Safety, Efficacy, and Performance of Implanted Recycled Cardiac Rhythm Management (CRM) Devices in Underprivileged Patients

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Introduction: *Patients in underdeveloped nations have limited access to life-saving medical technology including cardiac rhythm management (CRM) devices. We evaluated alternative means to provide such technology to this patient population while assessing the safety and efficacy of such a practice.*

Methods: *Patients in the United States with clinical indications for extraction of CRM devices were consented. Antemortem CRM devices were cleaned and sterilized following a protocol established at our institution. Surveillance in vitro cultures were performed for quality assurance. The functional status of pulse generators was tested with a pacing system analyzer to confirm at least 70% battery life. Most generators were transported, in person, to an implanting institution in Nicaragua. Recipients with a Class I indication for CRM implantation, and meeting economical criteria set forth, were consented for implantation of a recycled device.*

Results: *Between 2003 and 2009, implantation was performed in 17 patients with an average age of 42.1 ± 20.3 years. Of the 17 patients, nine were male and eight were female. Mean follow-up was 68 ± 38 months. Device evaluation occurred prior to discharge, 4 weeks post implantation, and every 6 months thereafter. There were three deaths during the follow-up period secondary to myocardial infarction, stroke, and heart failure. Hematoma formation occurred in one patient. No infections, early battery depletion, or device malfunction were identified during follow-up.*

Conclusions: *Our case series is the longest follow-up of recipients of recycled antemortem CRM devices. Our findings support the feasibility and safety of this alternative acquisition of life-saving technology. (PACE 2011; 34:653–658)*

pacemaker, reuse of devices, low- and middle-income countries, antemortem, resterilization

Introduction

Cardiovascular disease (CVD) is the leading cause of death globally.[1] In 2004, an estimated 17.1 million people died representing 29% of all global deaths.[1] Of these deaths, an estimated 7.2 million were due to coronary heart disease and 5.7 million were due to stroke.[1] Low- and middle-income countries are disproportionally affected: 82% of CVD deaths take place in low- and middle-income countries and occur almost equally in men and women.[1] By 2030, almost 23.6 million people will die from CVDs, mainly from heart disease and stroke. These are projected to remain the single leading causes of death.[2]

Our greatest challenges are the evident global inequalities that exist in cardiovascular health. There is clearly a lack of financial and economical resources in underprivileged nations. More specifically, in Nicaragua, over 1 million people live with limited access to health care. According to the World Bank, as cited by the United States Agency for International Development, Nicaragua is now the poorest country in the Americas, with an average per capita annual income of $430.[3,4] Clearly, access to life-saving medical technology, such as cardiac rhythm management (CRM) devices, is limited in Latin countries, such as Nicaragua, due to the impoverished lifestyle that is so pervasive.

The purpose of our study was to evaluate if recycled antemortem devices can be implanted safely with acceptable performance track record in underprivileged patients in a low- to middle-income country such as Nicaragua. The primary endpoints were to assess the feasibility,

functionality, and safety of implantation of recycled CRM devices in a population of low- to middle-income patients who cannot afford such medical therapy. The secondary endpoint was device-related complications such as infection, device malfunction, or death related to device malfunction.

Methods

Antemortem CRM Device Protocol

Explant Protocol

All donors were from one institution: Providence Hospital and Medical Center, Southfield, MI. All donors had clinical indications for device extraction and were consented for device removal and donation. Trained physicians in our institution interrogated all devices to assess function and to remove all patient data. The responsibility of recycling pacemakers was given to one nurse (NZ). CRM devices were checked with a pacemaker system analyzer (PSA), and only those devices with $\geq 70\%$ battery life were used in the study. All generators with signs of damage were excluded.

Sterilization Protocol

Antemoretm CRM devices were cleaned and sterilized utilizing three sterilization steps. The first step involved device removal and cleaning with sterile water and isopropyl alcohol using 4×4-cm sterile gauze and cotton swabs. This was carried out in the electrophysiology laboratory. The device was then aerated to dry and transported within 24 hours of explant to the Center for Sterilization Processing Department (CSPD).

