EDITORIAL COMMENTARY

The reality of implantable cardioverter-defibrillator longevity: What can be done to improve cost-effectiveness?

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Multiple clinical trials have demonstrated the mortality benefit of implantable cardioverter-defibrillator (ICD) therapy for the primary prevention of sudden cardiac death, expanding the indications for device therapy. However, ICDs are expensive and patient longevity often exceeds pulse generator longevity, so many patients will require replacement of pulse generators, which is associated with additional costs. Generator replacement also carries a substantial risk for complications even when performed electively.1–3 While the overall risk of initial implantation complications is 3.2% in the National Cardiovascular Data Registry ICD Registry,4 the risk of major complications for generator replacements is 4.1%–5.8%, with complications including death.1,3 Risks are even higher for patients undergoing system upgrade,2 and risks of pocket-related adverse events requiring surgical intervention increase with every consecutive replacement.5 Therefore, it is beneficial to reduce the need for upgrade or replacement of pulse generators.

In the current issue of HeartRhythm, Thijssen et al6 assess the longevity of 4673 ICDs implanted since 1996, identifying that 72% were replaced because of battery depletion. Overall, the mean device longevity was only 5.0 ± 0.1 years and slightly longer at 5.5 ± 0.1 years for devices replaced because of battery depletion.

What factors impact on device longevity?

Device longevity depends on a variety of factors including device type (single, dual, or cardiac resynchronization therapy [CRT]), manufacturer, generation, as well as the pacing rate, mode, percentage, and output. The current analysis shows that devices implanted after 2002 had a significantly better battery longevity compared with those implanted before 2002.5 Variability in ICD battery longevity was seen between manufacturers in the current study, as well as in previous studies.5–8 In general, devices manufactured by Medtronic appeared to have the longest longevity, followed by Guidant, with the shortest longevity in St Jude and Biotronik devices. The number of shocks did not appear to impact on device longevity.6,8

Single-chamber devices have a longer average longevity than do dual-chamber devices.9 Although the current analysis by Thijssen et al demonstrated an overall greater mean battery longevity of dual-chamber ICDs compared with that of single-chamber ICDs, the difference can be explained by the fact that devices were unequally distributed over time, with more single-chamber systems implanted in earlier years. Multivariable analysis demonstrated that this effect was reversed and single-chamber devices did have longer longevity.6 Despite the greater longevity for single-chamber devices, the National Cardiovascular Data Registry ICD Registry demonstrates that only 21% of ICDs implanted in the United States are single chamber.4 This is similar to findings reported in the 11th World Survey of Cardiac Pacing and Implantable Cardioverter Defibrillators for 2009, although the distribution of device type (single, dual, or cardiac resynchronization therapy) varies dramatically across the world.10 CRT, by definition, consumes more energy than does single- or dual-chamber demand pacing, and these devices have shorter longevity.6

In addition, device longevity depends on programmed settings and the use of some contemporary features such as enhanced electrogram storage, which may increase battery drainage. Devices are frequently implanted with out-of-the-box settings, and the manufacturer’s choice of programmed settings may influence battery longevity at onset, as adjustments may not be made at implantation or follow-up.

Although device longevity depends on many factors, it fundamentally relies on battery technology. This technology has improved over the years, but further improvements are needed to keep up with energy-consuming clinical applications of modern devices. Manufacturers might also consider the development of a renewable energy source, such as a rechargeable battery that can last the lifetime of most patients.9

In addition to device replacement for battery depletion, 28% of devices are replaced for other nonbattery reasons, such as device upgrade, infection, advisory or recall, system malfunction, or heart transplantation.6 Every effort should be made to minimize potentially avoidable reoperations, including appropriate device selection at the time of initial implantation, as well as techniques to reduce risks of infection.

Is ICD therapy cost-effective?

Previous cost analyses demonstrate a reasonable cost-effectiveness for ICD therapy, which compares favorably to other cardiac interventions.11–13 However, cost-effectiveness calculations are based on a projected ICD life span that is longer than the actual life span. Hauser9 reported the growing mismatch between patient longevity and device longevity in that the average ICD patient

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lives nearly 10 years after the implant procedure. A cost analysis was performed using an estimated device life span of 7 years in a Multicenter Automatic Defibrillator Implantation Trial II population, which is longer than the actual mean device life span of 4.0–5.0 years demonstrated in clinical practice.\textsuperscript{6,7} In addition, cost analysis for ICDs in primary prevention trials assumed that single-chamber devices were utilized in terms of both costs and complications,\textsuperscript{12,13} which is not the case in clinical practice.

What can be done to improve device longevity and the cost-benefit ratio?

1. Implanting physicians should do their best to make the correct initial device selection (single, dual, or cardiac resynchronization therapy), minimizing early reoperation for upgrades. For patients who are not candidates for CRT, careful selection of single vs dual devices is important to reduce upfront risk as well as cost. Despite the prevalence of dual-chamber ICDs in the United States, clinical trials demonstrating the benefit of ICDs for primary prevention of sudden death utilized single-chamber devices. Although there may be benefits of dual-chamber devices on outcome measures other than mortality, such as reduction of inappropriate shock therapy, this benefit was not clearly demonstrated in a recent meta-analysis and additional prospective trials are needed.\textsuperscript{14}

2. Physicians should pay particular attention to device programming to minimize unnecessary right ventricular or atrial pacing, and battery saving algorithms should be used for pacing. In addition, the use of other diagnostic features that may impact on battery drainage should be assessed.

3. Manufacturers should carefully consider out-of-the-box settings with respect to pacing outputs and other programmed features, as many devices will be left programmed at the original out-of-the-box parameters.

4. Although there has been a focus to reduce device size, it may occur at the expense of battery longevity. Manufacturers should reconsider the availability of longer lived batteries, with additional research efforts to further improve battery longevity. It should be noted that a survey revealed that the majority of patients would prefer a larger device with longer device longevity over a smaller device that is less noticeable but requires more frequent surgery.\textsuperscript{15}

At the present time, incentives are misaligned and there is little incentive for ICD manufacturers, physicians, and health-care systems to provide longer lived pulse generators, since reimbursements increase with replacement generators. Perhaps alternative incentives could be considered for device manufacturers and health-care systems to encourage the development and selection of devices with greater longevity. Health-care systems could also be evaluated for performance related to early replacements or upgrades, optimizing device selection upfront and reducing replacement devices for nonbattery reasons to <20%.

Conclusions

As patients frequently outpatient their ICDs and generator replacements are costly with associated procedural risks, the mismatch between patient longevity and the service life of ICDs needs to be addressed. In short, manufacturers, physicians, and health-care professionals should place increased awareness on device longevity issues. Manufacturers should work on further improvements in battery technology, and health-care providers should focus on optimal device selection and programming to enhance longevity.

Despite reports of potential “overusage” of ICDs in the media, clinical data from an outpatient prospective cohort study–Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE-HF) demonstrates “underusage.” Based on current guideline criteria, only 51% of patients who met eligibility criteria actually received ICDs with an unexplained variation across practices as well as disparities related to ICD usage.\textsuperscript{16} The goal should be to reduce gaps related to ICD therapy, although health-care resources are limited. In addition to better risk stratification, savings gained by appropriate device selection and increased device longevity may increase resources that can be used to provide this lifesaving therapy to more patients who are most likely to benefit.

References