Re-Use of Pacemakers: Comparison of Acute and Long Term Performances

Running title: Nava et al.; Pacemaker reuse

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Abstract:

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

Methods and Results—A cohort of 603 consecutive patients from 2000 to 2010 was studied in an ambispective non-inferiority study. The study group (n = 307) received a re-sterilized PM and the control group (n = 296) a new PM. A combined endpoint of three major outcomes was analyzed: Unexpected battery depletion, infection, and device dysfunction. A total of 85 PM had to be explanted 31 (10.5%) in the control group vs. 54 (17.6%) in the study group (RR 1.68, CI 95% 1.1 – 2.5; P = 0.02). Forty-three reach the primary endpoint, 16 (5.5%) in the control group vs 27(7.2%) in the study group (RR: 1.3; CI 95% 0.70 – 2.45; P = 0.794). Individual outcomes: (1) Unexpected battery depletion: 5 (1.7%) new PM vs 11 (3.6%) re-sterilized PM (RR 2.12, CI 95% 0.75 - 6; P = 0.116); (2) procedure-related infection: 3.7% in new PM vs 3.2% (RR 0.87, IC 95%: 0.38 - 2.03; P = 0.46); (3) malfunction: one case was encountered in the study group.

Conclusions—PM reuse is feasible and safe and a viable option for patient with bradyarrhythmias. Other than for the expected lower battery life, reuse of pacemaker generators is not-inferior to the use of new devices.

Key words: pacemaker, heart block, retrieval device
Introduction

Pacing through implantable devices (pacemakers [PM]) is a life saving therapy for patients with bradiarrhythmias. In countries without full medical coverage there are a significant proportion of patients that 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.\textsuperscript{1–7} However, serious concerns regarding safety and even efficacy have been raised against this behavior.\textsuperscript{8–13} Few studies have reported on this issue in the last years, and found no solid evidence against this procedure.\textsuperscript{1–7} In our institution, a tertiary referral center, cadaveric donation with subsequent re-sterilization and implant of these reused PM has been a common practice for patients in whom a new device cannot be obtained by other means of strategies. In order to provide more evidence that this behavior is safe, we studied a cohort of consecutive patients that received, either a new or a reused PM, considering a combined endpoint of three major determinants: Unexpected battery depletion, infection, and device dysfunction.

Methods

A single-center cohort of consecutive patients from 2000 to 2010 was studied in an ambispective, non-inferiority study. From 2000 to 2005 the analysis was made retrospectively and from 2005 to 2010 prospectively. Since there are no previous reports accounting for the percentage of patients with a primary outcome in re-sterilized devices, the number of patients needed to evaluate the non-inferiority margin was calculated taken into consideration previous reports on device performance\textsuperscript{14} and device infection.\textsuperscript{15} We assigned a value of 20\% of events for the primary outcome in the control group (new devices) with a relative risk of less than 1.5 in
the study group (re-sterilized devices), assuming a type I error significance level to two-tails of 0.05 and an error type II of 0.20 with a power of 0.80. The calculated number of patients necessary was 323 per group, considering 10% of losses during follow-up.

For this analysis, our control group consisted of those patients with 18 years of age or older, and a class I AHA/ACC/ESC indication for pacing, that could afford the cost of a new pacing device. Study group consisted of those that could not afford a new PM and that, after serious efforts to find a donation of a new one, with a waiting period defined by their attending physician according to cardiac status, could not get it, and were offered a re-sterilized device, 96% of them from cadaveric donation. All patients gave their informed consent after being informed in detail for all potential complications for the procedure and, for the study group, specifically of those regarding a re-sterilized device.

