic function (upper panel) and for Population B, patients with conditions with a SCD risk and impaired LV function due to ischaemic or non-ischaemic cardiomyopathy (lower panel), respectively.

Table 2 Base case analysis for Population B—patients with conditions with a SCD risk and impaired LV function due to ischaemic or non-ischaemic cardiomyopathy (cost in €2012)

Cost item	5 years longevity (%)	9 years longevity (%)	Savings 9 vs. 5 years longevity (%)
First implant			
Device cost	€10 000.00 (38.0)	€10 000.00 (53.6)	–
Procedure cost	€5000.00 (19.0)	€5000.00 (26.8)	–
Complications cost	€397.00 (1.5)	€397.00 (2.1)	–
Follow-up	€463.33 (1.8)	€463.33 (2.5)	–
First replacement			
Device cost	€5201.53 (19.8)	€2155.92 (11.6)	€3045.61 (39.8)
Procedure cost	€1040.31 (4.0)	€431.18 (2.3)	€609.12 (8.0)
Complications cost	€458.89 (1.7)	€190.20 (1.0)	€268.69 (3.5)[a]
Follow-up	€17.34 (0.1)	€7.19 (0.04)	€10.15 (0.1)
Second replacement			
Device cost	€2886.24 (11.0)	–	€2886.24 (37.7)
Procedure cost	€577.25 (2.2)	–	€577.25 (7.5)
Complications cost	€254.63 (1.0)	–	€254.63 (3.3)[a]
Follow-up	€9.62 (0.04)	–	€9.62 (0.1)
Total cost	€26 306.14 (100.0)	€18 644.82 (100.0)	€7661.32 (100.0)
Yearly cost	€1753.74	€1242.99	€510.75
Daily cost	€4.80	€3.40	€1.40

[a]These saving are primarily due to the lower cumulative rate of complications in favour of 9 years longevity ICD (3.88 vs. 6.40%).

Table 3 Base case analysis for Population C—patients with impaired LV function, mild heart failure (NYHA class II), and a wide QRS (cost in €2012)

Cost item	4 years longevity (%)	7 years longevity (%)	Savings 7 vs. 4 years longevity (%)
First implant			
Device cost	€14 000.00 (32.0)	€14 000.00 (46.5)	–
Procedure cost	€6000.00 (13.7)	€6000.00 (19.9)	–
Complications cost	€472.00 (1.1)	€472.00 (1.6)	–
Follow-up	€548.35 (1.3)	€548.35 (1.8)	–
First replacement			
Device cost	€8303.47 (19.0)	€6521.86 (21.6)	€1781.62 (13.1)
Procedure cost	€1660.69 (3.8)	€1304.37 (4.3)	€356.32 (2.6)
Complications cost	€732.55 (1.7)	€575.37 (1.9)	€157.18 (1.2)[a]
Follow-up	€27.68 (0.06)	€21.74 (0.07)	€5.94 (0.04)
Second replacement			
Device cost	€6021.98 (13.8)	€533.15 (1.8)	€5488.83 (40.3)
Procedure cost	€1204.40 (2.8)	€106.63 (0.4)	€1097.77 (8.1)
Complications cost	€531.27 (1.2)	€47.04 (0.2)	€484.24 (3.6)[a]
Follow-up	€20.07 (0.05)	€1.78 (0.006)	€18.30 (0.1)
Third replacement			
Device cost	€3283.01 (7.5)	–	€3283.01 (24.1)
Procedure cost	€656.60 (1.5)	–	€656.60 (4.8)
Complications cost	€289.63 (0.7)	–	€289.63 (2.1)[a]
Follow-up	€10.94 (0.03)	–	€10.94 (0.1)
Total cost	€43 762.66 (100.0)	€30 132.29 (100.0)	€13 630.38 (100.0)
Yearly cost	€2917.51	€2008.82	€908.69
Daily cost	€7.99	€5.50	€2.49

[a]These saving are primarily due to the lower cumulative rate of complications in favour of 7 years longevity CRT-D (7.80 vs. 11.15%).

