# ORIGINAL ARTICLE

# Infections Associated with Resterilized Pacemakers and Defibrillators

Thomas F. Khairy, Marie-Andrée Lupien, B.Sc., Santiago Nava, M.D., Frank Valdez Baez, M.D., Fernando Solares Ovalle, M.D., Nery E. Linarez Ochoa, M.D., Gerardo Sosa Mendoza, M.D., Cesar A. Carrazco, M.D., Christine Villemaire, M.Sc., Richard Cartier, M.Sc., Denis Roy, M.D., Mario Talajic, M.D., Marc Dubuc, M.D., Bernard Thibault, M.D., Peter G. Guerra, M.D., Lena Rivard, M.D., Katia Dyrda, M.D.,
Blandine Mondésert, M.D., Rafik Tadros, M.D., Ph.D., Julia Cadrin-Tourigny, M.D., Laurent Macle, M.D., and Paul Khairy, M.D., Ph.D.

# ABSTRACT

#### BACKGROUND

Access to pacemakers and defibrillators is problematic in places with limited resources. Resterilization and reuse of implantable cardiac devices obtained post mortem from patients in wealthier nations have been undertaken, but uncertainty around the risk of infection is a concern.

## METHODS

A multinational program was initiated in 1983 to provide tested and resterilized pacemakers and defibrillators to underserved nations; a prospective registry was established in 2003. Patients who received reused devices in this program were matched in a 1:3 ratio with control patients who received new devices implanted in Canada. The primary outcome was infection or device-related death, with mortality from other causes modeled as a competing risk.

#### RESULTS

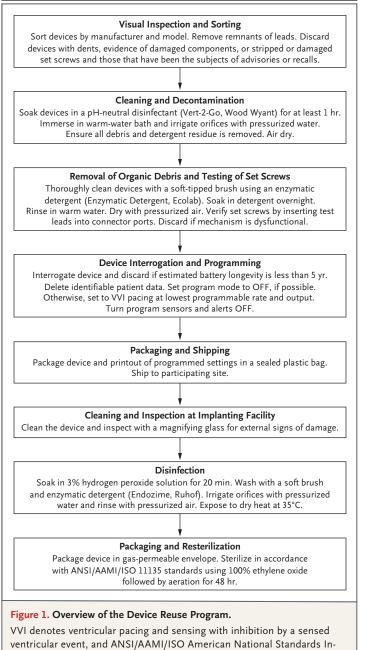
Resterilized devices were implanted in 1051 patients (mean [ $\pm$ SD] age, 63.2 $\pm$ 18.5 years; 43.6% women) in Mexico (36.0%), the Dominican Republic (28.1%), Guatemala (26.6%), and Honduras (9.3%). Overall, 85% received pacemakers and 15% received defibrillators, with one (55.5%), two (38.8%), or three (5.7%) leads. Baseline characteristics did not differ between these patients and the 3153 matched control patients. At 2 years of follow-up, infections had occurred in 21 patients (2.0%) with reused devices and in 38 (1.2%) with new devices (hazard ratio, 1.66; 95% confidence interval, 0.97 to 2.83; P=0.06); there were no device-related deaths. The most common implicated pathogens were *Staphylococcus aureus* and *S. epidermidis*.

# CONCLUSIONS

Among patients in underserved countries who received a resterilized and reused pacemaker or defibrillator, the incidence of infection or device-related death at 2 years was 2.0%, an incidence that did not differ significantly from that seen among matched control patients with new devices in Canada.

From the Montreal Heart Institute, Université de Montréal, Montreal (T.F.K., M.-A.L., C.V., R.C., D.R., M.T., M.D., B.T., P.G.G., L.R., K.D., B.M., R.T., J.C.-T., L.M., P.K.); Instituto Nacional de Cardiologia, Ignacio Chavez, Mexico City (S.N.); the Dominican Institute of Cardiology, Santo Domingo, Dominican Republic (F.V.B.); Clínicas Médicas las Américas, Guatemala City, Guatemala (F.S.O.); and Cardiología Hospital General del Sur, Choluteca (N.E.L.O.), and Instituto Nacional Cardiopulmonar (G.S.M.) and Medicina Interna-Programación de Marcapaso Definitivo, Instituto Nacional Cardiopulmonar, Tegucigalpa (C.A.C.) — all in Honduras. Address reprint requests to Dr. Paul Khairy at the Montreal Heart Institute Adult Congenital Center, Montreal Heart Institute, 5000 Belanger St. E., Montreal, QC H1T 1C8, Canada, or at paul.khairy@umontreal.ca.

