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Heart Rhythm Disorders: Viewpoint

The Growing Mismatch Between Patient Longevity and the Service Life of Implantable Cardioverter-Defibrillators

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Implantable cardioverter-defibrillators (ICDs) are lifesaving devices. Over 100,000 patients received ICDs in 2004 at a cost of $2 billion for the pulse generators alone. Because of expanded indications and coverage by Medicare, the number of ICD implantations and replacements is expected to increase dramatically during the next decade. The average ICD patient at our institution now lives nearly 10 years after the procedure. However, the service life of pulse generators has decreased from 4.7 ± 1 year for single-chamber units to 4.0 ± 1 year for dual-chamber devices. This mismatch between patient longevity and the service life of ICDs poses a significant clinical and economic burden that must be addressed. One near-term solution is for manufacturers to provide devices with larger batteries so that most patients can have an ICD pulse generator that lasts a lifetime. For the long-term, more robust or renewable energy sources are needed. (J Am Coll Cardiol 2005;45:2022–5) © 2005 by the American College of Cardiology Foundation

Over 100,000 patients received implantable cardioverter-defibrillators (ICDs) in 2004. At an estimated average selling price of $20,000, the ICD pulse generators alone cost $2 *billion*. The majority of these implants were dual-chamber models, and a substantial number were devices that are capable of cardiac resynchronization therapy (CRT). Based on data from the Multicenter Registry (1,2) and an analysis of our institution's ICD patient population, it is likely that 70% of pulse generators implanted in 2004 will require replacement because of battery depletion over the next five years. This means that approximately $1.4 billion will be spent to purchase replacement pulse generators for patients who underwent implantation last year. *These initial and replacement pulse generator costs are exclusive of hospital charges, provider fees, and expenses associated with leads, follow-up care, and surgical complications.*

The cost of ICD therapy is balanced by the clinical benefits. Multiple clinical trials have shown that ICD therapy prevents sudden cardiac death in susceptible populations (3–7), and current evidence suggests that the addition of CRT is clinically important for selected patients (8–10). Although improved risk stratification may decrease the number of ICD implants, the medical community, payers, and industry must collaborate to reduce ICD costs. The most feasible near-term solution is for industry to provide pulse generators with larger, longer-life batteries. Future ICD pulse generators should have robust energy sources that can be renewed, e.g., be rechargeable without costly surgery.

ICD PATIENT LONGEVITY

The cumulative survival of 1,280 patients who have received ICDs since 1987 at the Minneapolis Heart Institute is shown in Figure 1. The probability of a patient living 4, 5, and 6 years after ICD implantation is 79 ± 1%, 75 ± 1%, and 68 ± 2%. Over 40% of patients were still living at 10 years. The average ejection fraction was 34 ± 15%, and these patients had ischemic heart disease (73%), nonischemic cardiomyopathy (13%), hypertrophic cardiomyopathy (5%), and other cardiac conditions. These data suggest that the majority of ICD patients would not require a replacement procedure for battery depletion if the service life of ICD models was at least 10 years.

ICD PULSE GENERATOR SERVICE LIFE

The Multicenter Registry has gathered ICD pulse generator failure data since 1999. To date, of 1,107 ICD pulse generator failures, 90% were caused by normal battery depletion and 10% were caused by electronic or housing defects. The majority of pulse generators were manufactured by Guidant Inc. (St. Paul, Minnesota) (49%), Medtronic Inc. (Minneapolis, Minnesota) (31%), and St. Jude Medical Inc. (St. Paul, Minnesota) (19%). The average service life of these pulse generators was 4.3 ± 1.5 years (range <1 day to 8.9 years). Only 5% of pulse generators functioned for seven years. After excluding non-battery failures caused by electronic or housing defects, the average service life of 814 single-chamber pulse generators was 4.7 ± 1 year compared with 4.0 ± 1 year for 293 dual-chamber pulse generators

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Abbreviations and Acronyms

CRT = cardiac resynchronization therapy
ICD = implantable cardioverter-defibrillator
QALY = quality-adjusted life year

($p < 0.0001$). Thus, the service life of contemporary ICD models is far less than the expected patient longevity, and the shift to dual-chamber models has significantly shortened battery life. The growing proportion of dual-chamber implants may be inappropriate because patients who do not require bradycardia pacing support may be adversely affected by right ventricular stimulation (11).

