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Reuse of Pacemakers Comparison of Short and Long-term Performance

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Background—In developing economies, there are patients in whom pacemaker implantation is delayed because they cannot afford one. Reused devices have been a solution. To address concerns about safety, a cohort of consecutive patients implanted with a reused pacemaker was compared with a control group.

Methods and Results—A cohort of 603 consecutive patients from 2000 to 2010 was studied in an ambispective noninferiority study. The study group patients (n=307) received resterilized pacemakers, and the control group patients (n=296) received a new pacemaker. A combined end point of 3 major outcomes—unexpected battery depletion, infection, and device dysfunction—was analyzed. A total of 85 pacemakers had to be explanted, 31 in the control group (10.5%) and 54 in the study group (17.6%; relative risk, 1.68; 95% confidence interval, 1.1–2.5; $P=0.02$). Forty-three reached the primary end point, 16 in the control group (5.5%) and 27 in the study group (7.2%; relative risk, 1.3; 95% confidence interval, 0.70–2.45; $P=0.794$). In terms of individual outcomes, 5 new pacemakers (1.7%) and 11 resterilized pacemakers (3.6%) had unexpected battery depletion (relative risk, 2.12; 95% confidence interval, 0.75–6; $P=0.116$); 3.7% new pacemakers and 3.2% reused pacemakers had a procedure-related infection (relative risk, 0.87; 95% confidence interval, 0.38–2.03; $P=0.46$); and 1 pacemaker in the study group malfunctioned.

Conclusions—Pacemaker reuse is feasible and safe and is a viable option for patient with bradyarrhythmias. Other than the expected shorter battery life, reuse of pacemaker generators is not inferior to the use of new devices. (*Circulation*. 2013;127:1177-1183.)

Key Words: heart block ■ pacemaker ■ resterilization ■ retrieval device

Pacing with implantable devices (pacemakers) is a lifesaving therapy for patients with bradyarrhythmias. In countries without full medical coverage, a significant proportion of patients cannot afford such a device. Donations of new devices by different charities are a reality but rarely cover the full extent of patients requiring a device. Reuse of explanted devices from cadaveric donations, after careful selection and sterilization, has been a solution for these patients in several countries.¹⁻⁷ However, serious concerns about safety and even efficacy have been raised about this practice.⁸⁻¹³ A few studies have reported on this issue in recent years and found no solid evidence against this procedure.¹⁻⁷ In our institution, a tertiary referral center, cadaveric donation with subsequent resterilization and implantation of these reused pacemaker has been a common practice for patients for whom a new device cannot be obtained by other means or strategies. To provide more evidence that this practice is safe, we studied a cohort of consecutive patients who received either a new or a reused pacemaker, considering a combined end point of 3 major determinants: unexpected battery depletion, infection, and device dysfunction.

Clinical Perspective on p 1183

Methods

A single-center cohort of consecutive patients from 2000 to 2010 was studied in an ambispective, noninferiority study. From 2000 to 2005, the analysis was made retrospectively; from 2005 to 2010, it was done prospectively. Because no previous reports have accounted for the percentage of patients with a primary outcome in resterilized devices, the number of patients needed to evaluate the noninferiority margin was calculated by taking into consideration previous reports on device performance¹⁴ and device infection.¹⁵ We assigned a value of 20% of events for the primary outcome in the control group (new devices) with a relative risk (RR) of <1.5 in the study group (resterilized devices), assuming a 2-tailed type I error significance level of 0.05 and a type II error of 0.20 with a power of 0.80. The number of patients calculated to be required was 323 per group, with 10% loss to follow-up anticipated.

For this analysis, our control group consisted of patients ≥ 18 years of age with Class I American Heart Association/American College of Cardiology/European Society of Cardiology indication for pacing who could afford a new pacing device. The study group consisted of patients who could not afford a new pacemaker, could not obtain a new one through donation within a waiting period defined by their attending physician according to their cardiac status, and were offered a resterilized device, 96% of them from cadaveric donation. All patients gave informed consent after being informed in detail about all the potential complications from the procedure and, for the study group, specifically those from a resterilized device.