class II and wide QRS) was, per patient, €7.99 for a device longevity of 4 years and €5.50 for a longevity of 7 years, which correspond to a yearly cost of €2917.51and €2008.82, respectively. This amounts to a relative saving of 31% over the 15-year time horizon. The effect of any extension in device longevity compared with a standard longevity is shown in *Figure 2* (upper panel). Over a 15-year time horizon, the main cost-driver for devices with a 4-year and a 7-year longevity was attributable to the cost of the device for the first implant (32.0 and 46.5% of the total cost, respectively). Clinical follow-up after implantation contributed least to the total cost of therapy after the initial implantation or replacement (0.03 and 0.006% of the total cost for initial implantation and replacement, respectively). Total, yearly, and *per diem* savings from extending CRT-D device longevity to 7 years were €13 630.38, €908.69, and €2.49, respectively (*Table 3*). Avoidance of a generator replacement accounted for 52.1% of the saving, whereas 6.9% of the saving is due to the lower cumulative rate of complications for 7 years longevity CRT-D (7.80 vs. 11.15%).

As shown in *Table 4*, the cost per day for a CRT-D device in Population D (moderate heart failure in NYHA III and wide QRS) was, per patient, €7.02 for a device longevity of 4 years and €5.02 for a longevity of 7 years, which correspond to a yearly cost of €2564.64 and €1833.42, respectively. This amounts to a relative saving of 29% over the 15-year time horizon. The effect of any extension in device longevity compared with a standard longevity is shown in *Figure 2* (lower panel). Over a 15-year time horizon, the main cost-driver for devices with a 4-year and a 7-year longevity is attributable to the cost of the device for the first implant (36.4 and 50.9% of the total cost, respectively). Clinical follow-up after implantation contributed least to the total cost of therapy after the initial implantation or replacement (0.02 and 0.003% of the total cost of initial implantation and replacement, respectively). Total, yearly, and *per diem* savings from extending CRT-D device longevity to 7 years were €10 968.29, €731.22, and €2.00, respectively (*Table 4*). Avoidance of a generator replacement accounted for 46.6% of the saving.

The lower cumulative rate of complications in favour of 7 years longevity CRT-D (6.15 vs. 9.11%) translates into 5.7% of the saving.

The cost per day and the cost per year as a function of device longevity for all patient populations are shown in *Figure 3*.

Sensitivity analyses

For brevity, only the results of one-way sensitivity analysis comprising the 10 parameters with the greatest impact on base case daily saving

% Saving CRT-D cost Population C		Extended longevity											
		4	5	6	7	8	9	10	11	12	13	14	15
Standard longevity	4	0%	15%	25%	31%	36%	41%	44%	47%	49%	50%	51%	52%
	5	−17%	0%	12%	19%	25%	31%	35%	38%	40%	41%	43%	44%
	6	−33%	−13%	0%	9%	16%	22%	26%	29%	32%	34%	35%	36%
	7	−45%	−24%	−9%	0%	8%	14%	19%	23%	26%	28%	29%	30%
	8	−57%	−34%	−18%	−8%	0%	7%	13%	16%	19%	22%	23%	24%
	9	−70%	−45%	−28%	−17%	−8%	0%	6%	10%	13%	15%	17%	19%
	10	−80%	−53%	−35%	−24%	−14%	−6%	0%	4%	8%	10%	12%	14%
	11	−88%	−60%	−42%	−30%	−20%	−11%	−5%	0%	3%	6%	8%	10%
	12	−95%	−66%	−47%	−34%	−24%	−15%	−8%	−4%	0%	3%	5%	6%
	13	−101%	−71%	−51%	−38%	−28%	−18%	−12%	−7%	−3%	0%	2%	4%
	14	−105%	−75%	−54%	−41%	−30%	−21%	−14%	−9%	−5%	−2%	0%	2%
	15	118%	−77%	−57%	−43%	−32%	−23%	−16%	−11%	−7%	−4%	−2%	0%

