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Impact of ICD Battery Longevity on Need for Device Replacements—Insights from a Veterans Affairs Database

Indiresha Ramachandra, M.D.

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Abstract and Introduction

Abstract

Background: The number of implantable cardioverter defibrillator (ICD) replacements is increasing, which adds to patient risk and costs.
Objectives: To understand the impact of increasing ICD longevity on need for replacements, costs, and some of the risks.
Methods: Using the Veterans Affairs records, veterans with ICD implants between June 1992 and April 2007 and dead as of April 2009 were identified. Data were obtained by retrospective records review. The longevity of each ICD was the duration from implant to explant. For each ICD, the longevity needed to avoid one replacement was defined as longevity of that ICD plus the longevity of the subsequent ICD.
Results: The study cohort had 164 patients with 301 ICD implants. Ninety-two patients had at least one ICD replacement. Two patients were excluded for missing data. Twenty-seven patients had an ICD explanted for reasons other than battery depletion. Sixty-three patients received 83 ICDs for battery depletion alone. Among 27 patients who had ICD replacements for other reasons, four patients may have avoided a device infection related to ICD replacement if the initial ICD had lasted 7 years. If all ICDs had lasted 5, 7, or 9 years, then 26%, 58%, and 84% of patients, respectively, would not have needed an ICD replacement. Also 17, 37, and 53 ICD replacements, respectively, would have been avoided, saving US$314,500–US$980,500 over 15 years at 2005 Medicare reimbursement rates.
Conclusions: Prolongation of battery life to 7 or 9 years is important to reduce patient risks and decrease costs.

Introduction

The aging of the US population along with declining mortality rates from heart disease and stroke has significant economic and health impact. The population age group 65–74 years will increase from 6% to 10% of the total population between 2006 and 2030.[19] In 2004, 27.2% of all deaths were attributable to cardiac causes according to the National Center for Health Statistics.[1] Congestive heart failure, coronary artery disease (CAD), and dysrhythmias account for 24%, 41%, and 17% of all hospital discharges for heart disease, respectively, according to 2004 National Hospital Discharge Survey.[2]

Advances in therapy for CAD and HF have significantly increased the lifespan of these patients. Devices are part of the treatment armamentarium for heart failure and arrhythmic risk. Several randomized trials have shown that implantable cardioverter defibrillators (ICDs) are beneficial for secondary prevention of sudden cardiac death and for primary prevention in certain high-risk groups.[3–6] This has increased the annual number of devices implanted in the US from under a few thousand in 1990 to over 100 thousand in 2002.[7]

These expensive devices have a finite lifespan and the majority of them are replaced between 3 and 9 years.[8–10] In addition, some devices have to be replaced for reasons other than battery depletion such as manufacturer recall, device infection, device failure, or a change in the patient's condition needing a different type of device.[13,14] Generator replacement is not benign and has associated risks. The risks of generator replacement include lead damage, needing new lead placement with the attendant risk of pneumothorax, pocket infection, pocket hematoma, and death. Studies of ICD generator replacement have shown a 4.1% and 5.8% rate for major complications that

includes death.[11–13] This is higher than the 3.6% incidence of any major complication for first-time ICD implants in the National Cardiovascular Data Registry registry.[14]

Simultaneously miniaturization of devices has been possible because of development of higher current density battery sources, lead design, and advances in device programming including autocapture, autothreshold, and hysteresis features.[15–19] Device manufacturers' data suggest that there has been no change in the projected lifespan of these devices despite miniaturization. However, a recent review suggests that the actual longevity of pacemakers tested was 491 days less than the projected longevity based on programming parameters, the patient, and device characteristics.[20] The average implant time of single- and dual-chamber ICDs with rate responsive or cardiac resynchronization therapy-defibrillation (CRT-D) capabilities was significantly shorter than the average implant time of single- or dual-chamber devices without these features, mainly because of earlier battery depletion, unexpected device failure, or recalls.[21]

The average ICD patient now lives nearly 10 years after the procedure. The service life of pulse generators ranges from 4.7 ± 1 year for single-chamber units to 4.0 ± 1 year for dual-chamber units. This mismatch between patient longevity and the service life of ICDs poses a significant clinical and economic burden that must be addressed.[22]

The longevity of ICDs affects the need for device replacements. This in turn affects the exposure of patients to risk and adds to healthcare costs. The relationship of device duration to the impact on patient care is not adequately characterized.