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Criteria for Reuse

Pacemakers were obtained via cadaveric donation either by explantation of the devices at our center after family approval or by direct donation from family members who received the device in funeral homes or other hospitals. Devices are received by the Social Service Department of our institution and then submitted to the following procedure for sterilization. A special team of technicians in the Interventional Cardiology Department receive the device, clean the pacemaker, and inspect it with a magnifying glass. All generators with external signs of damage are excluded from reuse. Devices are placed in a solution of 3% hydrogen peroxide for 20 minutes and then washed with a soft brush with enzymatic detergent (Endozime). Orifices are irrigated with pressurized water and rinsed with pressurized air. Finally, devices are left in dry heat at 35°C. A physician in the Electrophysiology Department checks with the programmer to determine battery current, impedance, and programmed values. The pacemaker is then reprogrammed to the minimum heart rate and voltage output permitted by the device or the device is turned off if possible. Considering that the calculated life for a new device is ≈ 8 years, a reused device appropriate for implantation should have $\geq 50\%$ of the battery life left, so only devices with a battery expectancy of >4 years are approved for reuse. Finally, the device is packed, labeled, and sterilized in ethylene oxide for 15 hours and returned to the Social Service Department. When patients with a Class I indication for pacing (American College of Cardiology/American Heart Association indications) cannot afford a new pacemaker, the head of the Social Service Department assigns the device to those patients who are proven by a socioeconomic evaluation to be unable to buy a new device. Only devices resterilized in our center are used in our institution.

Implantation Procedure and Follow-up

Devices are implanted by an electrophysiologist or interventional cardiologist. All patients receive a prophylactic dose of antibiotic, usually cephalothin 1 g or equivalent intravenously, at implantation. One week later, patients attend the Wound Control Clinic where a trained nurse inspects the surgical wound, cleans it, and removes sutures. Six weeks after the procedure, patients are checked into the Pacemaker Clinic, and long-term pacing parameters are reprogrammed if appropriate. Afterward, patients are followed up twice a year in the same clinic and in the general Cardiology Outpatient Clinic.

End Point and Definitions

For this analysis, the following definitions were used. Expected battery depletion occurred when the elective replacement indication on the device was reached after 8 years. Unexpected battery depletion was defined according to the studied groups. For new pacemakers, early battery depletion was defined as depletion before the sixth year after implantation without relation to high pacing outputs or abnormal electrode impedances that would void the device warranty. Premature battery depletion was considered to have occurred when the elective replacement indication was reached between the sixth and eighth years after the initial implantation. For resterilized pacemakers, as previously mentioned, at our institution, we consider for reuse only those devices that have at least 50% of their calculated battery life left. If we consider the expected battery depletion for new devices to occur at 8 years, then the expected battery depletion in reuse devices would occur after the fourth year, early battery depletion, before the second year, and premature battery depletion between the second and fourth years. To define infection, we used the classification proposed by Byrd in the classic textbook by Ellenbogen et al¹⁶ that described 4 types of infection: I, right endocarditis with electrode involvement; II, sepsis without evidence of involvement of the circuit or pocket; III, infection of the pacemaker pocket; and IV, extrusion of wires or generator.

We considered early infection to occur in the first month after implantation and late infection to occur in the first year after implantation that could be considered to be related to the procedure. After the first year, infection is not considered to be related to the procedure.¹⁷

The primary end point was defined as the need to remove or change the device because of unexpected battery depletion (including early and premature battery depletion), infection, or device or electrode malfunction (software or hardware malfunction). For statistical analysis, groups were frequency matched.

An elective procedure was defined as an indication for pacing that would not put the patient's integrity in danger, and therefore the patient could be ambulatory. A procedure was considered urgent when the patient's integrity was at risk and the patient needed to be hospitalized until the procedure was done. A procedure was considered an emergency procedure when the patient's life was at risk (ie, low cardiac output, Stokes-Adams crisis, ventricular arrhythmias) or a temporary pacemaker had to be implanted.