At the CSPD, the devices were placed in a peel pouch with ethylene oxide chemical indicator and sterilized with a biological test pack (B1 spore). The devices were then left for approximately 2.5 hours and aerated for 12 hours for a total incubation time of approximately 15 hours. The B1 incubator was then confirmed with a control B1 incubator and read as either positive or negative. If the results were negative, then sterilization was completed successfully. If results were positive, the device was then rerun in another sterilizer.

To account for quality assurance, devices underwent surveillance *in vitro* cultures—aerobic, anaerobic, and fungal—every 3 months until time of device implantation abroad. Devices were unwrapped from their sterile packaging to perform this testing. Cultures were obtained with a standard Q-tip kit (Starplex Scientific Inc., Etobicoke, Canada, and Becton, Dickinson, and Company, Sparks, MD, USA) from two separate sites on the surface and from the lead insertion site inside the header of the device. After testing, the device was resterilized and repackaged in an identical fashion to the process described previously. This process was performed one time, at most, for any given device. No cultures were reported positive during 2 weeks of incubation. All devices were delivered and implanted within 6 months of initial sterilization. No devices were discarded due to bacterial growth during surveillance.

Implant Protocol

Once sterilized, devices were then transported in person or via FedEx to two implanting institutions in Nicaragua: (1) Centro de Cardiology Nacional and (2) Hospital Militar de Managua.

Patients included in the study were between the ages of 16–90 years old. Each participant was an established patient at one of the two institutions in Nicaragua. Prior to implant, all patients underwent a detailed socioeconomic evaluation by a local nonprofit medical organization (fornicaraguanhealth.org) and were deemed financially incapable of affording a CRM device. All patients considered had a Class I indication for CRM device implantation per the American College of Cardiology/American Heart Association/Heart Rhythm Society guidelines.[5] All recipients consented to receiving a recycled, donated device.

Decision to proceed with implantation was approached on a case-by-case basis. A case history and 12-lead electrocardiogram for each patient were sent to the senior investigator (CM) who reviewed each case individually. Cases were either approved individually (delivered by FedEx) or during planned medical excursions (delivered in person). An electrophysiologist and a local cardiologist performed each procedure. Implantation at the Hospital Militar de Managua occurred in an operating room, while those occurring at Centro de Cardiology Nacional took place in a catheterization suite. Third-party payers donated all device leads. Due to the limited functional and financial resources at the participating institutions, no periprocedural antibiotic therapy was used. All follow-up was done by DR and CD and communicated to the senior investigator (CM). All patients had device evaluation prior to hospital discharge, 4 weeks post device implantation, and every 6 months thereafter. Right atrial (RA) and ventricular (RV) sensing and capturing thresholds were measured at implant via a Medtronic PSA (model 5311B, Medtronic Inc., Minneapolis, MN, USA) and at follow-up via device programmer. In addition, RV shock impedances were measured. Complications in the acute setting, related to implantation, and during long-term follow-up were assessed and recorded.

Table I.

Baseline Patient Characteristics

Patient No.	Age (Years)	Gender	EF (%)	Type of Device	Indication	Acute Complications
1	65	M	20	CRT	Syncope, ischemic CMP, PPM dependent	0
2	77	F	50	DDD	SSS with symptomatic bradycardia	0
3	40	F	60	DDD	CHB	0
4	17	M	30	DDD/ICD	WPW, Epstein's, failed two ablations, AF and VF via AP	0
5	19	F	65	DDD	Congenital HB	0
6	15	M	65	DDD	CHB and CHD	0
7	40	M	30	VVI/ICD	DCM with syncope and NSVT	0
8	72	F	55	VVI	Syncope, SSS, bradycardia and AF	0
9	28	F	65	DDD	Congenital HB, syncope	0
10	16	M	65	DDD	Congenital HB, syncope	0
11	28	M	25	VVI/ICD	DCM with NSVT	0
12	36	F	55	DDD	Congenital HB, redo generator	0
13	50	M	30	VVI/ICD	DCM with syncope and NSVT	0
14	58	M	40	DDD	CHB post MI	Hematoma/heparin
15	65	F	60	DDD	SSS with symptomatic bradycardia	0
16	38	F	60	DDD	CHB	0
17	52	M	35	VVI/ICD	CAD, CMP, VT	0