**Criteria for reuse**

PM’s were obtained via cadaveric donation, either by explanting the devices at our center after family approval or by direct donation of family members that received the device in funerary 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, cleans the PM, and inspects 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, 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 of the Electrophysiology Department checks with the programmer: battery current, impedance, and programmed values. The PM is then reprogrammed to the minimum heart rate
and voltage output permitted by the device or even turns the device off, if possible. Considering that the calculated life for a new device is around 8 years, a reuse device appropriate for implant should have 50% or more of their battery lives, so only devices with battery expectancy of more than 4 years are approved for reuse. Finally, it is packed, labeled, and sterilized in ethylene oxide for 15 hours and returned to the Social Service Department. When a patient with a class I indication for pacing (ACC/AHA Indications) could not afford a new PM, the Head of the Social Service Department assigns the device to those who, after a socioeconomic evaluation, proves unable to buy a new device. Devices re-sterilized in our center are used only in our own 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 IV, or equivalent, at implant. One week after, patients attend the Wound Control Clinic were a trained Nurse inspects the surgical wound, clean it and removes sutures. Six weeks after the procedure, patients are checked in the Pacemaker Clinic and, if appropriate, chronic pacing parameters are reprogrammed. Afterwards, patients are followed 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: (i) Expected Battery Depletion, when the elective replacement indication (ERI) on the device is reached after 8 years. (ii) Unexpected Battery Depletion, defined according to the studied groups: 1.- *For new pacemakers* (a) Early battery depletion was defined as the depletion before the sixth year after the implant, without relation to high pacing outputs or abnormal electrode impedances that would make the device
warranty void; (b) Premature battery depletion was considered to have occurred when ERI was reached between the sixth and eighth year from the initial implantation. 2. - For re-sterilized pacemakers: as previously mentioned, in our institution we consider for reuse only those devices that have at least have 50% or more of their calculated battery life, since we considered 8 years the expected battery depletion for new devices, expected battery depletion was considered after the fourth year, early battery depletion was considered before the second year after the implant, and premature battery depletion between the second year and fourth. (iii) Infection: We used the classification proposed by Byrd in Ellenbogen’s classical textbook, 16 which consists of four types: I) right endocarditis with electrode involvement, II) sepsis without evidence of involvement of the circuit or pocket, III) infection of the PM pocket, IV) extrusion of wires or generator. 

We considered early infection when occurred in the first month after the implant and late when occurred in the first year of the implant and could be considered in relation to the procedure. After the first year, infection is not considered to be related to the procedure. 17

The primary endpoint was defined as the need to remove or change the device because of: Unexpected battery depletion (Includes early and premature battery depletion), infection or device or electrode malfunction (software-hardware malfunction). For statistical analysis, groups were frequency matched.

Elective procedure was defined as an indication for pacing that would not put in danger patient’s integrity and therefore they could be ambulatory. Urgent: When patient’s integrity was at risk and needed to be hospitalized until the procedure was done. Emergency procedure: When patient’s life was at risk (i.e. low cardiac output, Stokes-Adams crisis, ventricular arrhythmias, etc.) or a temporary PM had to be implanted.
Statistical Analysis

The clinical endpoint between groups was determined by relative risk (RR) with CI to 95%. Continuous variables were expressed as mean and standard deviation. Those without normal distribution were expressed as median and interquartile range. Student t and Mann-Whitney U tests were used for comparing continuous variables. Chi-square test and Fisher’s exact test were used for categorical variables. Kaplan-Meier curves with log-rank test were used for the survival analysis. A P value of 0.05 or less was considered significant.

Results

A total of 639 patients were studied, 323 in the study group (re-sterilized PM) and 316 in the control group (new PM). Thirty-six patients were lost for follow-up, 16 patients (4.9%) in the study group and 20 (6.3%) in the control group. For the final analysis, 603 patients were considered, 307 in the study group and 296 in the control group. In the general population median follow up was 4.16 years (Interquartile range P25 -P75  2.75 to 6 years) In the control group median follow up was 4.16 years (interquartile range P25 -P75  2.6 to 6.6 years) and 4.10 years (P25 -P75  range 2.83 to 5.65 years) for study group, (p= 0.397). General characteristics of both groups are shown in Table 1. Both groups were similar in age, gender, 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% for the control group vs 49.8% in the study group. Urgent procedures in 27% vs 24% of pts in the study group and emergency procedure in 11% in the control group vs 26% in study group P = 0.001). Also, the time spent in the hospital before the implant was longer for the study group, with a median of 4 days (1 to 8 days) vs 2 days (1 to 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, that was higher in the study group (88 ± 18.6 vs 84 ± 21.5, P = 0.009), output on the ventricular electrode was also higher in the study group (2.27 ± 0.47 V vs 2.14 ± 0.26 V, P = 0.026) and electrode impedances, but within normal range.