Statistical Analysis

The clinical end point between groups was determined by an RR with a 95% confidence interval (CI). Continuous variables were expressed as mean and SD. Variables without normal distribution were expressed as median and interquartile range. The Student *t* and Mann-Whitney *U* tests were used to compare continuous variables. The χ^2 test and Fisher exact test were used for categorical variables. Kaplan-Meier curves with log-rank test were used for the survival analysis. A value of $P \leq 0.05$ was considered significant.

Results

A total of 639 patients were studied, 323 in the study group (resterilized pacemakers) and 316 in the control group (new pacemakers). Thirty-six patients were lost to follow-up, 16 patients in the study group (4.9%) and 20 in the control group (6.3%). For the final analysis, 603 patients were considered, 307 in the study group and 296 in the control group. In the general population, the median follow-up was 4.16 years (interquartile range, 2.75–6 years). In the control group, the median follow-up was 4.16 years (interquartile range, 2.6–6.6 years). For the study group, the median follow-up was 4.10 years (interquartile range, 2.83–5.65 years; $P=0.397$). General characteristics of both groups are shown in Table 1. Both groups were similar in age, sex, and risk factors. Ejection fraction and indication for pacing were similar between groups. The procedure was considered elective in 55% of all patients, 61.4% of the control group, and 49.8% of the study group. Procedures were considered to be urgent in 27% of patients in the control group versus 24% of patients in the study group and emergency in 11% of patients in the control group versus 26% of patients in the study group ($P=0.001$). In addition, the time spent in the hospital before the implantation was longer for the study group at a median of 4 days (interquartile range, 1–8 days) versus 2 days (interquartile range, 1–4 days; $P=0.001$). In Table 2, device data before and after the procedure and during follow-up are summarized. No statistical differences between groups were observed except for the percentage of ventricular pacing time, which was higher in the study group ($88 \pm 18.6\%$ versus $84 \pm 21.5\%$; $P=0.009$). Output of the ventricular electrode was also higher in the study group (2.27 ± 0.47 versus 2.14 ± 0.26 V; $P=0.026$), as was electrode impedance, but within the normal range.

At the end of follow-up, 85 devices had to be explanted for any reason, 31 in the control group (10.5%) versus 54 in the study group (17.6%; RR, 1.68; 95% CI, 1.1–2.5; $P=0.02$). Of these 85 pacemakers, 43 were explanted because they had reached the primary event, 16 in the control group (5.5%) and 27 in the study group (7.2%), for an RR of 1.3 (95% CI,

Table 1. General Characteristics of the Study Population

	Study Group (n=307)	Control Group (n=296)	P
Age, mean±SD, y	59.91±20.57	60.36±19.08	0.783
Sex, n (%)			0.349
Male	158 (51.5)	158 (53.4)	
Female	149 (48.5)	138 (46.6)	
Diabetes mellitus, n (%)	79 (26.7)	79 (25.7)	0.431
Arterial hypertension, n (%)	163 (53.1)	152 (51.4)	0.364
Renal impairment, n (%)	38 (12.4)	31 (10.5)	0.272
Cardiomyopathy, n (%)	156 (50.8)	129 (43.5)	0.750
Ischemic	43 (14.0)	46 (15.5)	
Hypertensive	20 (6.5)	21 (7.1)	
Valvular	52 (17)	35 (11.8)	
Congenital	34 (11.1)	22 (7.4)	
Other	7 (2.3)	5 (1.7)	
LVEF, %	57.31±13.54	59.30±14.11	0.520
Sick sinus syndrome, n (%)	65 (21.2)	82 (27.7)	0.065
AV block, n (%)	194 (63.2)	169 (57.1)	0.143
AF with slow ventricular rate, n (%)	42 (13.7)	35 (11.8)	0.432
Other, n	6 (2)	10 (3.4)	0.263
Procedure, n (%)			0.001
Elective	153 (49.8)	182 (61.4)	
Urgent	74 (24.1)	80 (27.1)	
Emergency	80 (26.1)	34 (11.5)	
Waiting period before the implantation, median (interquartile range), d	4 (1–8)	2 (1–4)	0.001
First implantation, n (%)	259 (84.4)	257 (86.8)	0.229
Battery change, n (%)	48 (15.6)	39 (13.2)	0.432

AF indicates atrial fibrillation; AV, atrioventricular; and LVEF, left ventricular ejection fraction.

