Europace (2015) **17**, 1166–1168
doi:10.1093/europace/euv225

EDITORIAL

Longevity of biventricular defibrillators: not all devices are created equal

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This editorial refers to 'Longevity of implantable cardioverter-defibrillators for cardiac resynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer' by M. Landolina *et al.*, on page 1251–1258.

The biomedical industry has been facing a technological challenge for developing cardiac resynchronization therapy-defibrillators (CRT-Ds) because of the multiple requirements involving power supply and consumption. The batteries need to provide low-voltage output for frequent pacing, while being able to rapidly charge capacitors to deliver high-power shocks. The cells need to be efficient and have a high energy density in order to minimize the total volume of the generator, which are amongst the bulkiest of all cardiac implantable electronic devices (CIEDs). Discharge profiles need to be consistent in order to predict elective replacement and end-of-life. Demands on power consumption have been increasing as the complexity of device functions has been evolving, now including a number of diagnostic and telemetric functions. Production costs need to be contained, without compromising the quality and reliability of this life-saving therapy.

As indications for CRT-D have broadened to include patients with mild heart failure,[1] life expectancy of this population has outgrown that of the devices they are implanted with. In the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) trial, which included patients with NYHA I-II heart failure, 7-year survival in patients with left bundle branch block randomized to the CRT-D group was 82%.[2] If one assumes that CRT-D device longevity is 5 years, 88% of this patient population would have to undergo a generator replacement. This procedure is associated with major complications in 6% of the patients, which is greater than that observed with single- and dual-chamber devices.[3] Costs are evidently affected by device longevity. Boriani *et al.*[4] calculated that extending CRT-D longevity from 4 to 7 years would result in a total cost saving of €10 968–€13 630 per patient. Last but not least, the vast majority of patients (90% overall) prefer a larger device with greater longevity over a smaller and less noticeable one in order to avoid generator replacements.[5] This preference was consistent over the entire spectrum of patients of different ages, gender, and body habitus.

A list of potential factors that may affect device longevity is outlined in *Table 1*. Important factors are battery capacity and discharge characteristics. All modern CIED batteries are composed of a lithium anode with different cathode chemistries. The first implantable cardioverter-defibrillator (ICD) batteries were composed of lithium–vanadium pentoxide, and were later replaced by the more reliable lithium–silver vanadium oxide (Li/SVO) battery developed by Greatbatch Inc. (Clarence, NY, USA) which enabled the growth of this technology. Hybrid batteries combining Li/SVO and carbon monofluoride (CFx), either blended together in a single mixture or as a laminated structure (the SVO and CFx cathodes being separated by screens), have replaced the Li/SVO batteries for CRT-Ds due to greater longevity. Another battery chemistry that is also currently in use is lithium manganese dioxide (Li/MnO_2), which has a high energy density and excellent storage and discharge characteristics. These batteries are produced in-house by the device companies (Biotronik and Boston Scientific), contrary to the Li/SVO and Li/SVO–CFx (also known as QHR) batteries that are supplied by Greatbatch Inc. An excellent review on CIED battery technology has recently been published by Mond and Freitag[6] for those readers who wish to dig deeper into this topic.

In this issue of *Europace*, Landolina *et al.*[7] report CRT-D longevity in 1726 consecutive patients (the largest series reported to date) implanted between January 2008 and March 2010 in nine Italian centres. The report includes devices from the five major companies released onto the market from 2003 to 2010 and followed-up over a median of 43 months. Five years after implantation, almost half (46%) of the devices needed to be replaced due to battery depletion. Factors found to independently affect device longevity were:

- *A high (>2.5 V/0.5 ms) left ventricular (LV) lead pacing output* which adversely affected longevity (HR: 1.96; 95% CI: 1.57–2.46; $P < 0.001$). A trend in reduced longevity was found for a high right ventricular (RV) output, which did not reach statistical significance due to the small numbers involved (<5% of patients with a high output compared with 24% of patients for the LV lead). A high atrial output did not affect longevity,

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Table 1 Factors affecting ICD/CRT-D longevity

Battery characteristics (size, chemistry, energy density, self-discharge, etc.)
Numbers of shocks
Frequency of battery reforming
Consumption of electrical circuitry ('housekeeping current')
Numbers of pacing leads (and multipoint pacing)
Percentage of pacing
Lead impedance
Pacing output (amplitude and duration)
Device algorithms and memory storage
Physiological sensors
Remote monitoring

because atrial pacing is usually infrequent in these patients and will therefore have a minor impact.