COST EFFECTIVENESS

In the U.S., the generally accepted benchmark for economically attractive cost-effective care is $50,000 per life year. The cost effectiveness of ICDs depends, in part, on the population being studied and the frequency and cost of pulse generator replacement. A recent study by the Blue Cross Blue Shield Association (12) evaluated the cost effectiveness of ICDs in the Multicenter Automatic Defibrillator Implantation Trial (MADIT)-II population. The base case assumed a *7-year pulse generator lifespan* and a 67% reduction in sudden cardiac death. Given these assumptions, the investigators estimated that the cost effectiveness of ICDs was $51,000 per quality-adjusted life year (QALY). Sensitivity analyses showed that cost effectiveness was $44,300 per QALY if the pulse generator was replaced every 11 years but decreased to $58,100 per QALY if the pulse generator was replaced every 5 years. Based on the average longevity of devices in the Multicenter Registry's database, the base-case assumption overestimated the cost effectiveness of ICDs. Nevertheless, this study showed how important pulse generator longevity is to the cost-effective application of ICD therapy.

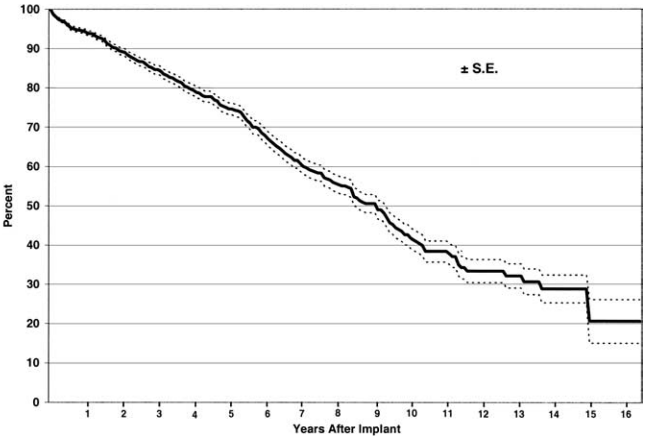

Figure 1. Survival of patients after implantable cardioverter-defibrillator implantation. SE = standard error of the mean.

EFFECT OF BATTERY CAPACITY ON SERVICE LIFE

The ICD pulse generators use proprietary lithium silver vanadium oxide batteries that are capable of delivering ampere-level current. One manufacturer (Guidant Inc.) has offered four ICD models with a choice of battery capacities, i.e., a standard battery (0.92 to 1.06 AmpHr) or a large battery (1.44 to 1.75 AmpHr). This allowed a multicenter comparison of the effect of different battery capacities on pulse generator service life (13). The results are shown in Figure 2. Large-capacity batteries increased average service life by 2.3 years. The number of therapeutic shocks did not seem to affect battery longevity in either group. Large-capacity batteries increased pulse generator size and weight by 5 cc and 11 g. The added battery longevity reduced *annual* pulse generator costs by $1,000 to $1,600 *per patient*. These data suggest that larger batteries can reduce costs by significantly prolonging the service life of ICDs with only a small increase in pulse generator size.

Physicians tend to believe that patients would resist any increase in pulse generator size. However, a recent study by Wild et al. (14) found that 90% of patients thought that ICD and pacemaker longevity was more important than size. The vast majority of patients preferred a larger device that could reduce the number of potential replacement procedures. This preference was consistent across the spectrum of patients with a previous implant, those undergoing initial implantations, those returning for routine follow-up, and patients of various ages, gender, and body habitus. However, large pulse generators may increase the risk of pocket complications, including erosion and discomfort, and some patients may not be suitable candidates for such models.

Physicians are also concerned that a long-lived pulse generator may become technologically obsolete as newer models are introduced. Consequently, it is argued that patients may be denied the benefits of new features or functions. Such reservations, however, are not supported by clinical studies that quantify the risks and benefits of regular pulse generator replacement. Moreover, pulse generator replacement is associated with known complications, including infection and the potential for lead damage. More than one-half of all pacemaker and ICD infections occur after replacement procedures (15). An ICD infection often requires complex lead extraction that is associated with significant morbidity and mortality (16). Thus, pulse generator replacement is not desirable except in patients whose clinical circumstances warrant the risks and costs of upgrading to a new model.