0.70–2.45; $P=0.794$; Figure 1). Thus, for reaching our primary end point, resterilized pacemakers are not inferior to new pacemaker. During follow-up, 45 patients died in the control group (15.2%) versus 39 patients in the study group (12.7%; RR, 0.83; 95% CI, 0.56–1.24; $P=0.376$). Because differences in follow-up times could influence results, cumulative survival analysis was performed for the primary event and for all explanted pacemakers and showed no difference between groups for the primary end point ($P=0.340$) and a significant difference between groups for all pacemakers explanted for any reason ($P=0.048$; Figure 2A and 2B). This difference is evident only after the fifth year of follow-up, which is most likely explained by the difference in battery life for resterilized pacemakers.

Each of the events that composed the primary end point was analyzed separately.

Battery Duration

Unexpected battery depletion was observed in 5 devices in the control group (1.7%) versus 11 in the study group (3.6%; RR,

Table 2. Pacemakers Parameters in Studied Patients

	Study Group	Control Group	P
DDD, n (%)	128 (41.7)	123 (41.6)	0.510
VVI, n (%)	179 (58.9)	173 (58.4)	0.645
Minimum pacing rate, bpm	59±3.8	59±4.6	0.433
Ventricular pacing %	88±18.6	84±21.5	0.009
Battery voltage, V	2.76±0.3
Battery current, μ A	12±3.4
Battery impedance, $k\Omega$	1.30±1.9
Estimated battery life, y	5.61±1
Capture			
Amplitude, V			
Atrial	0.55±0.2	0.58±0.2	0.936
Ventricular	0.58±0.2	0.63±0.2	0.473
Pulse width, ms			
Atrial	0.44±0.06	0.43±0.07	0.634
Ventricle	0.43±0.08	0.44±0.07	0.632
Sensitivity, mV			
Atrial	3.71±1.3	3.3±1.2	0.090
Ventricle	11.9±4.3	12±4.5	0.571
Output			
Amplitude, V			
Atrial	2.14±0.2	2.10±0.2	0.251
Ventricle	2.27±0.4	2.14±0.2	0.026
Width, ms			
Atrial	0.43±0.06	0.42±0.7	0.612
Ventricle	0.44±0.06	0.43±0.7	0.745
Electrode impedance, Ω			
Atrial	606±203	596±184	0.013
Ventricle	650±196	610±197	0.011
Energy, μ J	3.07±1.7	3.03±1.9	0.118

2.12; 95% CI, 0.75–6; $P=0.116$; Figures 1 and 3). Early battery depletion was observed in 5 devices in the study group (1.6%) versus 1 device in the control group (0.3%) with no statistical significance ($P=0.198$). Premature battery depletion was seen in 6 devices in the study group versus 4 devices in the control group ($P=0.399$). Expected battery depletion was observed in 15 devices in the control group (5%) versus 32 of the study group (10%; RR, 2.1; 95% CI, 1.1–3.75; $P=0.031$). In devices with expected battery depletion, the average duration for new devices was 8.8±0.24 years compared with 6.3±0.3 years for the resterilized pacemakers ($P=0.001$). In devices with unexpected battery depletion, the duration was 6.31±0.79 years compared with 2.47±0.9 years in the study group ($P=0.002$).

Procedure-Associated Infection

During follow-up, 10 cases of procedure-associated infection were observed in the study group (3.2%) compared with 11 in the control group (3.7%; RR, 0.87; 95% CI, 0.38–2.03; $P=0.466$). There were no differences in early or late infection and type of infection (types I–IV) between groups (Figure 4).