The purpose of this retrospective review of a cohort of patients in the Veterans Affairs (VA) system was to examine the actual device longevity in these veterans, explore the relationship between device longevity and patient risk, as well the impact on system costs.

Study Design and Methods

Patient Enrollment

The procedure log books of the surgical operating room and the electrophysiology lab were used to obtain a list of all patients who underwent device-related procedures at the Louis Stokes Cleveland VA Medical Center (LSCDVAMC). These lists were cross-checked against physician-specific lists maintained by the major device companies as well as a hospital's computer-generated administrative list of all VA patients who underwent device procedures. After obtaining institutional review board approval in February 2008, a retrospective chart review was performed of all veterans who underwent at least one ICD-related procedure in the LSCDVAMC between August 1992 and April 2009. The study enrollment was closed in April 2009 for purposes of analysis.

Data Collection

Data related to the dates of device implant, the indication for the implant, the device manufacturer and model, the date and reason for replacement or explants, the date of the patient's death when applicable, and the state of the device battery life on the last available device interrogation record prior to the patient's death were all collected. In some instances, only the month and year or only the year of the implant was available. In these instances, the device was assumed to have been implanted on the first of that month and year or on January first of that year. In this manner, the device was assumed to have lasted longer than it may have actually lasted. If patients had device implants or procedures performed at other institutions, details were obtained through a review of VA practitioner records and copies of records from other institutions. If details of the implant procedure were not available, then that patient was excluded from the analysis. Patients were matched against the Social Security Death Index (SSDI) to identify those who were no longer alive. Those veterans who were no longer alive as of April 1, 2009, were analyzed separately as prespecified. Patients who had an upgrade to a CRT-D device from an ICD or permanent pacemaker (PPM) were considered in the CRT-D group. Patients who had an upgrade from a PPM to an ICD were considered in the ICD group.

Once the data were collected, all personal identifiers were erased as per the protocol. The de-identified data were entered in a Microsoft Excel Spreadsheet (MS Office 2008, Microsoft Corp., Redmond, WA, USA) and analyzed.

Data Analysis

From the data collected, the device longevity was defined as the duration in days that each device was utilized for until explant or replacement. This was calculated using the duke date calculator.[23] The first ICD or CRT-D device is called the initial device. All replacements are called subsequent devices. Among the prespecified cohort of patients who were no longer alive, the length of time an ICD was needed was defined as the duration from the date of their first ICD implant to their death.

Results

The database consisted of 379 patients who had 646 ICDs/CRT-Ds placed and a total of 710 ICD/CRT-D-related procedures between January 1992 and April 2007. Of these, 161 patients had died by April 2009 and 216 were alive. Some relevant characteristics are shown in Table I.

Table 1. Characteristics of Patient Groups

Characteristic	Group I—Patients No Longer Alive as of April 2009	Group II—Patients Who Were Alive as of April 2009
Total number (n)	161	216
Number of patients with ICDs	151	186
Number of patients with CRT-Ds	10	30
Average number of devices per patient	1.87	1.60
Number of patients with only one device	68 (1 had missing data)	128 (109 ICDs + 19 CRT-Ds)
Patients with upgrade to ICD	9	8
Patients with upgrade to CRT-D	5	5
Patients without adequate data	2	5
Total number of ICDs/CRT-Ds	301	345
Total number of device procedures.	322	388
Device infections (prim implant/second implant)	3 + 5	4 + 5
Device replacement for recalls or malfunction	8	7
Number of devices replaced for battery depletion alone	147	66

Group I—Patients No Longer Alive as of April 2009

Of the 161 patients who had died, two did not have adequate data. Sixty-seven had received only one defibrillator during their lifespan. Of the remaining patients, 31 had devices replaced for either infection, device recall, or for

upgrade to a different device and not for battery depletion. Sixty-one patients had 147 devices replaced for battery depletion alone. The serviceable life of 89 devices replaced for battery depletion is shown in Figure 3. For 14 devices, exact implant dates could not be obtained. Only the year of implant was available. The device was assumed as being implanted on January 1 of that year. This overestimates device serviceable life. Two patients had device upgrades at the time of replacement for elective replacement indicator (ERI). Two patients needed a new device due to inadequate safety margin at time of defibrillator threshold testing shortly after implant. These two patients were included in the analysis. These two devices that were replaced were not included in the analysis. The data of 61 patients were used to estimate the impact of ICD battery longevity on replacements.