EF = ejection fraction; CRT = cardiac resynchronization therapy; DDD = dual-chamber pacemaker (with sensing and pacing in the atria and ventricle); ICD = implantable cardioverter-defibrillator; VVI = single-chamber ventricular pacemaker (with sensing and pacing in the ventricle); CMP = cardiomyopathy; PPM = permanent pacemaker; SSS = sick sinus syndrome; CHB = complete heart block; WPW = Wolff Parkinson White; AF = atrial fibrillation; VF = ventricular fibrillation; AP = accessory pathway; CHD = congenital heart disease; DCM = dilated cardiomyopathy; NSVT = nonsustained ventricular tachycardias; HB = heart block; MI = myocardial infarction; CAD = coronary artery disease; VT = ventricular tachycardias.

Statistical Techniques

Continuous variables are expressed as a mean ± 1.0 standard error of measurement and were compared using Student's *t*-test or nonparametric analysis as appropriate. Nonparametric Mann-Whitney U test was used to compare medians. A two-tailed P value of < 0.05 indicated statistical significance. Statistical analyses were performed using the SPSS software package (version 17.0, SPSS Inc., Chicago, IL, USA). Results are reported for the time of implant and 36-month follow-up in the same sequence throughout the manuscript. All authors had unrestricted access to all of the data collected and analysis performed. There were no extramural sources of funding used for this research.

Results

From 2003 to 2009, 17 patients received CRM device implants during medical missions to Nicaragua with recycled antemortem CRM devices. Of the donors, 10 had CRM devices removed for upgrades and seven for infections. The time range period from implant to explant in a donor device was 11–22 months. The mean age for recipients was 42.1 ± 20.3 years. The overall average ejection fraction (EF) was 47.6 ± 16.2%. Among implantable cardioverter-defibrillator (ICD) recipients, the average EF was 30.0 ± 6.4% (Table I). The baseline characteristics are summarized in Table I. The mean follow-up period was 68 ± 38 months. All but one of the patients was a first-time recipient of an implanted device. Among recipients, three had transvenous pacemakers prior to implant, one received a cardiac resynchronization therapy (CRT) device, five received ICDs (four single chamber, one dual chamber), and 11 received pacemakers (10 dual chamber, one single chamber). The battery life at time of implant was 2.62–2.74 V for a pacemaker
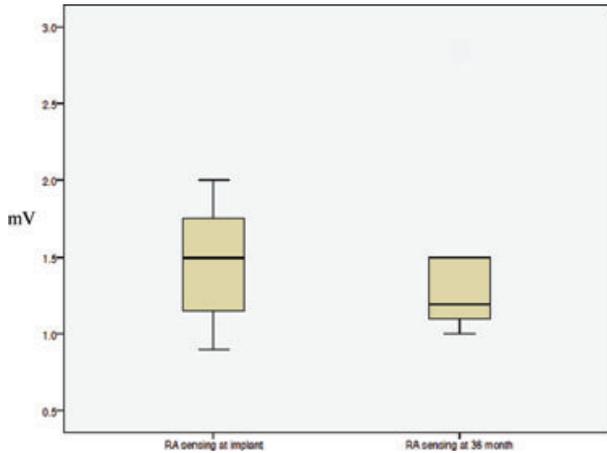
Figure 1. *Right atrial sensing thresholds at implantation and 36 months. RA = right atrium; mV = milivolts.*
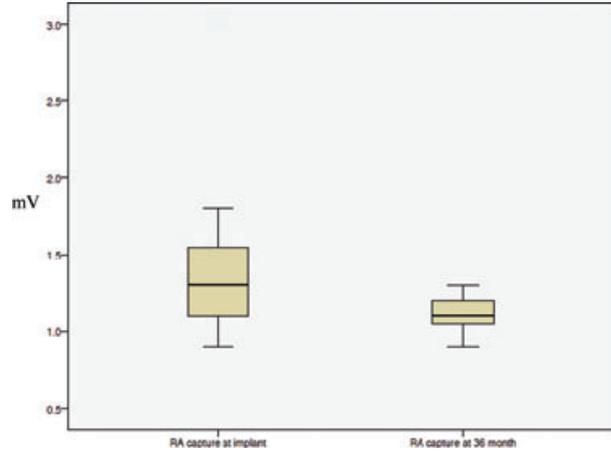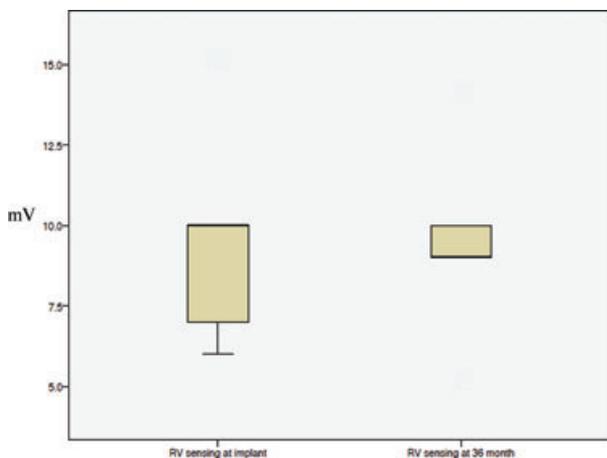