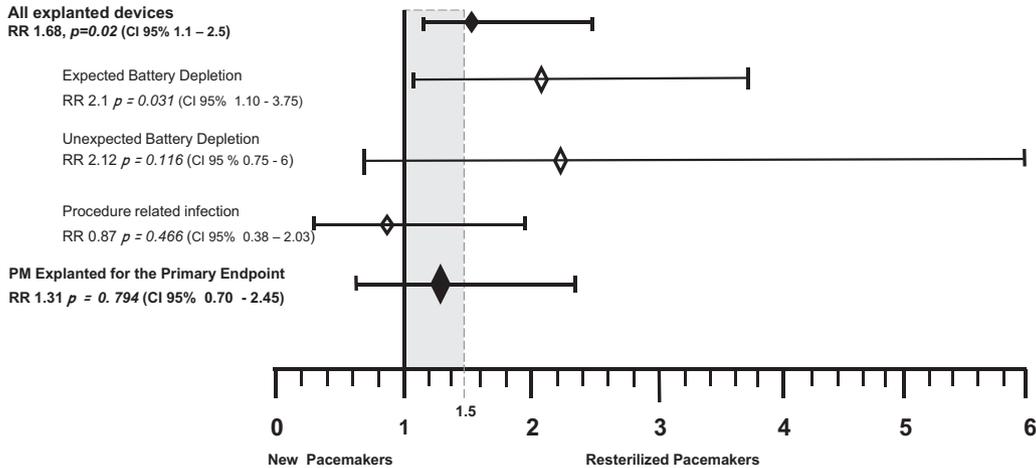


Figure 1. Graphic showing a noninferiority margin for the study group in the composite primary end point and in specific individual end points: infection, unexpected battery depletion, and expected battery depletion. CI indicates confidence interval; PM, pacemaker; and RR, relative risk.

Software or Hardware Malfunction

There was only 1 case of malfunction during follow-up in the study group, which presented as intermittent failure to sense and capture. When reviewing the case, we found that an initial malfunction for sensing and capture occurred during the implantation. The cause was screw deterioration, and the implanting physician decided to use silicone as an adhesive to maintain the electrode in position, with good results at that time. Two years after the implantation, the same malfunction was detected again in the Pacemaker Clinic, and the patient received a brand new device and electrode. The patient did not suffer any harm from this complication. Since then, a policy of careful inspection of screws before reesterilization of devices has been implemented. No other problems with screws have been reported. No malfunctions were seen in the control group.

Discussion

A total of 603 patients were analyzed in this study, 307 of whom received a reesterilized pacemaker because they were unable to

pay for a new one or could not get a new donated device after serious efforts in a time span short enough that patient well-being was not compromised. A total of 43 pacemakers reached the primary end point defined in our study (unexpected battery depletion, infection, and/or device or electrode malfunction), 16 (5.5%) in the control group and 27 (7.2%) in the study group. The RR for the primary event was 1.3, even though the patients in the study group required more urgent procedures (elective procedure in 61.4% versus 49.8% in the study group; $P=0.001$) and had a longer hospital stay before implantation because of the waiting period to find a pacemaker (median, 4 days [interquartile range, 1–8 days] for the study group versus 2 days [interquartile range, 1–4 days] for the control group; $P=0.001$). Thus, receiving a reesterilized pacemaker, with the protocol that was predefined in this study, was noninferior to receiving a new device (Figures 1A and 2). Considering all explanted pacemakers (Figure 1B), the cumulative probability for explanting a device for any reason is significantly higher for reused pacemakers ($P=0.048$). This difference is evident