The growing economic burden of ICD therapy is likely to accelerate as more ICD implants include CRT. These devices are more expensive and use more energy than standard ICDs. Over the past 5 years, the Minneapolis Heart Institute's annual new and replacement ICD implantations have more than doubled from 148 in 2000 to 326 in 2004 (Fig. 3). In addition, the proportion of ICDs with

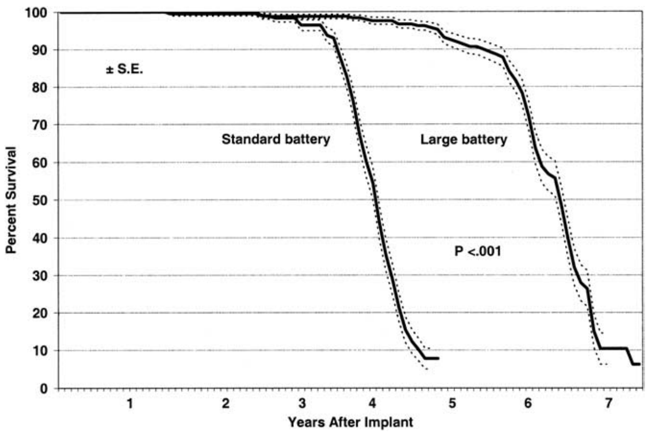

Figure 2. Longevity of standard and large-battery-capacity implantable cardioverter-defibrillator pulse generators. Non-battery failures were censored. SE = standard error of the mean.

CRT capability (ICD-CRT) has increased from nil in 2000 to 44% in 2004. During this same period, our hospital's total ICD device supply costs increased from $2.6 to $7.0 million, and ICD-CRT models accounted for 55% of ICD device costs in 2004 (Fig. 4). The growth and shift to ICD-CRT models were driven by the results of clinical trials rather than changes in our practice or patient population. With the recent publication of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) (7), we expect a substantial increase in the number of ICD-eligible patients, and device costs will grow accordingly.

Unfortunately, as of this writing, only one manufacturer provides a large-battery-capacity ICD, and this option is available for one dual-chamber model. Thus, we do not have the choice of implanting large-battery-capacity single-chamber or CRT ICDs because they are not available. The ICD manufacturers have no incentive to provide long-lived pulse generators. Indeed, the opposite is true, namely frequent replacements increase sales and profits. Although rechargeable batteries exist, they are not being used.

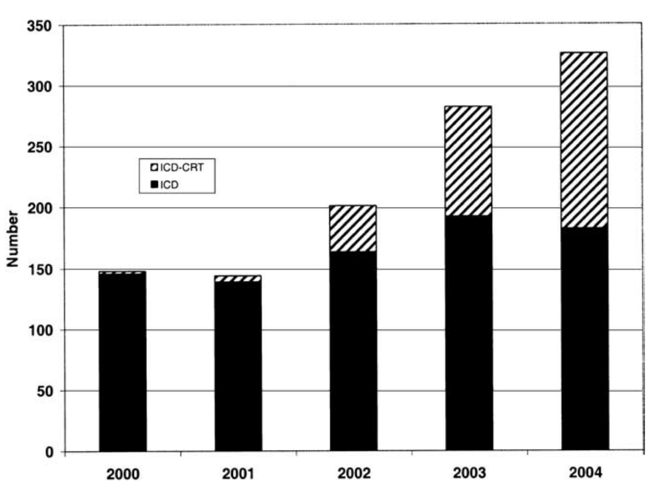

Figure 3. The implantable cardioverter defibrillator (ICD) implants at the Minneapolis Heart Institute during the past five years. CRT = cardiac resynchronization therapy.

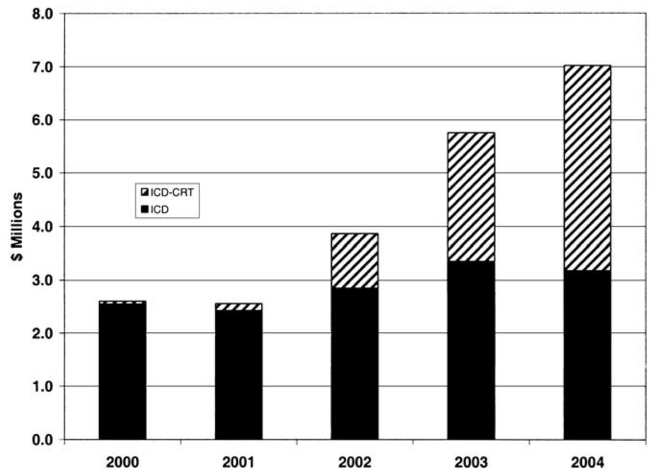

Figure 4. Cost of implantable cardioverter-defibrillator (ICD) pulse generators at the Minneapolis Heart Institute during the past five years. CRT = cardiac resynchronization therapy.