At the end of the follow-up, 85 devices had to be explanted for any reason 31 (10.5%) in the control group vs 54 (17.6%) in the study group (RR 1.68, CI 95% 1.1 – 2.5, p = 0.02). Of this 85 PMs, 43 were explanted because they had reached the primary event, 16 (5.5%) in the control group and 27 (7.2%) in the study group for a relative risk of 1.3 (CI 95% 0.70 - 2.45, P = 0.794) (Figure 1). So for reaching our primary end point, re-sterilized PM's are not inferior to new PM. During follow up 45 patients died (15.2%) in the control group vs 39 patients (12.7%) in the study group (RR 0.83, CI 95% 0.56- 1.24, p = 0.376. Since differences in follow-up times could influence results, cumulative survival analysis was performed for the primary event and for all PM explanted, showing no difference between groups, for the primary end point, P = 0.340, and a significant difference between both groups for all PM explanted for any reason, with a P = 0.048, (figure 2 A and B), this difference is evident only after the fifth year of follow-up, explained most probably by the difference in battery life for re-sterilized PM.

Each of the events that composed the primary endpoint was analyzed separately:

**Battery duration**

Unexpected battery depletion was observed in 5 (1.7%) devices in the control group vs. 11 (3.6%) in the study group (RR 2.12, CI 95% 0.75 - 6, P = 0.116) (Figures 1 and 3). Early battery depletion was observed in 5 devices in the study group (1.6%) vs. 1 device in the control group (0.3%) with no statistical significance (P = 0.198). Premature battery depletion in 6 devices in the study group vs 4 devices in the control group, P = 0.399. Expected battery depletion was
observed in 15 (5%) devices of the control group vs. 32 (10%) of the study group (RR 2.1. CI 95% 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 vs. 6.3 ± 0.3 years for the re-sterilized PM’s (P = 0.001). In devices with unexpected battery depletion, duration was 6.31 ± 0.79 years vs 2.47 ± 0.9 years in the study group with a P = 0.002.

**Procedure-associated infection**

During follow-up, 10 cases (3.2%) of procedure-associated infection were observed in the study group vs 11 (3.7%) in the control group (RR 0.87 CI 95% 0.38 – 2.03, P = 0.466). There were no differences between early or late infection and type of infection (Types 1 – IV) between groups (Figure 4).

**Software-Hardware malfunction**

There was only one case of malfunction during follow-up in the Study Group, presenting as intermittent failure to sense and capture. When reviewing the case, we found that an initial malfunction for sensing and capture occurred during the implant. 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 moment. Two years after the implant, in the Pacemaker Clinic, the same malfunction was detected again, 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 re-sterilizing devices was implemented. No other problems with screws have been reported since. No malfunctions were seen in the control group.

**Discussion**

A total of 603 patients were analyzed in this study, 307 received a re-sterilized PM because the
patient was unable to pay for a new one or could not get a new donated device after serious efforts in a span of time sufficient enough as to not compromise patient security. A total of 43 PM’s 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 relative risk for the primary event was 1.3, even though the patients in the study group required a more urgent procedure (elective procedure in 61.4% vs. 49.8% in the study group; P = 0.001) and had a longer hospital stay before implant because of the waiting period to find a pacemaker, a median of 4 days (1 to 8 days) study group vs. 2 days (1 to 4 days) with a P = 0.001. Thus, receiving a re-sterilized PM, with the protocol that was predefined in this study, was non inferior to receiving a new device (Figures 1A and 2). Considering all explanted PM's (Figure 1B) the cumulative probability for explanting a device for any reason, is significantly higher for reused PM's (P = 0.048), This difference is only evident after the fifth year of follow-up and could be explained by the shorter battery life in re-sterilized PM's (average duration 6.3 ± 0.3 years versus 8.8 ± 0.24 years; P = 0.001).