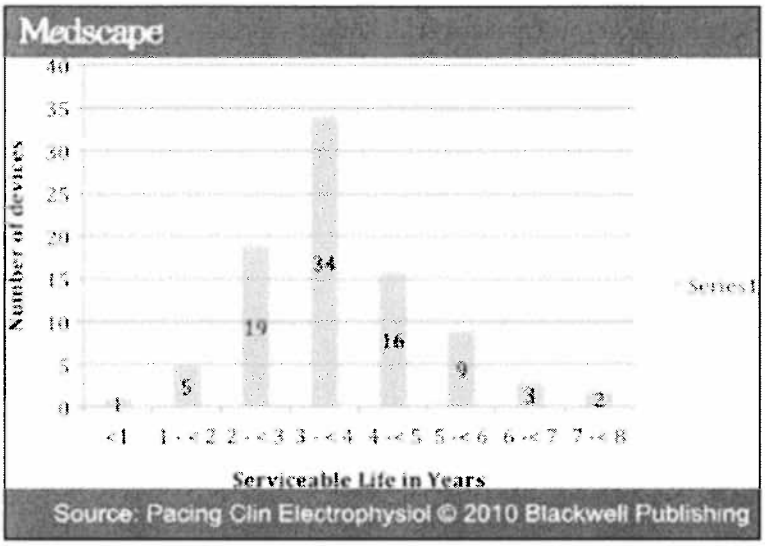

Figure 3. Service life of devices replaced for battery depletion alone in patient cohort not alive as of April 2009.

Estimation of the Effects of Increased Longevity on Device Replacements

One of the goals of an increase in ICD longevity is to avoid replacements. The total longevity of an ICD needed to avoid one replacement for each patient was defined as the longevity of the initial ICD plus the longevity of the subsequently implanted ICD. These total longevities were calculated for each ICD and then grouped into intervals in years. The number of ICD replacements that could be avoided for each interval of total longevity, stratified by year of implant is shown in Figure 1. If all ICDs were to last for 5, 7, or 9 years, then 24, 57, and 75 replacements, respectively, would have been avoided.

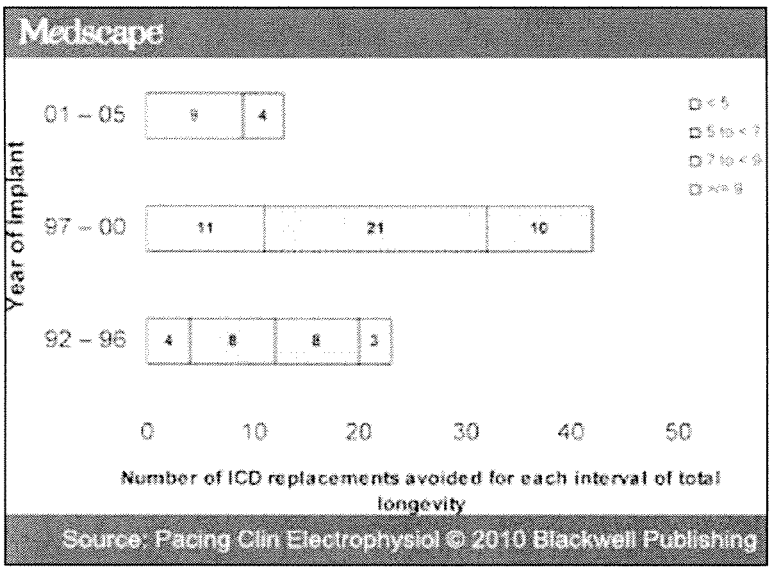

Figure 1. ICD replacements avoided.

