Feasibility of postmortem device acquisition for potential reuse in underserved nations

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OBJECTIVES The purpose of the present study was to examine the feasibility and efficacy of a program to acquire devices with adequate battery life from crematories and funeral homes for potential reutilization in underserved nations.

BACKGROUND There exists a great health-care disparity between the industrialized world and underserved nations—specifically in the frequency of pacemaker implantation.

METHODS Flyers were mailed to all 1057 members of the Michigan Funeral Directors Association providing information to download a consent-for-explant form and request a postage-paid envelope from www.myheartyourheart.org in order to send explanted devices. Donated devices from funeral homes and crematories nationwide were also collected from World Medical Relief. Adequate battery life was defined as ≥75% or ≥4 years of estimated longevity.

RESULTS A total of 3176 devices (65% pacemakers, 21% implantable cardioverter-defibrillators [ICDs], 12% biventricular ICDs, and 3% biventricular pacemakers) were donated to the reutilization program. Five hundred fifty devices (21%; 95% confidence interval [CI] 19.4–22.6%) were found to have an acceptable battery life for reutilization. Among these devices, 313 were pacemakers (17.9%; 95% CI 16.1–19.8%), 118 were ICDs (17.9%; 95% CI 15.1–21.1%), 112 were biventricular ICDs (30.3%; 95% CI 25.6–35.2%), and 7 were biventricular pacemakers (17.3%; 95% CI 16.0–18.7%).

CONCLUSIONS Approximately 21% of donated devices and 30% of donated biventricular ICDs possess an adequate battery life for potential reuse. Device donations from funeral homes and crematories appear to be a potential resource for device reutilization for those in need in underserved nations.

KEYWORDS Health-care disparities; Pacemaker; Reuse

ABBREVIATIONS **CIs** = confidence intervals; **ICDs** = implantable cardioverter-defibrillators; **LMICs** = low- and middle-income countries; **MHYH** = My Heart–Your Heart

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Introduction

Cardiac pacemakers and implantable cardioverter-defibrillators (ICDs) ± resynchronization therapy have improved the mortality and morbidity associated with cardiovascular disease for many in the industrialized world. However, the associated cost of device implantation can be as much as $55,000[1]—nearly 6 times the gross national income per capita of low- and middle-income countries (LMICs).[2] LMICs such as South Africa have 54 new pacemaker implants per million as compared with 752 new pacemaker implants per million in the United States.[3] In an effort to reduce the great disparity seen between the industrialized world and underserved nations, postmortem device reutilization has been proposed to be a feasible and ethical means of delivering health care to those in great need.[4–6]

The purpose of the present study was to examine the feasibility and efficacy of a program to acquire devices with adequate battery life from crematories and funeral homes for potential reutilization in underserved nations.

Methods

Project My Heart–Your Heart (MHYH) is a joint collaborative between the citizens, physicians, crematories, and funeral directors of the state of Michigan, the University of Michigan Cardiovascular Center, Implant Recycling LLC (Detroit, MI), and World Medical Relief, Inc—a nonprofit organization specializing in the delivery of medical equipment for distribution to hospitals and clinics in underserved nations.[4] The goal of the initiative is to create a framework

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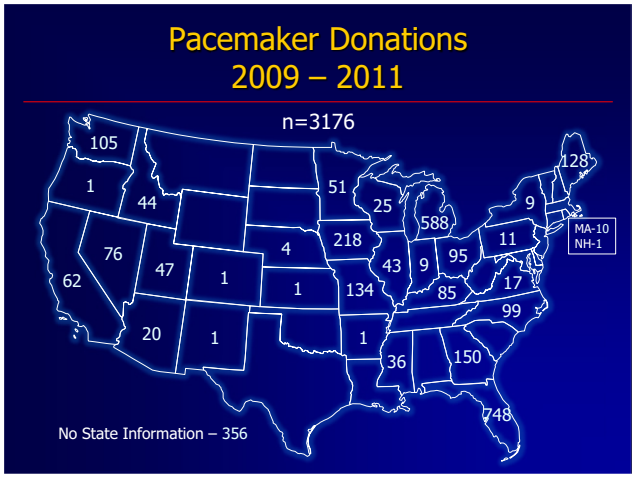

Figure 1 National map illustrating origin of devices received by state.

for funeral directors, patients, and next of kin to donate pacemakers and ICDs for potential reuse in patients in LMICs who have no other access to device therapy.