Figure 3. *Right atrial capture thresholds at implantation and 36 months. RA = right atrium; mV = milivolts.*

and 3.04–3.15 V for an ICD. Devices included those manufactured by Guidant (Sylmar, CA, USA), Medtronic, and St. Jude Medical (St. Paul, MN, USA) companies.

All threshold variables were measured at implant and at 36-month follow-up. RA sensing thresholds were measured in seven (43.8%) patients (1.46 ± 0.4 mV vs 1.46 ± 0.6 mV, P = 1.0, Fig. 1). RV sensing was measured in five patients (9.6 ± 3.5 mV vs 9.4 ± 3.2 mV, P = 0.94, Fig. 2). RA capture thresholds were measured in 11 patients (1.42 ± 0.6 mV vs 1.11 ± 0.13 mV, P = 0.09, Fig. 3). RV capture thresholds were measured in 16 patients (1.08 ± 0.55 mV vs 0.98 ± 0.16 mV, P = 0.48, Fig. 4). And lastly, RV shock impedances were measured in six patients (42 ± 2.8 Ω vs 42 ± 2.1 Ω, P = 1.0, Fig. 5). All variables measured

showed no statistical difference when measured at implant and at 36 months.

Prespecified criteria defining complications were set forth by the senior investigator (CM). Data were collected and catalogued during patient follow-up. Only one hematoma was reported. There were no infections, early battery depletion, or device malfunction reported during follow-up. To date, only one patient was found by device interrogation to be at elective replacement indicator and subsequently underwent generator change at 46 months post implant. Three deaths occurred from acute myocardial infarction, cerebral vascular accident, and progressive heart failure within 30–46 months post implant. There was no association between device donor infections and recipient-related death. Among the three deaths,

Figure 2. *Right ventricular sensing at implantation and 36 months. RV = right ventricle; mV = milivolt.*
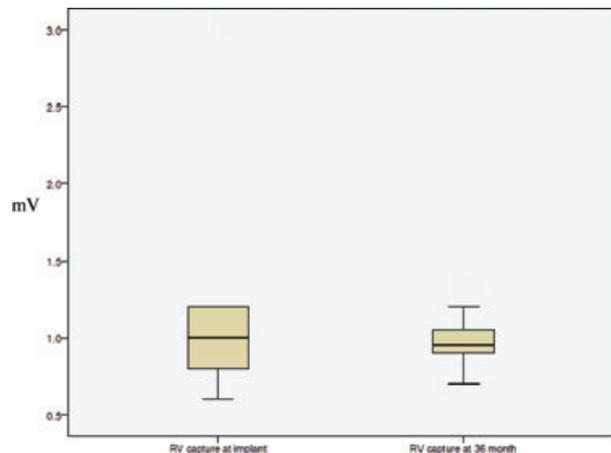
Figure 4. *Right ventricular capture thresholds at implantation and 36 months. RV = right ventricle; mV = milivolt.*
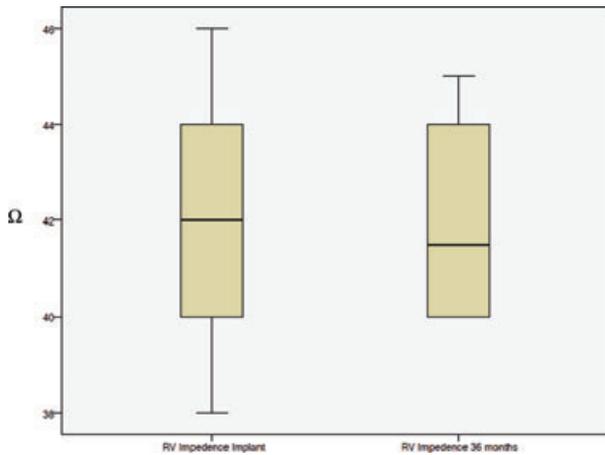
Figure 5. *Right ventricular impedance measurements at implantation and 36 months. RV = right ventricle; Ω = Ohms.*