% Saving CRT–D cost Population D		Extended longevity											
		4	5	6	7	8	9	10	11	12	13	14	15
Standard longevity	4	0%	14%	23%	29%	33%	37%	40%	42%	43%	44%	45%	46%
	5	−16%	0%	10%	17%	22%	27%	30%	33%	34%	35%	36%	37%
	6	−30%	−12%	0%	7%	13%	18%	22%	25%	27%	28%	29%	29%
	7	−40%	−20%	−8%	0%	6%	12%	16%	19%	21%	22%	23%	24%
	8	−50%	−29%	−15%	−7%	0%	6%	10%	13%	15%	17%	18%	19%
	9	−59%	−37%	−23%	−14%	−6%	0%	5%	8%	10%	12%	13%	13%
	10	−67%	−43%	−28%	−19%	−12%	−5%	0%	3%	6%	7%	8%	9%
	11	−73%	−48%	−33%	−23%	−15%	−8%	−3%	0%	2%	4%	5%	6%
	12	−77%	−52%	−36%	−26%	−18%	−11%	−6%	−2%	0%	2%	3%	4%
	13	−80%	−55%	−39%	−29%	−20%	−13%	−8%	−4%	−2%	0%	1%	2%
	14	−82%	−57%	−40%	−30%	−22%	−14%	−9%	−6%	−3%	−1%	0%	1%
	15	−84%	−58%	−42%	−31%	−23%	−15%	−10%	−7%	−4%	−2%	−1%	0%

Figure 2 Impact of extending device longevity on cost of CRT-D therapy in a 15-year time horizon. The yellow part highlights the relative saving in CRT-D cost attainable by any extension in device longevity in comparison with a previous standard longevity as a reference, for Population C, patients with impaired LV function, mild heart failure (NYHA class II), and a wide QRS (upper panel) and for Population D, patients with impaired LV function, moderate heart failure (NYHA III), and a wide QRS (lower panel), respectively.

Table 4 Base case analysis for Population D—patients with impaired LV function, moderate heart failure (NYHA III), and a wide QRS (cost in €2012)

Cost item	4 years longevity (%)	7 years longevity (%)	Savings 7 vs. 4 years longevity (%)
First implant			
Device cost	€14 000.00 (36.4)	€14 000.00 (50.9)	–
Procedure cost	€6000.00 (15.6)	€6000.00 (21.8)	–
Complications cost	€472.00 (1.3)	€472.00 (1.7)	–
Follow-up	€442.72 (1.2)	€442.72 (1.6)	–
First replacement			
Device cost	€7392.11 (19.2)	€4809.74 (17.5)	€2582.38 (23.5)
Procedure cost	€1478.42 (3.8%)	€961.95 (3.5)	€516.48 (4.7)
Complications cost	€652.15 (1.7%)	€424.33 (1.5)	€227.82 (2.1)[a]
Follow-up	€24.64 (0.06)	€16.03 (0.06)	€8.61 (0.1)
Second replacement			
Device cost	€4252.03 (11.1)	€289.97 (0.8)	€3962.07 (36.1)
Procedure cost	€850.41 (2.2)	€57.99 (0.2)	€792.41 (7.2)
Complications cost	€375.12 (1.0)	€25.58 (0.1)	€349.54 (3.2)[a]
Follow-up	€14.17 (0.04)	€0.97 (0.003)	€13.21 (0.1)
Third replacement			
Device cost	€1947.87 (5.1)	–	€1947.87 (5.1)
Procedure cost	€389.57 (1.0)	–	€389.57 (1.0)
Complications cost	€171.85 (0.4)	–	€171.85 (0.4)[a]
Follow-up	€6.49 (0.02)	–	€6.49 (0.02)
Total cost	€38 469.56 (100.00)	€27 501.28 (100.00)	€10 968.29 (100.00)
Yearly cost	€2564.64	€1833.42	€731.22
Daily cost	€7.02	€5.02	€2.00

[a]These saving are primarily due to the lower cumulative rate of complications in favour of 7 years longevity CRT-D (6.15 vs. 9.11%).