- *A unipolar LV lead*, corresponding to an extended bipolar (LV tip to RV coil) or unipolar pacing configuration (HR: 1.58, 95% CI: 1.25–2.01; $P < 0.001$). Unipolar pacing (LV to can) is currently only possible with Boston Scientific CRT-Ds. This finding can be explained by lower impedances with these configurations compared with true bipolar pacing, thus adversely affecting current drain (remember Ohm's law: $I = V/R$).
- *Battery chemistry* with greater longevity of Li/SVO–CFx (HR: 0.28, 95% CI: 0.16–0.50, $P < 0.001$) or Li/MgO_2 (HR: 0.37, 95% CI: 0.22–0.64, $P < 0.001$) compared with Li/SVO.
- *Recent generation devices,* i.e. *released after 2007* (HR: 0.57, 95% CI: 0.45–0.72; $P < 0.001$). This finding was consistent across the different manufacturers (the numbers were however too small for analysing Biotronik devices). The differences reflect not only changes in battery chemistry (e.g. adoption of Li/MgO_2 batteries by Boston Scientific) but also a change in battery models using the same chemistry (e.g. St Jude Medical), and the advent of threshold algorithms that automatically adjust LV output, allowing lower safety margins (Medtronic and St Jude Medical).
- *Device manufacturer*, with Boston Scientific CRT-Ds displaying greatest longevity (HR: 0.64; 95% CI: 0.47–0.89; $P = 0.008$). This finding was essentially due to a change in the battery chemistry, as none of the devices from this manufacturer had automatic LV output algorithms at the time of the study. The considerable extension in longevity of the recent generation Boston Scientific CRT-Ds has prompted the manufacturer to extend the 100% replacement warranty on their latest devices from 3 to 4 years, which is the longest currently available.

A factor that did *not* affect longevity was delivery of shocks. This may seem surprising but was probably due to the fact that very few patients received frequent shocks (only 3% of the cohort received >10 shocks over the entire follow-up). Another consideration is that the delivery of a shock will reset the timer for the next capacitor reforming (which equates to a full capacitor charge and is performed nominally every 3–6 months), thereby limiting the total number of capacitor charges. For most manufacturers, resetting of the capacitor charge timer only occurs if shocks are programmed to full (or close to full) energy. This is one of the reasons to avoid programming lower energy shocks (e.g. 15J), especially as pain to the patient will be the same (another reason being a lower probability of atrial cardioversion in case of inappropriate shock due to rapidly conducted atrial fibrillation).

It is surprising that none of the patients in this large multicentre cohort were placed on remote device management. In the ECOST (Effectiveness and Cost of ICDs Follow-up Schedule with Telecardiology) trial, patients implanted with a single- or dual-chamber ICD who were randomized to the remote monitoring group had significantly fewer inappropriate shocks, resulting in prolonged device longevity.[8] Remote monitoring may also allow the physician to more confidently extend generator replacement until the elective replacement indicator is reached, triggering transmission of an alert message (the audible alerts being often unreliable[9]). On the other hand, depending upon the device manufacturer, frequent transmissions may cause an excessive current drain on the battery that may have an adverse effect on longevity.

The findings published in this issue confirm a recent report by Alam *et al.*[10] in 646 patients implanted with a CRT-D during a similar period. Longevity was also significantly affected by LV pacing output and by the device manufacturer. The 4-year device survival rate was 94% for Boston Scientific, 92% for St Jude Medical, and 67% for Medtronic ($P < 0.001$). The results for CRT-D devices are in contrast to those reported for single- and dual-chamber ICDs, where Medtronic devices outlived those of the other manufacturers.[11–13] This finding illustrates the complexity resulting from the specific requirements of CRT-Ds. The current generation of Medtronic CRT-Ds has evolved considerably from a technological standpoint, which is likely to have a favourable effect on device longevity. The Li/SVO battery has been replaced by a Li/SVO–CFx model. The new wet Tantalum capacitors (now also used by other manufacturers) do not require reforming anymore (which drains almost 1 month of device life with each charge). Quadripolar LV leads allow more options to lower capture thresholds, with 95% of patients having thresholds ≤2.5 V without phrenic nerve capture, and average thresholds of the programmed vector being 1.1 ± 0.8 V.[14] An algorithm has been introduced which automatically measures thresholds and impedances of each of the 16 vectors. The device then calculates the estimated gain in longevity with each vector, thereby allowing programming to optimize battery consumption. Finally, an algorithm designed to promote fusion pacing (between intrinsic AV conduction and left univentricular capture) to improve haemodynamics, means that the percentage of RV pacing will be reduced, thereby reducing current drain. Future reports will be of interest to determine the impact of these changes on CRT-D longevity of Medtronic devices.

In addition to the favourable effect on patient outcome and healthcare costs, improved longevity is also an important factor which is taken into account by physicians and hospital purchasing departments for choosing devices. This has a positive impact on market share of manufacturers proposing durable devices. However, the commercial return may be mitigated in the long run by a reduction in the turnover of generator replacements, which, combined with the global pressure on prices, is likely to result in reduced income for the companies. The CIED industry has, however, proved itself in the past to react remarkably well when faced with challenges. Natural market selection and survival of the fittest device will lead to evolution of therapy that will ultimately benefit our patients.

Acknowledgements

The author wishes to thank Mr Christian Auer (Biotronik), Mrs Yvonne Bouix (Boston Scientific), Mr Gianni Rossetti (Medtronic), Mr Florian Schueffelgen (Sorin), and Mr Germain Witkowski (St Jude Medical), for having replied to technical queries.

Conflict of interest: H.B. has received speaker honoraria and fellowship support from Biotronik, Boston Scientific, Medtronic, Sorin, and St Jude Medical.

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