PM reuse is a common practice in many countries. Although several reports have found similar results to the ones herein presented,1-7 some authors have expressed their concern against this behavior and in many countries legislations made this behavior difficult or impossible to be applied.8-13 Recently, there has been increased interest on the possibility of donating used devices to countries where patients cannot afford the cost of a new device. Once again, safety issues have been addressed.18 Baman et al. published a meta-analysis based on all the different studies published on this issue, finding no difference in major events for reused PM’s. Some limitations related to all meta-analysis, and correctly addressed by the author, should be taken into consideration. Only five out of the 18 trials used for the analysis had a direct comparison against
new devices, analysis was based on non-randomized studies, and three studies were published only as abstracts. The authors find a low infection rate, in general, but they did not sub-classify infection type or time of occurrence. Also, Linde et al.¹ found no differences in infection (actually a higher rate in patients with new devices, seven vs. one) but there was also a lack of a proper definition for infection and time of occurrence. In our study, a total of 21 events were considered infections (Figure 4): 10 (3.2%) in the study group vs. 11 (3.7%) in the control group (P = 0.46). Only two patients had an early infection, one in each group, and the rest were considered late infections. In Baman’s meta-analysis, device malfunction came as the major concern against reused devices, mainly screw abnormalities, although the general incidence was very low (0.68%). We only found one event associated to device malfunction and it was also a screw malfunction as we described above. Since that event, special attention to screws existence and function has been given to this point during the refurbishing process and no other event has been detected. We agree that thorough inspection of screws is essential to guarantee pacemaker function.

Battery depletion is an obvious disadvantage for re-sterilized devices as we mentioned above, and an issue against PM reuse, since there might be associated risks in future PM generator changes.¹⁹ Interestingly, even when the average duration for all reused devices was lower than new devices, it was only two and a half years less (6.17 ± 1.67 years [4 years minimum estimate] vs. 8.9 ± 0.68 years in controls) so, actually the average duration for the re-sterilized PMs was longer than expected. Re-sterilized devices do have a shorter battery life, as should be expected, and there is a tendency to have “unexpected battery depletion” in higher rates than in new PM’s. Although we don’t have an explanation for this behavior on reused PM, several factors could play a role. We observed a higher percentage of pacing time and pacing
voltage in the study group (Table 2). Also, battery reading depends on the parameters that are programmed at the time of interrogation. Once the PM is reprogrammed according to the new patient needs (voltage thresholds, impedance, percentage of pacing, etc), it might change the actual life expectancy of the PM. This should be considered at the moment of choosing reused PM’s according to battery spam.

The final question that should be addressed is if reused PM’s are good options for treating patients from the medical and ethical point of view, once safety has been proven. The Food and Drug Administration (FDA, USA) states that “there is a serious question whether pacemakers can be properly re-sterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker”.11 Legislation in regards to this issue varies widely according to each country. The European Union, in 1998, established that the manufacturer had to establish if their device was for single use or not and if a single-use device should be reused it had to go through the same approval process as a new one.9 The FDA published a similar statement in 2000.12 All companies producing devices label them for single use only, although there is no evidence that re-sterilizing could be ominous or dangerous. Some companies in our country even have a policy of not supplying new electrodes for re-sterilized PM’s. Evidence like the one provided by this article supports the view that it might be unethical not offering such a life-saving procedure, once proven that the procedure is safe. In this study, we provide evidence that, all other economic considerations apart, scientifically re-sterilized PM’s are a good option for treating patients with bradyarrhythmic disturbances that require pacing and it is at least non-inferior to the best therapy available, which is a new device. Mond et al.20 observed that the number of PM implants per million inhabitants in low-income countries was significantly lower than in industrialized countries. Perhaps cost is one of the reasons. The interest for donating
devices to low income countries have been recently addressed in several publications.\textsuperscript{19-23} A recent survey revealed that most explanted devices 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.\textsuperscript{22} In another survey directed to EP’s, the majority, dispose of explanted devices as medical waste and very few were donated for reuse in underserved nations or to veterinary hospitals.\textsuperscript{23} Baman and Kirkpatrick have launched a formal initiative to donate devices to impoverished nations around the world.\textsuperscript{19} Organizations like Heart beat international (Heartbeat International website, http://www.heartbeatintl.org) specialize in donation and delivering new devices to third-world countries, and have been of great help but they do not cover the extent of the problem so re-sterilizing can be an answer. We consider that our results provide solid evidence about the safety of re-sterilized PM’s, and provide a proven protocol for doing so. In a world of economic recession, of huge government health care deficit, without full medical coverage for all individuals, conscious, careful use of re-sterilized devices should be considered as 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**