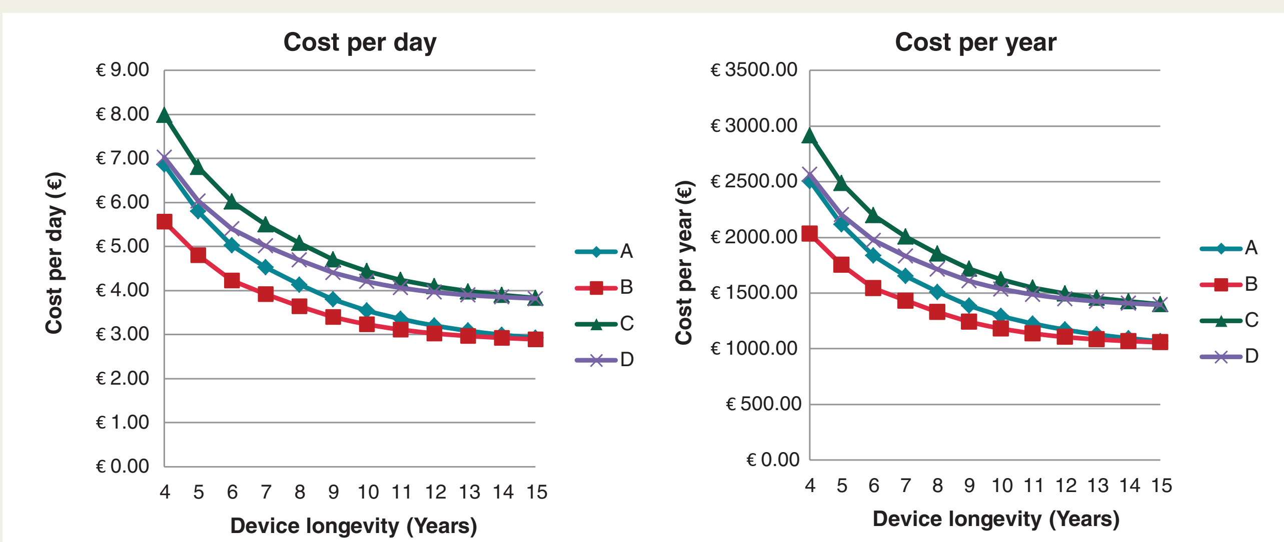

Figure 3 Cost per day (left panel) and cost per year (right panel) of ICD and CRT-D therapy according to the different patient populations.

are reported. As expected for healthcare programmes that stretch over years, base case results are particularly sensitive to variations in the real social discount rate (*Figure 4*).

Leaving costs undiscounted (i.e. replacing the 3% base case real discount rate with 0%) increased the base case daily saving for a 9-year lasting ICD by 21.11% (i.e. €2.41 vs. €1.99) in Population A and by