N Engl J Med 2020;382:1823-31. DOI: 10.1056/NEJMoa1813876 Copyright © 2020 Massachusetts Medical Society. CCESS TO PERMANENT PACEMAKERS and implantable cardioverter-defibrillators (ICDs) is problematic in some countries with limited resources.<sup>1</sup> One potential strategy to address disparities in access to cardiac devices is for wealthier nations to harvest devices post mortem so that devices in good condition



stitute, Association for the Advancement of Medical Instrumentation, and

International Organization for Standardization.

with adequate remaining battery life can be resterilized and reused. Although the concept of reusing cardiac implantable electronic devices was introduced decades ago, the paucity of safety data regarding infections has been an important reservation expressed about programs that reuse devices.<sup>2</sup> Small, predominantly single-center case series provide reassuring data but are subject to methodologic limitations such as the lack of a comparator group with new devices and insufficient statistical power.<sup>3-10</sup>

In 1983, a program was established at the Montreal Heart Institute to send recycled pacemakers and ICDs to underserved nations for resterilization and reuse; this program subsequently evolved into a citywide initiative. In 2003, a prospective registry was created to track outcomes. The objectives of the current study were to quantify the incidence of infection after primary implantation of a resterilized and reused pacemaker or ICD, identify factors associated with infections, and compare the incidence of infection among patients with reused devices with that among matched control patients who received new devices.

#### METHODS

## DEVICE REUSE PROGRAM AND REGISTRY

A total of 28 funeral homes and crematories in the province of Quebec, Canada, have participated in the Montreal Heart Institute device reuse program since it was established in 1983. In accordance with the Quebec civil code, pacemakers and ICDs are extracted post mortem with written authorization provided by the patient before death or authorization from the next of kin. The pacemakers and ICDs are then sent to the Montreal Heart Institute, where they are sorted, cleaned, decontaminated, and interrogated. Usable devices are then sent to the implanting facility for disinfection, resterilization, and reuse. An overview of the decontamination. disinfection, and resterilization process is summarized in Figure 1 and in the Supplementary Appendix, available with the full text of this article at NEJM.org. Patients or their proxies provide consent for implantation of reused cardiac devices after receiving explicit information regarding the potential hazards and unknown risks particular to reused devices.

In 2003, the prospective Heart to Heart registry was created as a quality-control measure to enable the tracking of outcomes in patients in the device reuse program. The registry includes deidentified data on institutional characteristics, the date of surgery, and the primary indication for device implantation; the patient's sex and the patient's age at the time of surgery; and the type of device (i.e., pacemaker or ICD, with or without cardiac resynchronization therapy), device mode, manufacturer and model of the device, and number and location of implanted leads.

# OUTCOMES STUDY

A subset of implanting centers participating in the device reuse program was selected for participation in the current outcomes study. The study was approved by the research and ethics committees at the Montreal Heart Institute.

Inclusion criteria for implanting centers participating in the outcomes study are listed in Table S1 in the Supplementary Appendix. Participating centers had between two and five implanting physicians. At all sites, the most senior implanting physician had more than 5 years of experience. All centers had on-site ethylene oxide sterilization facilities that complied with the American National Standards Institute, Association for the Advancement of Medical Instrumentation, and International Organization for Standardization (ANSI/AAMI/ISO) 11135 standards. At least one dose of an intravenous antibiotic (i.e., cephalosporin, penicillin derivative, or vancomycin) was administered prophylactically before the procedure at all sites. All interventions were performed in operating rooms, where the skin was assiduously disinfected before surgery. The first follow-up visit was scheduled within 4 to 6 weeks after the procedure. Thereafter, patients with ICDs or cardiac resynchronization therapy devices were followed at least twice a year, and those with pacemakers were followed at least once a year.