Whereas hospitals could benefit financially by using shorter-life ICDs, our analysis of the diagnosis-related groups suggest that institutions will have difficulty recovering the costs of ICD pulse generator replacements unless the replacement device is an upgrade, e.g., from a single-chamber to a dual-chamber model.

It is time to revise reimbursement methods to encourage manufacturers to produce and hospitals to implant longer-life devices. Several approaches could be adopted by payers and offered by manufacturers, including a program that would cap device costs for the life of an individual patient and reward ICD longevity. Patients and payers would benefit because the frequency of replacement surgery would decrease, and the cost-benefit of ICD therapy would improve. Further, it is more reasonable for Medicare to focus its cost containment efforts on the actual costs associated with delivering ICD therapy than to limit reimbursable indications by arbitrary coverage decisions. Whatever the solution, the problem is clear, i.e., the health economy is facing a staggering expense. The SCD-HeFT study results alone could double the number of ICD implants. The medical community, payers, and industry must address this critical issue in 2005. If we begin now, most patients could receive a *lifetime* ICD pulse generator by 2007. Although additional strategies will be needed to control the costs of ICD therapy, longer-life models can narrow the mismatch between patient and device longevity.

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REFERENCES

1. Hauser RG, Hayes D, Parsonnet V, et al. Feasibility and initial results of an Internet-based pacemaker and ICD pulse generator and lead registry. Pacing Clin Electrophysiol 2001;24:82–7.
2. Hauser R, Hayes D, Cannom D, et al. Performance of pacemaker and implantable cardioverter defibrillator pulse generators and leads: results

from the Multicenter Registry. In: Tse H-F, Lee KLF, Lau C-K, editors. Clinical Pacing and Electrophysiology. Bologna, Italy: Monduzzi Editore, 2003:173–9.
3. The Antiarrhythmic Versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med 1997;337:1576–83.
4. Moss AJ, Zareba W, Hall WJ, et al., and the Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877–33.
5. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. N Engl J Med 2000;342:1937–45.
6. Kadish A, Dyer A, Daubert JP, et al., and the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Investigators. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med 2004;350:2151–8.
7. Bardy GH, Lee KL, Mark DB, et al., for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225–37.
8. Abraham WT, Fisher WG, Smith AL, et al., for the MIRACLE Study Group. Cardiac resynchronization in chronic heart failure. N Engl J Med 2002;346:1845–53.
9. Linde C, Braunschweig F, Gadler F, Brailleul C, Daubert JC. Long-term improvements in quality of life by biventricular pacing in patients with chronic heart failure: results from the Multisite Stimulation in Cardiomyopathy Study (MUSTIC). Am J Cardiol 2003;91:1090–5.
10. Bristow MR, Saxon LA, Boehmer J, et al., and the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Investigators. Cardiac resynchronization therapy with or without an implantable defibrillator in advanced heart failure. N Engl J Med 2004;350:2140–50.
11. Wilkoff BL, Cook JR, Epstein AE, et al., and the Dual Chamber and VVI Implantable Defibrillator Trial Investigators. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) trial. JAMA 2002;288:3115–23.
12. Special report. Cost-effectiveness of implantable cardioverter-defibrillators in a MADIT-II population. Blue Cross Blue Shield Association TEC Assessment Program. Vol. 19, No. 5, April 2004. Available at: http://www.bcbs.com/tec/vol19/19_03.html. Accessed January 11, 2005.
13. Hauser RG, Hayes DL, Cannom D, Epstein AE, Song SL, Kallinen L. Effect of battery capacity on the longevity of implantable cardioverter defibrillators. Pacing Clin Electrophysiol 2005. In press.
14. Wild DM, Fisher JD, Kim SG, Ferrick KJ, Gross JN, Palma EC. Pacemakers and implantable cardioverter defibrillators: device longevity is more important than smaller size: the patient's viewpoint. Pacing Clin Electrophysiol 2004;27:1526–9.
15. Bracke FA, Meijer A, van Gelder LM. Lead extraction for device related infections: a single-centre experience. Europace 2004;6:243–7.
16. Saad EB, Saliba WI, Schweikert RA, Al-Khadra AS, Abdul-Karim A, Niebauer MJ, Wilkoff BL. Nonthoracotomy implantable defibrillator lead extraction: results and comparison with extraction of pacemaker leads. Pacing Clin Electrophysiol 2003;26:1944–50.