one patient with a dual-chamber ICD device received appropriate shock therapy for ventricular fibrillation; however, the patient died 2 years post implantation secondary to acute myocardial infarction with cardiogenic shock. Inappropriate shock therapy was recorded in one patient with a dual-chamber ICD for atrial fibrillation and atrial tachycardia at 9 and 13 months post implantation. This patient was subsequently treated medically with antiarrhythmic therapy with no recurrent inappropriate shock therapy. We continue to follow all surviving patients.

Discussion

For the past 25 years, Heartbeat International, a charitable organization, has been responsible for the implantation and follow-up of donated nonrecycled pacemaker devices in over 9,000 recipients in developing countries.[6] The idea was started in Guatemala over 30 years ago by Dr. Frederico Alfaro; however, Dr. Henry D. McIntosh created the organization in 1984. The organization depends on Pacemaker Banks that were created in over 24 countries where devices have been donated. The idea of pacemaker reuse is not new. There has also been a long history of pacemaker reuse in much of the world, outside of the United States. Other organizations, including collaborative work with the World Medical Relief organization and Baman et al., have successfully implanted postmortem recycled pacemakers in the Philippines.[7] Reports from Canada and Sweden indicate the safety and cost savings of selective pacemaker reuse.[8–10] Multiple studies have demonstrated that there is no increased rate of infection.[10–12] According

to a preliminary meta-analysis report performed by Romero and colleagues, a total of four trials enrolling more than 600 patients showed no significant increase in overall complications when comparing new pacemaker implantation to pacemaker reuse (odds ratio 0.98; [0.64–1.49], P = 0.91). This meta-analysis demonstrated that there was no evidence of increased risk of infection, complications related to implantation, or device malfunction.[13]

The idea of pacemaker reuse appears to be well accepted by the general population. According to a survey of the general population in 2009, 71% of the general public and 87% of patients with pacemakers are willing to donate a device to people in need in another country, if given the chance.[7] The main obstacle is involving our national health care system that currently, according to the Food and Drug Administration, prohibits the reimplantation of CRM devices within the United States. However, there are no federal prohibitions on harvesting used CRM devices. The 2002 American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guideline Update even acknowledges that pacemaker reuse "may eventually add significantly to the cost effectiveness of cardiac pacing."[14] More recently, logistical, legal, and ethical barriers have been addressed, raising awareness of the potential future of recycled CRM devices.[15] We also support the most recent initiative by Baman et al. to urge the patient population and medical field to validate the process of recycled devices in the United States.[16]

We recognize that limitations in our study include a small sample size, limited access to health care, and short-term follow-up of devices in Nicaragua. Our small sample size may have failed to capture surgical or hardware malfunction directly related to our harvesting and resterilization process. All patients continue to have follow-up in Managua, and to date, no device infection or further mortality has been reported. We anticipate reporting of long-term results once these data are analyzed.

Conclusions

All previous studies published evaluated the reuse of pacemakers in the postmortem setting. To our knowledge, our study is the first to evaluate implantation of antemortem devices in patients in developing nations. Our data emphasize that CRM device reuse is safe, effective, feasible, and well accepted by donors and recipients, especially in patients who cannot afford such therapies. Further research is necessary to evaluate the concepts of pacemaker donation programs as

well as a registry documenting both antemortem and postmortem CRM device reuse. Similar to our recycling process, we recommend that any institution considering CRM device reuse define and approve appropriate guidelines and protocols to guide the process and establish a collaborative approach to ensure safety, effectiveness, and feasibility.

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