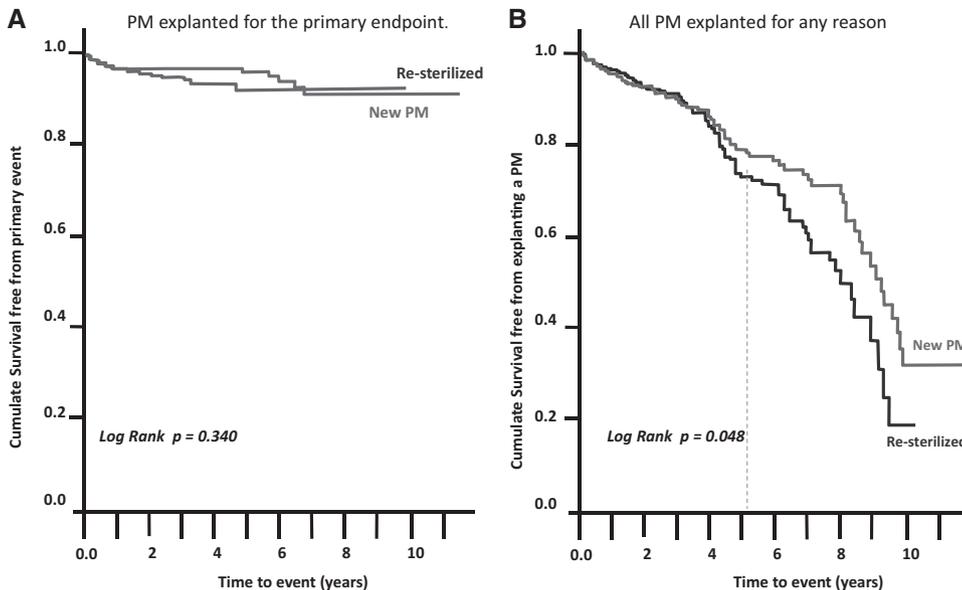


Figure 2. **A**, Kaplan-Meier curves for the composite primary event (unexpected battery depletion, infection, malfunction), showing no statistical significance between groups. **B**, Kaplan-Meier curves for explanted pacemakers for any reason between groups. Curves separate between the fourth and sixth years. Battery depletion in the study group starts exactly at this point. For a 10-year period, there would be a statistically significant difference between groups.

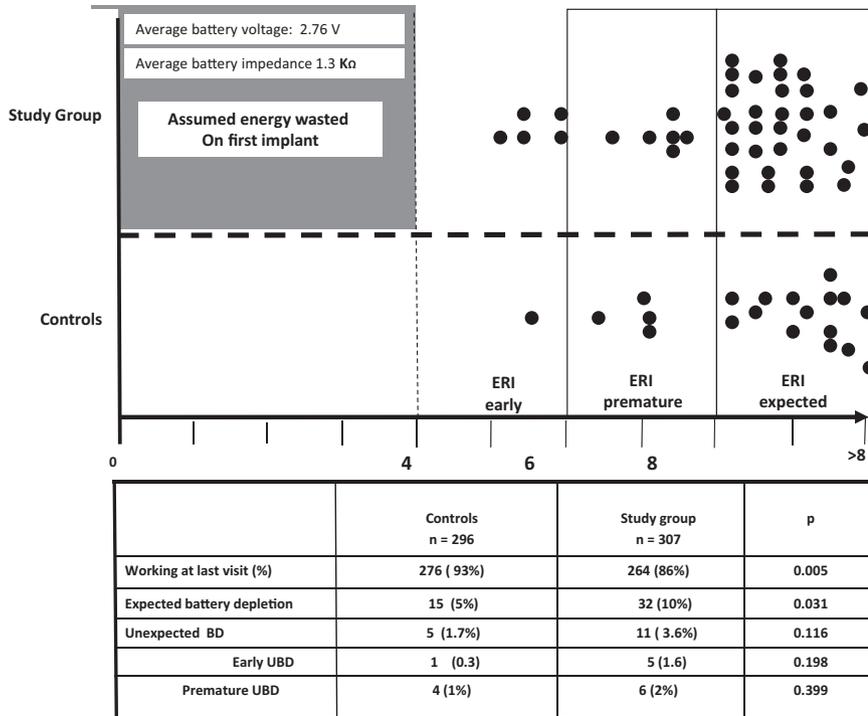


Figure 3. Battery performance between groups. **Top**, Battery performance between groups for battery duration. Resterilized pacemakers start at the fourth year according to definitions. Black dots are the events registered in time for each battery end point. Note that the majority of battery events occurred at the expected battery depletion end point in both groups. **Bottom**, The actual data for each event. Working means the number of implanted devices still functioning properly in each group. BD indicates battery depletion; ERI, elective replacement indication; and UBD, unexpected battery depletion.

only after the fifth year of follow-up and could be explained by the shorter battery life in reesterilized pacemakers (average duration, 6.3 ± 0.3 versus 8.8 ± 0.24 years; $P=0.001$).