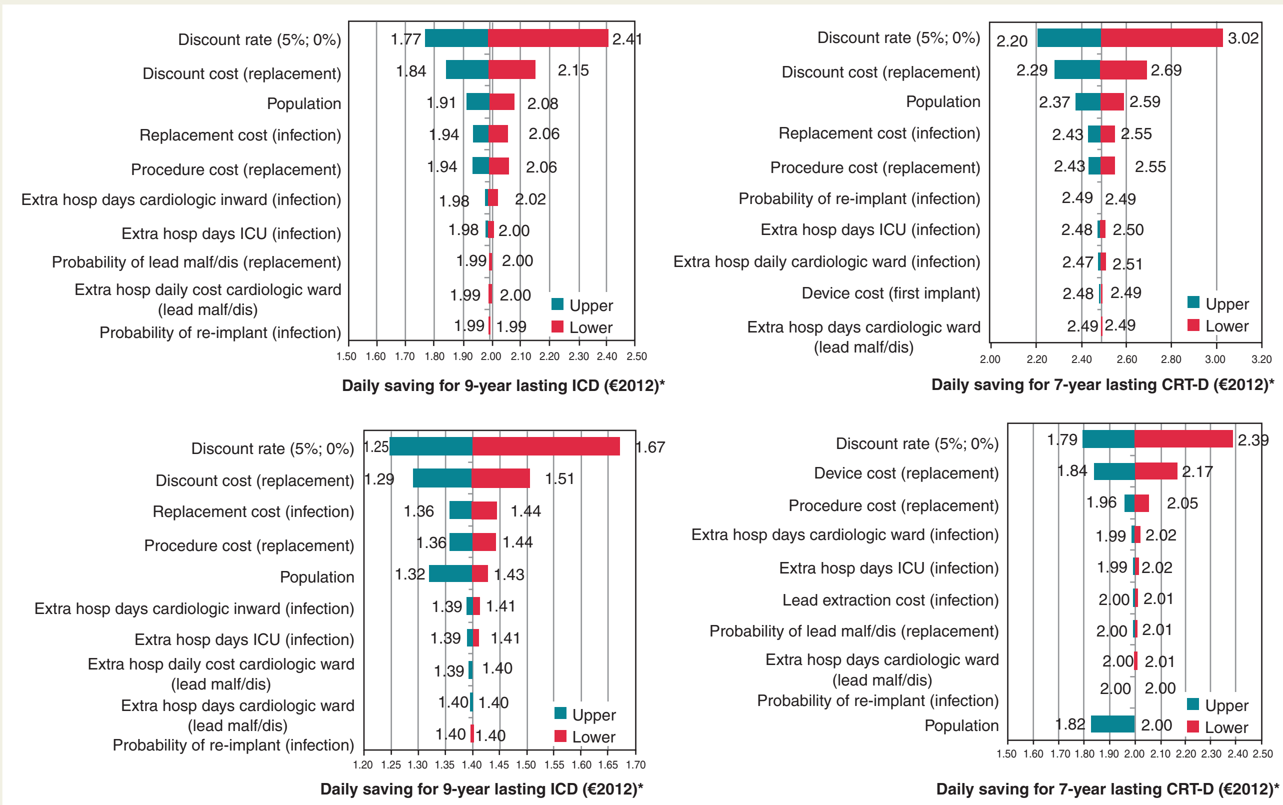

Figure 4 One-way sensitivity analysis of ICD therapy for Populations A (upper left panel) and B (lower left panel) and for CRT-D therapy for Populations C (upper right panel) and D (lower right panel). Extra hosp, extra hospitalization; malf/dis, malfunction/dislodgement.

19.29% (i.e. €1.67 vs. €1.40) in Population B (*Figure 4*, upper and lower left panels).

Similar findings emerged from analyses of CRT-Ds, in which avoiding discounting raised the base case daily saving for 7-year lasting ICD by 21.29% (i.e. €3.02 vs. €2.49) for Population C and by 19.5% (i.e. €2.39 vs. €2.00) for Population D (*Figure 4*, upper and lower right panels).

Interestingly, increasing the real social discount rate from 3 to 5% has less impact on the base case daily savings. Indeed, the base case daily saving for 9-year lasting ICD was reduced by 11.06% for Population A and by 10.71% for Population B, whereas it decreases by 11.64 and 10.5% for Populations C and D, respectively. For all populations, daily savings were slightly influenced by variations in device costs for initial implantations and replacements, whereas changing the device cost at the first implant did not lead to significant differences in cost, compared with base case estimates (data not shown). Varying expected survival probabilities ranked third in the list of the most critical assumptions that affect the base case daily savings for Populations A and C.

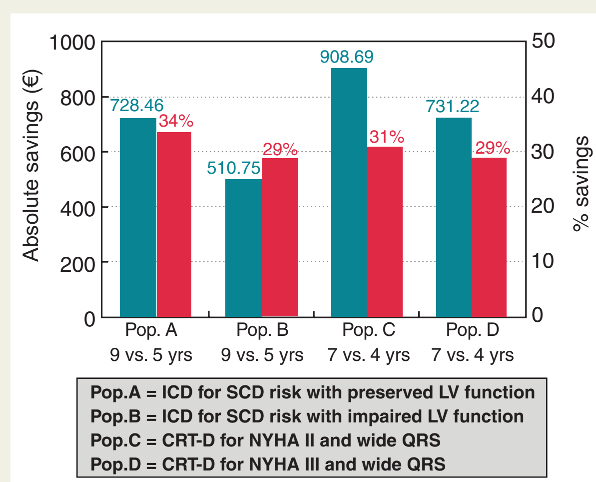

Figure 5 Yearly saving with extended longevity devices (saving in €2012).