Estimation of the Effects of Increased Longevity on Patients

The length of time an ICD was needed for each patient was arranged in yearly intervals. The number of patients in each time interval was determined for both those who had ICD replacements as well as those who never needed a device replacement. If every ICD had lasted for a duration equal to or greater than the upper limit of a time interval, then all patients in that time interval would have needed only one ICD. In other words, for each time interval, these patients would never have needed a replacement or been exposed to the risks of replacement if their initial ICD had lasted for longer than that time interval. These data are shown in Figure 2. The cumulative number of patients who would not have needed device replacements is shown in Table II.

Table 2. Cumulative Number of Patients Who Would Have Avoided Risks of ICD Replacement

Length of Time ICD was Needed or ICD longevity Needed to Avoid Replacements	Patients Who Needed ICD Replacement (n = 61)	Cumulative Number of Patients Who Would Have Avoided Exposure to Risks of ICD Replacement (%)
3	5	5 (8)
>3 to 4	6	11 (18)
>4 to 5	6	17 (28)
>5 to 6	7	24 (39)
>6 to 7	12	36 (59)
>7 to 8	8	44 (72)
>8 to 9	7	51 (83)
>9	10	61 (100)

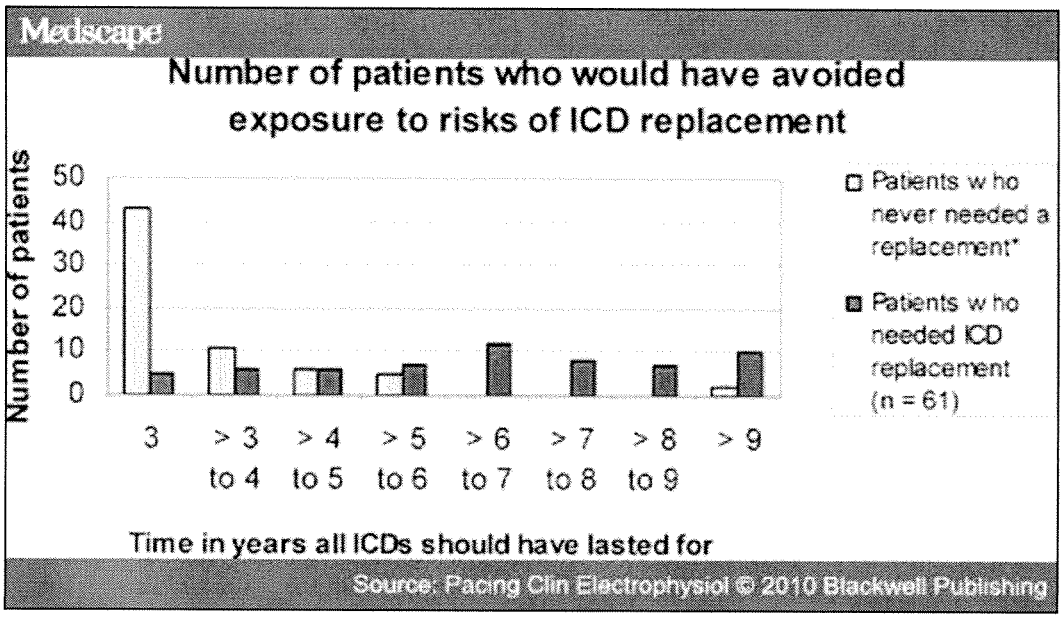

Figure 2. Patients who would have avoided risks of ICD replacement.

Avoidance of Device-related Infections

There were five patients in this cohort who had an infection of their subsequently replaced ICDs. The assumption is that these patients would have avoided the infection related to a replacement procedure if their initial device had lasted long enough to avoid a replacement. To avoid these infections, their initial ICDs should have lasted 6 1/12, 7 6/12, 7 10/12, 8 1/12, and 10 9/12 years, respectively. In other words, one and four device-related infections could have been avoided if all ICDs lasted at least 7 or 9 years, respectively.

Group II—Patients Who were Alive as of April 2009

There were 216 patients in this group. One hundred and twenty-eight patients had received only a single device. Thirty-five patients had devices replaced for reasons other than battery depletion alone. Fifty-five patients had 66 device replacements for battery depletion alone. In this cohort, the metric length of time device needed is not applicable. Only in 13 patients who had received three or more devices was it possible to calculate the longevity needed to avoid a replacement. These 13 patients had 17 replacements for battery depletion of which three and nine replacements would have been avoided if all devices had lasted 7 years and 9 years, respectively.