Pacemaker reuse is a common practice in many countries. Although several reports have found results similar to those presented here,¹⁻⁷ some authors have expressed their concern about this behavior, and in many countries, legislation has made this practice difficult or impossible.⁸⁻¹³ Recently, there has been increased interest in the possibility of donating used devices to countries where patients cannot afford a new device. Once again, safety issues have been addressed.¹⁸ Baman et al¹⁹ published a meta-analysis of all the different studies published on this topic and found no difference in major events for reused pacemakers. Some limitations related to all meta-analyses, and correctly addressed by the author, should be taken into consideration. Only 5 of the 18 trials used for the analysis had a direct comparison with new devices; analysis was based on nonrandomized studies; and 3 studies

were published only as abstracts. The authors found a low infection rate in general, but they did not subclassify infection type or time of occurrence. In addition, Linde et al¹ found no differences in infection (actually a higher rate in patients with new devices, 7 patients versus 1 patient), but there was also a lack of a proper definition of infection and time of occurrence. In our study, a total of 21 events were considered infections (Figure 4), 10 in the study group (3.2%) versus 11 in the control group (3.7%; $P=0.46$). Only 2 patients had an early infection, 1 in each group; the rest were considered late infections. In the Baman et al meta-analysis, the major concern about reused devices was device malfunction, mainly screw abnormalities, although the general incidence was very low (0.68%). We found only 1 event associated with device malfunction; it was also a screw malfunction as described above. Since that event, special attention to the existence and function of screws has been given during the refurbishing process, and no other event has been detected. We agree

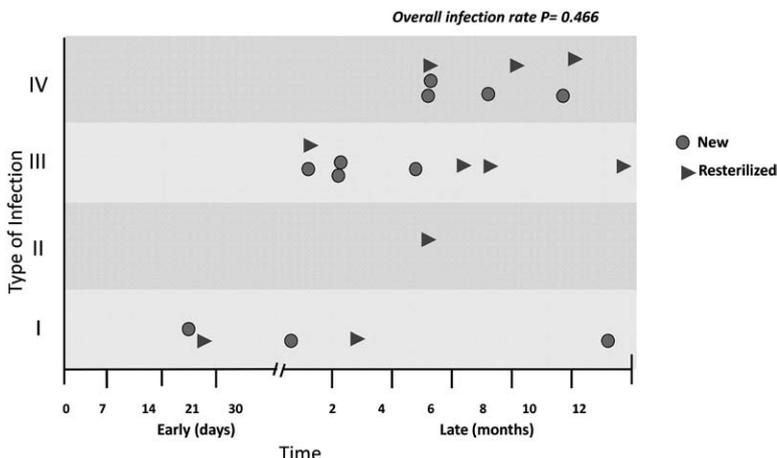


Figure 4. Procedure-related infection between groups. Number of detected infections according to the classification during the first year after implantation. Infection types are as follows: I, right endocarditis with electrode involvement; II, sepsis without evidence of involvement of the circuit or pocket; III, infection of the pacemaker pocket; and IV, extrusion of wires or generator. Overall infection rate was not significant. Triangles indicate reesterilized devices; circles, new pacemakers.

that thorough inspection of screws is essential to guarantee pacemaker function.

Battery depletion is an obvious disadvantage for resterilized devices, as we mentioned above, and a reason not to reuse pacemakers because there might be associated risks in future pacemaker generator changes.¹⁹ Interestingly, even when the average duration for all reused devices was lower than that for new devices, it was only 2½ years less (6.17 ± 1.67 years [4-year minimum estimate] versus 8.9 ± 0.68 years in control subjects), so, the average duration for the resterilized pacemakers was actually longer than expected. Resterilized devices do have a shorter battery life, as should be expected, and there is a tendency to have higher rates of unexpected battery depletion than in new pacemakers. Although we do not have an explanation for this tendency for reused pacemakers, several factors could play a role. We observed a higher percentage of pacing time and pacing voltage in the study group (Table 2). In addition, battery reading depends on the parameters that are programmed at the time of interrogation. Once the pacemaker is reprogrammed according to the new patient needs (voltage thresholds, impedance, percentage of pacing, etc), it might change the actual life expectancy of the pacemaker. This should be considered during the process of choosing reused pacemakers according to battery life.