Flyers were mailed to all members of the Michigan Funeral Directors Association providing information to download a consent-for-explant form and request a postage-paid envelope from www.myheartyourheart.org in order to send explanted devices. Each mailed package included biohazard bags and instructions for explantation and delivery in order to comply with U.S. Department of Transportation shipping laws. Previous publications in the medical literature have also provided information on the donation Web site.[4,7] Donated devices from funeral homes and crematories nationwide were also collected from World Medical Relief. Trained personnel at the University of Michigan inspected the external physical integrity of the devices and performed interrogations with device programmers in order to determine battery life and, presumably, to detect any evidence of device malfunction. Adequate battery life was defined as ≥75% or ≥4 years of estimated longevity. Battery longevity of Medtronic (Minneapolis, MN) ICDs and pacemakers utilizing an ICD interrogation platform was estimated by using the date of implant and battery voltage as provided by Medtronic Technical Services (personal communication, January 26, 2010). All funding for this program was provided by philanthropic grants and donation.

Devices with adequate battery life would be used for an observational pilot study to determine the safety and efficacy of device reutilization in underserved nations pending governmental approval. ICDs would be used only as pacemakers in this initial pilot study. Devices with inadequate battery life would be sent to an environmental company in order to recycle the metal by-products.

Statistical analysis

Confidence intervals (CIs) for proportions were calculated with the package "Epitools" for R, version 0.5-6.[8,9] The influence of device type on the probability of adequate battery life for reuse (pacemaker, ICD, biventricular ICD, biventricular pacemaker) was assessed with a generalized linear model. All analyses were performed with the statistical software R, version 2.12.0.[10]

Results

All members of the Michigan Funeral Directors Association (n = 1057) were mailed flyers with a Web site address for further information regarding MHYH. The project Web site had 2153 external visits from April 1, 2010, to June 1, 2011.Two hundred and thirty-three funeral directors requested a postage-paid envelope for device donation. The majority of funeral directors were from the state of Florida (24%) followed by the state of Michigan (19%) (Figure 1). Each funeral director requested a package for an average of 5.6 ± 11 devices. In addition, World Medical Relief, Inc, received devices from 91 funeral homes and crematories nationwide.

A total of 3176 devices (65% pacemakers, 21% ICDs, 12% biventricular ICDs, and 3% biventricular pacemakers) were donated to the reutilization program. Two thousand two hundred fifty-five devices were donated from World Medical Relief, Inc, while 921 devices were sent directly to the University of Michigan.

A total of 550 devices (21%; 95% CI 19.4–22.6%] were found to have an acceptable battery life for reutilization. Among these devices, 313 were pacemakers (17.9%; 95% CI 16.1–19.8%), 118 were ICDs (17.9%; 95% CI 15.1–21.1%), 112 were biventricular ICDs (30.3%; 95% CI 25.6–35.2%), and 7 were biventricular pacemakers (17.3%, 95% CI 16.0–18.7%) (Figure 2). Of the devices with adequate battery life, average time from implantation was 2.1 ± 1.0 years.

Biventricular ICDs were more likely to have an adequate battery life when compared with donated pacemakers and ICDs ($P < .001$). The manufacturer was not a predictor of devices with adequate battery life ($P = .126$). However, St Jude Medical (St Paul, MN) devices tended to have a higher proportion with adequate battery life (Figure 3).

Discussion

Main findings

To our knowledge, the present study is the first to evaluate the feasibility and efficacy of device acquisition from the

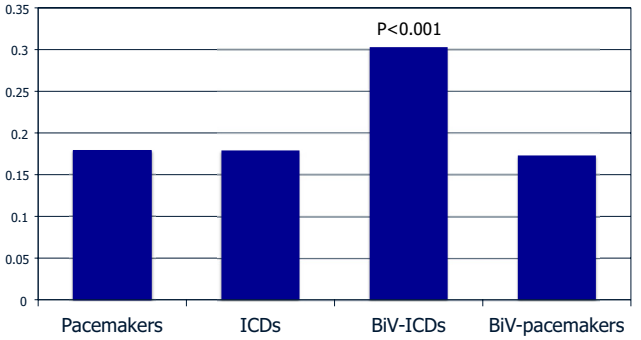

Figure 2 Graph depicting distribution of devices with adequate battery life by type.

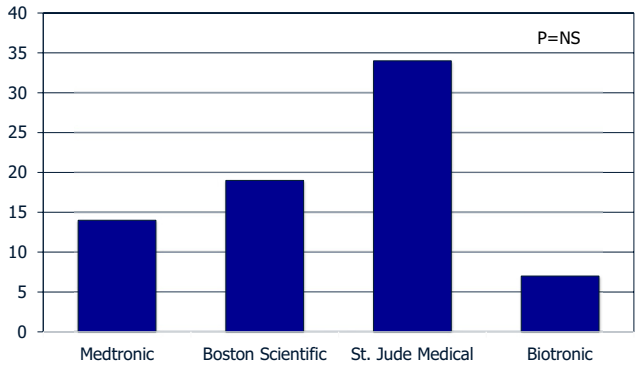

Figure 3 Graph depicting distribution of devices with adequate battery life by brand.

community for potential reutilization in LMICs in patients who are currently unable to afford bradyarrhythmia therapy. This study shows that a substantial number of funeral homes and crematories nationwide are willing to actively participate in the Project MHYH reutilization program. In addition, 21% of devices and 30% of biventricular ICDs donated to the program possess an adequate battery life for potential reutilization.