Of the 30 live patients with CRT-Ds, 26 had a CRT-D device as their first implant and seven had a CRT-D device replaced for ERI. Four had ICDs upgraded and one had ICD upgrade to CRT-D while undergoing a V lead revision. That device got infected and the system explanted and a new CRT-D was placed. Three had ICD replacements for ERI but all three ICDs were upgraded to CRT-Ds before ERI. The data of these patients could not be used to estimate the impact of device battery longevity.

Effect on Costs

The direct costs of ICD replacement are estimated to be around US$18,500 in 2005 Medicare dollars. For the patients in both groups, if all ICDs were to last 5, 7, or 9 years then US$444,000, US$1,110,000, and US$1,609,500 in replacements costs, respectively, would have been avoided for this healthcare system over a period of 15 years.

Discussion

The study demonstrates that longer lasting ICDs reduce the need for replacements. While this is intuitive, the magnitude of impact is surprising. For both groups combined, 60 (28%) and 87 (40%) of the 213 device replacements would have been avoided if all ICDs were to last for 7 and 9 years, respectively. Since some patients needed more than one replacement, 39 (22%) and 63 (35%) of 181 patients would not have needed replacement procedures if all ICDs were to last for 7 and 9 years, respectively.

Nearly 150,000 ICDs are implanted annually, of which about 25% are replacements. This means that annually 37,000–40,000 patients are exposed to the risks associated with device replacement. Device replacements are not a "minor procedure" but associated with risks. The recently published Canadian experience showed that device replacements are associated with a 9.1% complication rate, including 0.44% risk of death.[24] Extrapolating these data implies that increasing device longevity to 7 or 9 years can reduce need for replacements by 28–40%. Potentially 10,300–16,000 patients annually would avoid the exposure to the risks of replacement, 940–1,450 patients would not have a complication, and 45–70 deaths could be avoided. This could reduce direct healthcare expenditures for device replacements by $190–296 million in 2005 Medicare dollar costs over 15 years.

In addition, five of 17 device-related infections may have been avoided if battery longevity is 9 years for every ICD.

These numbers relating to prevention of deaths, reducing patient risks, and saving healthcare costs are not insignificant. We feel that increased battery longevity is a target for improvement. Device manufacturers are to be commended for their success in improving device design and achieving miniaturization through a combination of improvements in both hardware and software, without significantly decreasing projected ICD longevity. However, we believe that an increase in projected longevity is necessary.

Achieving increases in device battery longevity is feasible. Theoretically, for a single-chamber ICD, assuming 100% pacing and 200 shocks with 75% efficiency, a 1.1 A hour battery should last 5 years.[25] Manufacturing devices with slightly larger batteries is technologically feasible. In fact, batteries of the early 1990s tended to be larger and often 3.0 A hours in capacity.[26]

Larger batteries will mean an increase in device size. This brings up the acceptance of devices by patients. In a study, 90% of 151 patients preferred a larger device. Among ICD recipients, 91% of those who expressed a preference did so for a larger device.[26] In a survey in the Cleveland VA Medical Center (as yet unpublished results), 85% of 97 patients preferred a larger device if it would last 2 or 3 years longer.

Physicians and industry representatives need to rethink the balance between miniaturization and device longevity in order to identify goals that would benefit individual patients and society.

Conclusions

Increasing ICD longevity is an important target that will help to reduce patient risks related to replacements as well as to reduce costs.

Limitations

This has all the drawbacks of a retrospective study. Although the VA Computerized Patient Record System is reasonably comprehensive, some patients obtained part of their care outside the VA system and data were missing in a few patients. Currently, implanted ICDs are different from most ICDs used in these patients. These data were not adjusted for device size, pacing needs, or for number of shocks. This was deliberately done as we were interested in the actual longevity in the real-world conditions. It was also difficult to obtain reliable data regarding pacing needs or shocks delivered. This study did not aim to compare actual longevity with projected longevity. Newer devices employing hybrid battery designs are expected to live longer, which will hopefully favorably impact patient care.

Future directions—a similar analysis of the National ICD registry will allow more robust inferences to be drawn regarding the impact of extending device longevity on reducing patient risk or system costs.

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