### STUDY PATIENTS AND CONTROLS

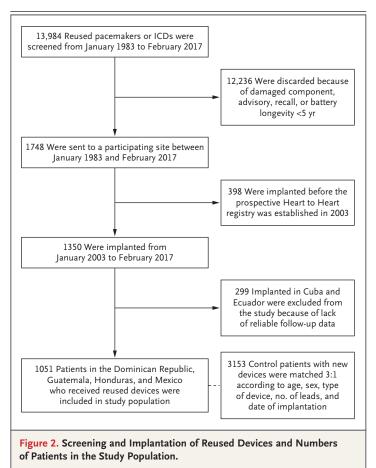
The study population consisted of patients of any age from a participating site who had primary implantation of a reused pacemaker or ICD that had been sent from Montreal during the period from January 2003 through February 2017. Each patient with a reused pacemaker or ICD was matched with three control patients in whom new devices had been implanted at the Montreal Heart Institute. Exact matching without replacement was performed according to type of device, patient's age and sex, number of leads, and date of implantation. Controls were identified through the Paceart Optima (Medtronic) database at the Montreal Heart Institute. Matching was performed with a two-step hierarchical selection process. First, eligible control patients of the same sex as the registry patient were identified with an identical year of implantation, type of device (pacemaker or ICD, with or without cardiac resynchronization therapy), and number of implanted leads (1, 2, or 3). From this set, the three control patients closest in age to the registry patient (within a 5-year age range) were retained.

#### FOLLOW-UP DATA AND OUTCOMES

Follow-up information on registry patients and matched control patients was retrospectively collected at each participating center until November 2019 and transmitted without patient identifiers. The data collected included device changes, date of the last visit, and details regarding infections and deaths (device-related or other). The primary outcome was a composite of infection or device-related death over 2 years of follow-up. Infection was defined according to American Heart Association guidelines on cardiac electronic device infections and included breaching of the skin due to erosion, generator-pocket infection, lead infection, and device-related infectious endocarditis.11 Device-related death was defined as death attributable to a device-related infection, malfunction, or premature battery depletion.<sup>12</sup> Malfunction included failure of the pacemaker, defibrillator, or lead and inappropriate shocks leading to death.

## STATISTICAL ANALYSIS

Continuous variables are summarized as means and standard deviations or medians and interquartile ranges, depending on the normality of distribution. Categorical variables are represented by frequencies and percentages. Freedom from infection or device-related death was plotted with the Kaplan–Meier product-limit method. After proportionality assumptions were verified, factors associated with infection or device-related



death were assessed with a competing-risk Cox proportional-hazards model, from which subhazard ratios were derived.<sup>13</sup> Death unrelated to the device was modeled as a competing risk, with censoring of data at the end of the 2-year period or at the last follow-up.

In assessing the association between reused, as compared with new, devices and the primary outcome, we conducted several sensitivity analyses. First, a cause-specific hazard function was derived from a Cox regression model that considered death unrelated to the device as a competing risk.<sup>14</sup> Second, subhazard and cause-specific hazard functions were assessed in models that assumed that all losses to follow-up were non-device-related deaths. Third, subhazard and cause-specific hazard functions were derived from models that assumed that all losses to follow-up were due to infection or device-related death. Finally, subhazard and cause-specific hazard ratios were assessed in models in which exact matching of the device manufacturer was performed by fine balancing (i.e., exact balancing that does not require individually matched treated and control subjects) with the use of a patterned distance matrix.<sup>15</sup> A two-tailed P value of less than 0.05 was considered to indicate statistical significance. Only the P value related to the primary outcome is presented, with no adjustment for multiple testing. Statistical analyses were performed with the use of SAS software, version 9.4 (SAS Institute).

# RESULTS

#### STUDY POPULATION

Figure 2 shows the numbers of devices screened and implanted and the numbers of patients included in the study population. Since the device reuse program was initiated in 1983, a total of 13,984 previously used pacemakers and ICDs were screened for eligibility; 1748 (12.5%) were retained and sent to eight participating sites in Cuba, the Dominican Republic, Ecuador, Guatemala, Honduras, and Mexico for primary implantation. Patients who received devices before the prospective registry was established in 2003 were excluded (398 patients), as were those whose devices were implanted at the centers in Cuba and Ecuador, which did not meet eligibility criteria (299 patients). The study population consisted of the remaining 1051 patients from Mexico (378 patients [36.0%]), the Dominican Republic (295 [28.1%]), Guatemala (280 [26.6%]), and Honduras (98 [9.3%]). The patients in the study population were matched in a 1:3 ratio to 3153 control patients who had undergone primary implantation of new devices in Montreal.