Current resources for device acquisition in LMICs

Approximately 1 million patients worldwide die annually because of a lack of bradyarrhythmia device therapy.[11,12] Currently, there exist few options for patients in underserved nations who are unable to afford a new pacemaker. Founded in 1984 by Henry D. McIntosh, MD, Heartbeat International is a highly successful non-for-profit organization that supplies pacemakers via Rotary International and the generous donations of devices close to sterility expiration from manufacturers.[12] To date, >9000 patients in over 24 countries and 4 continents have received a new device free of charge. However, this program remains dependent on the generosity of device companies who possess a limited supply of devices close to expiration. Although the accomplishments of this organization can only be described as "exemplary," novel methods of health-care delivery must be further explored to alleviate the morbidity of the 1 million people unable to acquire pacemakers because of a lack of affordability.

For many years, altruistic electrophysiologists have implanted resterilized pacemakers acquired postmortem in LMICs.[13] Prospective studies in the modern era have shown this practice to be safe and efficacious with no complications although severely limited by sample size (total n = 60).[5,6,14] The safety of device reutilization is further supported by a recent meta-analysis examining 18 clinical studies from 1970 to 2010 and >2200 reused devices that found the overall rate of infection and device failure to be <2% and <1%, respectively.[13]

Establishing the feasibility of a pacemaker reutilization program for LMICs

Previous studies have shown that funeral directors, patients, and families of loved ones overwhelmingly support a reuse initiative.[7,15,16] Approximately 84% of funeral directors currently store devices with no intended purpose or discard them as waste.[7] Our data suggest that a significant proportion of these devices have adequate battery life.

These results are not surprising when one considers that in the United States there are approximately 300,000 pacemakers and ICDs implanted annually.[17,18] Median survival after initial pacemaker implantation may be long (~8.5 years),[19] but it is lower in patients who undergo generator replacements. One-year mortality in the SCD-HeFT trial was about 7% and in the COMPANION trial was 12%.[20,21] Patients with an ICD who receive an appropriate shock experience a mean time to death of 168 days.[22] Thus, many device recipients underutilize the expected battery life of 7 to 10 years as described by the manufacturers.

The goal of our proposed initiative is to create a reproducible model where funeral directors are given a framework to consent families of loved ones for device removal prior to burial or cremation. Under current regulations, all pacemakers and ICDs must be explanted prior to cremation because of the risk of device explosion.[23] The Cremation Association of North America estimates a cremation rate of 39% in 2010 and 59% for 2025.[24] Therefore, a theoretical majority of the nearly 2 million individuals with pacemakers and ICDs expected to be cremated in 2025 will have their device explanted per routine protocol.

Regulatory considerations

Although pacemaker reutilization was supported by the 1985 North American Society of Pacing and Electrophysiology Policy Conference[25] and the 2002 American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guideline Update for Implantation of Cardiac Pacemakers,[26] the United States Food, Drug, and Cosmetic Act prohibits the "introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded."[27] In other words, the Food and Drug Administration might consider the acts of resterilizing and transporting a device to an underserved nation as a regulated activity even if the intent is humanitarian export. Two viable solutions exist to alleviate the regulatory concerns. First, the interested parties could simply collect explanted devices and transport them to the underserved nation for subsequent resterilization and reimplantation. The concern with this approach is that the burden of sterilization is placed upon the party who is least able to perform the duties optimally. The other approach is for the interested party to seek Food and Drug Administration approval for export via sections 801(e)(1) and 802 of the federal Food, Drug, and Cosmetic Act.[28,29] Project MHYH is currently in the process of applying for a Food and Drug Administration export license and has received confirmation from potential implanting centers outside of the United States stating that the initiative is not in conflict with the laws of the recipient's country.

Limitations

This study has several limitations. First, determination of remaining battery life is an estimate and may vary according to the frequency of pacing and outputs. Second, further studies are necessary to validate the safety of resterilization prior to the implementation of any pacemaker reutilization initiative. Third, a significant proportion of our devices were donated from Michigan and Florida and, thus, estimation of overall battery life adequacy in funeral homes or crematories may not be generalizable to other regions of the country. Fourth, the analyses of the impact of device type on the probability of adequate battery life were not adjusted for the duration of device use (implant to explant); these data were not available for most of the devices. Therefore, the impact of device types and manufacturers has to be interpreted with caution.

Conclusions

Device donations from funeral homes and crematories appear to be a potential resource for device reutilization for those in need in underserved nations. Approximately 21% of devices and 30% of biventricular ICDs possess an adequate battery life for potential reuse. Establishing a validated pacemaker reutilization program could transform a currently wasted resource into an opportunity for a new life for many citizens in our world.

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