Discussion

In this modelling study of device therapy in four different, typical patient populations, we have shown that device longevity has an important impact on the long-term costs of device therapy. Adopting a long time horizon of 15 years and the hospital perspective, extended longevity led to substantial savings, ranging from 29 to 34%, according to the population in question (*Figure 5*). The impact of extending device longevity was particularly evident in patients with preserved LV systolic function, a subset of patients with a relatively long survival in whom avoidance of device replacements is paramount. For all populations, however, a device longevity ≥8 years had profound effects on the cost of device therapy over a time horizon of 15 years.

According to literature,[27–30] the actual longevity of devices implanted in the last 10 years was in the range of 5–6 years for ICDs and 3.5–4.0 years for CRT-D devices. Our results are noteworthy since recent advances in battery, circuitry, and capacitor design have contributed to significant extensions in the longevity of ICDs and CRT-Ds[29] that are commercially available. In the future the possibility to develop externally rechargeable implantable devices for pacing and defibrillation, with a technology similar to that applied to devices for cardiac contractile modulation, might be an object of consideration, as an additional option for extending the longevity of implanted devices.

According to our modelling results, extending longevity translates into a reduction in device replacements, hospitalizations, and complications, as well as reduced costs. Admittedly, these data are derived from a model based on data from other studies,[9,27] which is no replacement to validation and confirmation in the real-world setting, where other factors, such as co-morbidities, lead failure, and device recalls add to the complexity of device therapy. It is worth to promote the institution of registries for collecting independent data on actual device longevity, thus avoiding the obvious limitation of data obtained from single institutions. Our analysis probably underestimated another source of saving, that is, the potential lengthening of follow-up visits due to longer-lasting devices.[27,34] In fact, independently from device longevity we assumed a background number of two follow-up visits *per year* after the first implant. This amount was considered to rise to three follow-up visits during the year of replacement (one more follow-up visit). Hence, the lower the number of replacements, the higher the number of follow-up visits (and related cost) saved. Certainly, a wider adoption of remote monitoring could reduce the number of annual follow-up visits; however, the one-way sensitivity analysis performed on this variable, did not show any relevant change on the findings of our study. This can be explained by the fact that reducing follow-up visits will benefit both the long-lasting devices group and the traditional one.

Compared with drugs, the up-front costs for cardiac implantable electrical devices are clearly higher.[35] We should consider, however, that device therapy is more akin to a surgical than to pharmacological therapy,[4,35] insofar as the initial outlay is, essentially, an investment for therapy over the patient's lifetime. Nevertheless, the daily cost of device therapy is lower than the cost of pharmacological treatments for conditions such as chronic myelocytic leukaemia or human immunodeficiency virus infection.[7,36]

Limitations

The ethical objection to submitting patients to an operation with no expected benefit limits the degree to which studies of device therapy can be controlled.[37] This not only applies to acute and short-term studies but also, to long-term studies. Necessarily, therefore, many of the aspects of long-term device therapy cannot be quantified empirically. In addition, we should consider that much of the data relating to long-term device therapy relates to outdated device technology and surgical procedures (e.g. abdominal implantation), which are not relevant to current practice. Moreover, most ICD and CRT-D trials are finalized before device replacement becomes necessary.[21] It is on this basis that our modelling analyses rely heavily on experts' consensus on what is considered most relevant to current practice. Despite the assumptions taken by this approach, it is likely to be superior and more credible than no guidance at all.[38,39] It is expected that the sensitivity analyses provided herein address some of the variations in the base case assumptions.

Eventually, the results of our research may benefit from updating consistently with the future trend towards devices with lower costs and longer longevity.

Conclusions

Extending device longevity has an important impact in reducing long-term costs of device therapy, with substantial daily savings in favour of devices with extended longevity, in the range of 29–34%, depending on the clinical scenario. If given ICDs and CRT-Ds are considered to be equally effective, device longevity should be a determining factor in device choice by physicians and healthcare commissioners. The marked reduction in the daily costs of device therapy provided by extended device longevity may help overturn the misconception that up-front cost is the only metric with which to value these treatments.

Supplementary material

Supplementary material is available at *Europace* online.

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