## BASELINE CHARACTERISTICS

The baseline characteristics of patients who received reused or new pacemakers or ICDs are shown in Table 1. (Characteristics according to country of implantation are provided in Table S2.) The mean (±SD) age of patients with reused devices was 63.2±18.5 years; 43.6% were women. Overall, 85% received pacemakers and 15% received ICDs; 60 devices were cardiac resynchronization therapy devices, of which 7 were pacemakers and 53 were ICDs. Single leads were implanted in 55.5% of the patients, two leads in 38.8%, and three leads in 5.7%. Primary indications for device implantation were atrioventricular block (687 patients [65.4%]), sinus node dysfunction (134 [12.7%]), heart failure with reduced ejection fraction (98 [9.3%]), slow atrial fibrillation (66 [6.3%]), ventricular tachyarrhythmia or resuscitated cardiac arrest (36 [3.4%]), and syncope (30 [2.9%]). Device manufacturers included Medtronic (61.7%), St. Jude Medical (36.7%), and Boston Scientific (1.6%). The age of the 3153 control patients with new pacemakers or ICDs was similar to that of the patients with reused devices, and the two groups had identical characteristics with respect to sex, type of device implanted, number of leads, and year of implantation.

# OUTCOMES

Outcome ascertainment during the 2-year follow-up period was complete in 1027 patients (97.7%) with reused devices and in 3087 (97.9%) with new devices. No device-related death occurred. Non-device-related deaths occurred in 42 of 1051 patients (4.0%) with reused devices and in 124 of 3153 control patients (3.9%) with new devices.

Data on freedom from infection or devicerelated death among patients with reused as compared with new devices are shown in Figure 3. During follow-up, 21 infections (2.0%) occurred among patients with reused devices and 38 (1.2%) occurred among patients with new devices (hazard ratio, 1.66; 95% confidence interval [CI], 0.97 to 2.83; P=0.06). Infections occurred a median of 66 days (interquartile range, 42 to 239) after device implantation among patients with reused devices as compared with 61 days (interquartile range, 24 to 200) after implantation among patients with new devices. The most common implicated pathogen was Staphylococcus aureus (in 13 patients [61.9%] with infections involving reused devices and in 23 patients [60.5%] with infections involving new devices), followed by S. epidermidis (3 [14.3%] and 9 [23.7%], respectively). Additional infectious agents included Cutibacterium acnes (1 infection involving a reused device and 3 involving a new device). Pseudomonas aeruginosa (0 and 2 infections, respectively), and other or unknown (4 and 1 infections, respectively).

Associations between baseline characteristics and infection or device-related deaths are sum-

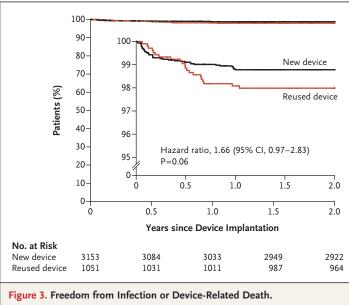
Table 1. Characteristics of the Patients and Devices at Baseline.*		
Characteristic	Reused Pacemaker or ICD (N=1051)	New Pacemaker or ICD (N=3153)
Age — yr	63.2±18.5	64.4±17.4
Female sex — no. (%)	458 (43.6)	1374 (43.6)
Country in which device was implanted — no. (%)		
Mexico	378 (36.0)	—
Dominican Republic	295 (28.1)	—
Guatemala	280 (26.6)	—
Honduras	98 (9.3)	_
Canada	—	3153 (100)
Type of device — no. (%)		
Pacemaker	893 (85.0)	2679 (85.0)
ICD	158 (15.0)	474 (15.0)
Number of leads — no. (%)		
1	583 (55.5)	1749 (55.5)
2	408 (38.8)	1224 (38.8)
3	60 (5.7)	180 (5.7)
Device manufacturer — no. (%)		
Medtronic	648 (61.7)	994 (31.5)
St. Jude Medical/Abbott	386 (36.7)	1297 (41.1)
Boston Scientific/Guidant	17 (1.6)	293 (9.3)
Biotronik	—	332 (10.5)
Sorin Group/ELA Medical	_	237 (7.5)