The final question that should be addressed is whether reused pacemakers are good options for treating patients from medical and ethical points of view once safety has been proven. The US Food and Drug Administration states that “there is a serious question whether pacemakers can be properly resterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker.”¹¹ Legislation on this issue varies widely according to country. In 1998, the European Union established that the manufacturer had to indicate whether a device was for single use or not, and if a single-use device were to be reused, it would have to go through the same approval process as a new one.⁹ The Food and Drug Administration published a similar statement in 2000.¹² All companies producing devices label them for single use only, although there is no evidence that resterilizing could be ominous or dangerous. Some companies in our country even have a policy of not supplying new electrodes for resterilized pacemakers. Evidence like that provided here supports the view that, once the procedure is proven safe, not offering such a lifesaving procedure might be unethical. In this study, we provide evidence that, all other economic considerations aside, scientifically resterilized pacemakers are a good option for treating patients with bradyarrhythmic disturbances that require pacing and that reuse is at least noninferior to the best therapy available, which is a new device. Mond et al²⁰ observed that the number of pacemaker implantations per 1 million inhabitants in low-income countries was significantly lower than in industrialized countries. Perhaps cost is one of the reasons. The interest in donating devices to low-income countries has been addressed recently in several publications.^{19–23} A recent survey revealed that most devices explanted by morticians went to medical waste (44%) and only 18% were donated for human use in developing nations. Patients and/or family members indicated a willingness to

have their devices interrogated after death and returned to manufacturers. Morticians in this survey agreed that routine explantation and return of devices would be feasible.²² In another survey directed at electrophysiologists, the majority indicated that they disposed of explanted devices as medical waste and that very few were donated for reuse in underserved nations or veterinary hospitals.²³ Baman et al¹⁹ have launched a formal initiative to donate devices to impoverished nations around the world. Organizations like Heartbeat International (<http://www.heartbeatintl.org>) specialize in donating and delivering new devices to third-world countries. They have been of great help, but their donations do not cover the extent of the problem, so resterilizing can be an answer. We believe that our results provide solid evidence of the safety of resterilized pacemakers, and we provide a proven protocol for doing so. In a world of economic recession with huge government healthcare deficits without full medical coverage for all individuals, conscious, careful use of resterilized devices should be considered an option to achieve universal access to cardiac health care in emerging and developing economies and should not be ruled out or advised against.

Conclusions

Pacemaker reuse is feasible and safe and is a viable option for patients with bradyarrhythmias. Other than the expected lower battery life, reuse of pacemaker generators is noninferior to the use of new devices.

Disclosures

None.

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CLINICAL PERSPECTIVE

In developing economies, there are patients in whom pacemaker implantation is delayed or not performed because they cannot afford a device. Reused devices have been a solution for many patients in these countries. Until now, publications on pacemaker reuse have lacked sufficient scientific evidence to prove that reuse is safe and feasible. Reasonable questions on reuse have been raised, and reuse has even been judged to be unethical. In the last few years, however, renewed interest in pacemaker reuse has stirred up an old controversy. The question of whether reuse is safe and feasible needs an answer because many patients are receiving these devices. We have carefully analyzed the data and have concluded that reused devices are safe if handled properly. We are the first to establish proper definitions for the end points analyzed and to provide solid evidence with a sufficient number of patients to confirm our findings. This article challenges the general view that resterilizing pacemakers can be deleterious and unethical, provides a proven protocol for resterilization, and tries to establish a channel for communication between industrialized countries and developing countries on one of the main issues of modern medicine: cost and availability of medical care.