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**Safety and Efficacy of Pacemaker
 Reuse in Underdeveloped Nations
 A Case Series**

To the Editor: The morbidity and mortality associated with cardiovascular disease (CVD) has been steadily declining in industrialized nations over recent decades due to innovations in technology and widespread access to health care; however, the prevalence of CVD is expected to increase 137% between 1990 and 2020 for those living in low- and middle-income countries (LMIC). The increasing prevalence as well as a lack of financial means to address the associated morbidity will result in further disparities between developed nations and LMIC (1). The gap in medical treatment is clearly evident in the field of cardiac electrophysiology—specifically device implantation. This study examines the safety and efficacy of post-mortem pacemaker donation from the U.S. to patients in LMIC.

From January 2008 to July 2008, a total of 50 pacemakers were donated from Detroit metropolitan area funeral homes to World Medical Relief—a nonprofit charitable organization specializing in delivery of medical equipment to LMIC. Of these devices, 18 (36%) were found to have battery life $\geq 70\%$. One of the devices was excluded due to visual defects in structural integrity of the lead terminals.

Informed consent was obtained from all patients' families in order to remove and donate the pacemakers post-mortem. Trained physicians at World Medical Relief inspected and interrogated all pacemakers to assess functionality and remove all patient identifiers. Only pacemakers with $\geq 70\%$ battery life were incorporated into the study. Devices from patients with evidence of communicable infectious disease or that were previously recalled were not accepted.

Devices included in the study were then prepared for sterilization. Pipe cleaners and other instruments were employed to ensure that all debris was removed, specifically at the lead insertion sites. Devices were then bathed with isopropyl alcohol, and soaked overnight in Asepti-zyme (Ecolab, St. Paul, Minnesota) at a concentration of 1:128. Pacemakers were wiped with 70% ethanol, air dried, packed in gas permeable envelopes, and decontaminated via an 8-h ethylene oxide gas sterilization protocol.

Twelve patients were selected for pacemaker implantation at the University of Philippines-Philippine General Hospital utilizing guidelines for standard of care during the period of September 2008 to December 2008. All patients underwent a detailed socioeconomic evaluation and were deemed financially incapable of procuring a permanent pacemaker.

Of the refurbished devices, 8 were implanted as single-chamber devices while the remaining 4 were implanted as dual-chamber devices. For all devices, new leads were purchased through third-party vendors.

The average age of recipients of refurbished pacemakers was 62 ± 10 years (range 28 to 82 years), with 50% of recipients being men. Eleven patients received their initial pacemaker while 1 patient was undergoing elective replacement due to battery end-of-life. Indications for pacemaker placement included complete heart block

(n = 10) and sick sinus syndrome (n = 2). Three patients required transvenous pacing before device placement (Table 1).

There were no complications in the patients with refurbished pacemakers. All patients presented for follow-up at 1 week and 2 months post-procedure. There were no deaths during this follow-up period. Six patients continue to be monitored at the University of Philippines-Philippine General Hospital while 6 patients have been referred to their primary cardiologist for follow-up and monitoring.

In this study, we examined the feasibility and safety of post-mortem pacemaker donation for underserved nations. In our cohort of 12 patients, all refurbished devices were functioning appropriately within 2 months of implantation. Moreover, none of the patients experienced procedural complications such as device malfunction or pacemaker infection despite the fact that several patients were higher risk due to temporary pacing before permanent device implantation. We believe that post-mortem pacemaker implantation is a safe and effective method of delivering health care to those in underserved countries such as the Philippines.

Urbanization, globalization, and increasing age have culminated in an epidemiological evolution of CVD as the primary cause of death globally (2). Moreover, of the 17.5 million deaths worldwide attributed to CVD in 2005, 80% occurred in LMIC (3). Many of these countries lack the financial resources to address this epidemic of CVD. As a result, resources are often directed away from high-cost treatment strategies such as implantable cardiac rhythm management devices.

The argument for pacemaker reuse has been debated for decades within national health care systems. Although the reuse of explanted pacemakers in the U.S. is restricted by the Food and Drug Administration, countries such as Canada and Sweden have published reports highlighting the clinical safety and efficacy of reimplantation (4–6). The 2002 American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology Guideline Update for Implantation of Cardiac Pacemakers even acknowledges that pacemaker reuse “may eventually add significantly to the cost-effectiveness of cardiac pacing.”

In light of the widening health care disparity seen between the industrialized world and developing nations, we feel that pacemaker reuse is an ethical obligation to address the medical needs for those who could not afford therapy otherwise. In accordance with previous studies, our data re-emphasizes that post-mortem pacemaker donation is a safe and effective method of alleviating the morbidity associated with CVD in many individuals. Ongoing research is necessary to evaluate the feasibility of regional and potentially nationwide pacemaker donation programs in order to further alleviate the morbidity and mortality of symptomatic bradyarrhythmia seen in underprivileged nations.

Table 1 Clinical Characteristics of Patients Receiving Refurbished Pacemakers

Patient #	Age (Yrs)	Sex	Pacemaker Indication	Clinical Symptoms	Device Manufacturer	Single Versus Dual Chamber	Complications	Notable Events
1	68	M	Sick sinus syndrome	Syncope	Medtronic	Single	None	—
2	74	M	Third degree block	Dyspnea	St. Jude Medical	Dual	None	—
3	70	M	Sick sinus syndrome	Pre-syncope	Biotronik	Dual	None	—
4	28	F	Third degree block	Syncope	Medtronic	Single	None	—
5	76	F	Third degree block	Syncope	Medtronic	Single	None	*, †
6	47	F	Third degree block	Syncope	Medtronic	Single	None	‡
7	65	F	Third degree block	Syncope	St. Jude Medical	Single	None	*, §
8	55	M	Third degree block	Syncope	St. Jude Medical	Single	None	†
9	60	F	Third degree block	Syncope	St. Jude Medical	Dual	None	—
10	61	M	Third degree block	Syncope	St. Jude Medical	Dual	None	—
11	55	F	Third degree block	Syncope	St. Jude Medical	Single	None	†
12	82	F	Third degree block	Syncope	Biotronik	Single	None	*

*Required transvenous pacing before device placement; †patient had syncopal episodes for 1 year before device placement; ‡device was placed due to end of battery life on previous pacemaker; §patient remained in hospital for 15 days with transvenous pacemaker while waiting for procurement of device.

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REFERENCES

- Joshi R, Jan S, Wu Y, MacMahon S. Global inequalities in access to cardiovascular health care: our greatest challenge. *J Am Coll Cardiol* 2008;52:1817–25.
- Mendis S, Lindholm LH, Mancia G, et al. World Health Organization (WHO) and International Society of Hypertension (ISH) risk prediction charts: assessment of cardiovascular risk for prevention and control of cardiovascular disease in low and middle-income countries. *J Hypertens* 2007;25:1578–82.
- World Health Organization. Cardiovascular Disease. Available at: <http://www.who.int/mediacentre/factsheets/fs317/en/index.html>. Accessed March 6, 2009.
- Linde CL, Bocray A, Jonsson H, Rosenqvist M, Radegran K, Ryden L. Re-used pacemakers—as safe as new? A retrospective case-control study. *Eur Heart J* 1998;19:154–7.
- McGregor M. The reuse of cardiac pacemakers. *Can J Cardiol* 1992;8:697–701.
- Rosengarten M, Chiu R, Hoffman R. A prospective trial of new versus refurbished cardiac pacemakers: a Canadian experience. *Can J Cardiol* 1989;5:155–60.

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