\* Plus-minus values are means ±SD. Percentages may not total 100 because of rounding. ICD denotes implantable cardioverter-defibrillator.

marized in Figure 4A. The only factor significantly associated with the primary outcome was younger patient age (hazard ratio, 0.98 per year of age; 95% CI, 0.97 to 0.99). In a multivariable analysis including all factors associated with infection or device-related death, the point estimate for the association between reused as compared with new devices and the primary outcome was essentially identical to that in the univariable analysis (hazard ratio, 1.66; 95% CI, 0.98 to 2.83). Sensitivity analyses yielded consistent results (Fig. 4B).

#### DISCUSSION

Lack of patient access to cardiac implantable electronic devices in countries with limited resources contributes to global disparities in care.<sup>16</sup> Physi-



Shown are Kaplan–Meier curves for freedom from infection or device-related death among patients with reused and new devices. The inset shows the same data on an expanded y axis.

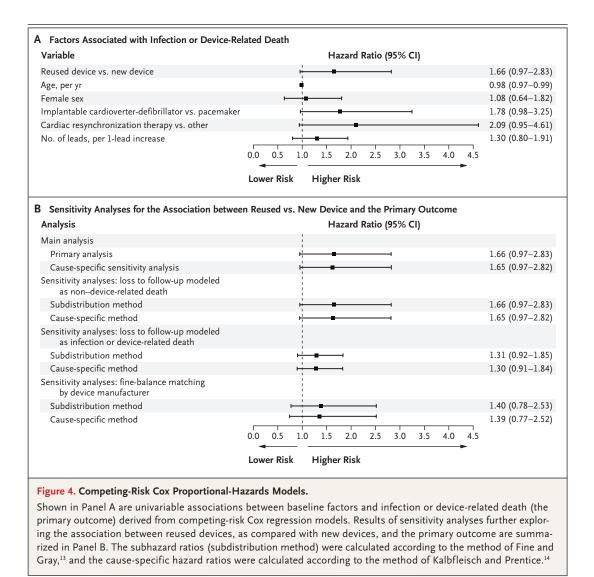
cians in underserved areas cite unaffordable costs as the greatest impediment to offering device therapy to their patients.<sup>2</sup> Indeed, the cost for a new pacemaker generator has been estimated to be (U.S.) \$2,500 to \$8,000 and for an ICD approximately \$10,000 to \$18,000.<sup>12</sup> To address the need for wider access to these devices, programs have emerged to donate previously used devices to underserved nations.

Surveys indicate that most physicians and device recipients are receptive to resterilization and reuse programs.<sup>2</sup> Nevertheless, a common reservation expressed is the uncertain risk of infection.<sup>2</sup> In our study, we found a reassuringly low incidence of infection (i.e., 2.0% at 2 years) among more than 1000 patients with reused devices from four participating resource-limited countries - the Dominican Republic, Guatemala, Honduras, and Mexico. Moreover, the incidence of infection among patients with reused devices was not significantly higher than that for more than 3000 control patients with new devices matched according to age, sex, type of device, number of leads, and year of implantation. The 95% confidence interval for the hazard ratio in the primary competing-risk analysis ranged from 0.97 to 2.83, which suggests that,

in a larger study, the difference between groups might have been statistically significant. As such, these results cannot definitively exclude the possibility of a higher risk associated with reused devices. Nevertheless, in this study, in which the incidence of infection was low, the estimated absolute difference in risk was less than 1 percentage point.

A recent systematic review identified nine small, single-center, observational studies involving device reuse with results published between 2009 and 2017.12 Four case series with no controls included 12 to 81 patients in the Philippines, Nicaragua, and India who received reused devices.<sup>3,6-8</sup> One study from China involved 99 infected devices resterilized and reimplanted in the same patients.<sup>17</sup> The remaining four studies from Mexico, South Africa, Romania, and India included a combined total of 757 patients with reused devices and 1145 nonmatched control patients with new devices who were followed for a median of less than 3 years.<sup>4,5,18,19</sup> Infections occurred in 2.0% of the patients (15 of 757) with reused devices and in 1.8% of the patients (21 of 1145) who received new devices.<sup>12</sup> The findings from our multicenter study, which includes more than 1000 patients with more than 3000 controls, are therefore consistent with these findings. Moreover, we found the pattern of infectious agents to be similar among patients with reused devices and those with new devices, with more than 75% of infections due to S. aureus or S. epidermidis.

There are several practical and ethical issues to consider in establishing device reuse programs. Although cardiac implantable electronic devices must be removed before cremation owing to the risk of battery explosion if incinerated, practices are inconsistent regarding burial. Depending on local jurisdictions, explanting a pacemaker or ICD may or may not be legally required. For example, in Sweden, postmortem retrieval is required by health authorities and cannot be refused by patients. In the United States, there are no federal statutes specific to ownership of medical devices after death.1 In Canada, devices have historically been considered the property of patients or their next of kin. A survey of funeral directors in Michigan indicated that in 85% of cases, cardiac implantable electronic devices are buried with the patient.<sup>20</sup>



When the devices are retrieved, 84% are stored with no intended purpose or are discarded as medical waste. Yet, in the current era, more than 60% of pacemakers and more than 50% of ICDs function normally after they are removed from a person who has died, with projected longevity of more than 7 years on average.<sup>21</sup>

All device manufacturers label their products as appropriate for single use only, such that in the United States, Europe, or Canada, they cannot be reimplanted. In fact, the Food and Drug Administration considers pacemaker reuse to be "an objectionable practice," raising "a serious question whether pacemakers can be properly resterilized following initial implantation . . . ."<sup>22</sup> Although the risk appears to be low, transmission of infectious diseases remains a potential issue; the transmission of entities such as acquired Creutzfeldt–Jakob disease is of particular concern, considering that prions are resistant to conventional sterilization methods. The restrictive regulatory climate in high-income countries neither precludes nor sanctions the donation of devices after a person's death to regions that have no viable alternatives.

Despite the large sample size that resulted from our multicenter experience with prospective identification of device recipients, the study is observational and limited by the retrospective ascertainment of outcomes and restricted number of variables collected. Considering the challenges in obtaining robust data from various resource-limited settings, sites without established infrastructures for routine documented follow-up were excluded and outcomes were limited to infections and deaths. Nonetheless, it is possible that reporting limitations could have reduced our ability to identify and include some events in the group of patients who received reused devices. Matched control patients had their new devices implanted in a high-income country, thereby introducing a potential selection bias away from the null hypothesis. For example, a higher burden of coexisting conditions has been associated with an increased risk of complications after implantation of cardiac electronic devices,<sup>23</sup> and poor nutritional status can alter immune function and resistance to infection.24 It is therefore possible that the nonsignificant difference in infection rates between reused and new devices would have been even smaller if devices had been implanted in the same clinical environments. Finally, the results obtained in our study were based on the use of a systematic protocol for device recovery, cleaning, inspection, decontamination, and sterilization, as well as specific requirements for the implanting centers. Results with less rigorous protocols may not be similar and potentially could be associated with a higher risk of poor outcomes in patients with reused cardiac implantable electronic devices.

Ethical barriers prevent the conduct of a randomized trial of device reuse in a high-income country. Efforts to pursue such a trial in underserved nations are in progress, although several hurdles remain to be resolved, including generating sufficient funds, providing the necessary infrastructure for trial participation and followup, and securing the donation of cardiac implantable electronic devices and leads.<sup>25</sup>

In conclusion, we evaluated patients in underserved countries who had received resterilized and reused cardiac implantable electronic devices and observed an incidence of infection or device-related death of 2.0% at 2 years. We compared outcomes in these patients with those in matched control patients who received new devices implanted in a high-income country. We did not detect a significant difference between the two groups in the incidence of infection or device-related death at 2 years.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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