PM reuse is feasible and safe and a viable option for patient with bradyarrhythmias. Other than for the expected lower battery life, reuse of pacemaker generators is not-inferior to the use of new devices.

**Conflict of Interest Disclosures:** None.
References:


<table>
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<th>Table 1. General characteristics of study population.</th>
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<tr>
<td>Gender</td>
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<tr>
<td>Male (%)</td>
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<tr>
<td>Female (%)</td>
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<tr>
<td>Diabetes Mellitus (%)</td>
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<tr>
<td>Arterial Hypertension (%)</td>
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<tr>
<td>Renal Impairment (%)</td>
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<tr>
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<tr>
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<tr>
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<tr>
<td>AF with slow ventricular rate (%)</td>
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<tr>
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<tr>
<td>Procedure (%)</td>
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<td>Waiting period before the Implant (days) median (P_{25-75})</td>
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<tr>
<td>Battery Change</td>
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Table 2. Pacemakers parameters in studied patients.

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<th>Parameter</th>
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<th>Control group</th>
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<td>DDD (%)</td>
<td>128 (41.7)</td>
<td>123 (41.6)</td>
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<td>VVI (%)</td>
<td>179 (58.9)</td>
<td>173 (58.4)</td>
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<td>Minimum pacing rate (bpm)</td>
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<td>88 ± 18.6</td>
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<td>Battery current (μA)</td>
<td>12 ± 3.4</td>
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<td>****</td>
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<td>Battery impedance (KΩ)</td>
<td>1.30 ± 1.9</td>
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<tr>
<td>Estimated battery life (years)</td>
<td>5.61 ± 1</td>
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Figure Legends:

Figure 1. Graphic showing a Non-Inferiority margin for study group in the composite primary endpoint and in specific individual endpoints: infection, unexpected battery depletion and expected battery depletion.
**Figure 2.** A) Kaplan-Meier graphics for the composite primary event (Unexpected battery depletion, Infection, malfunction) showing no statistical significance among groups. B) Kaplan-Meier graphics for explanted pacemakers for any reason, among groups. Curves separate apart between the 4th and 6th year. Battery depletion in study group starts exactly at this point. For a 10-year period there would be a statistical significant difference among groups.

**Figure 3.** Battery performance between groups. In the upper panel we show battery performance among groups for battery duration. Re-sterilized pacemakers start at the fourth year according to definitions. Black dots are the events registered in time for each battery endpoint. Note that the majority of battery events occurred at the expected battery depletion endpoint in both groups. In the lower panel the actual data for each event. Working: represents the number of devices that are still functioning properly en each group since they were implanted. UBD: Unexpected Battery Depletion.

**Figure 4.** Procedure-related infection between groups. Number of detected infections according to classification during the first year after implant. Infection type: I) right endocarditis with electrode involvement. II) Sepsis without evidence of involvement of the circuit or pocket. III) Infection of the pacemaker pocket. IV) Extrusion of wires or generator. Blue triangles represent re-sterilized devices. Red circles represent new pacemakers. Overall infection rate was not significant.
**Expected Battery Depletion**
RR 2.1, $p = 0.031$ (CI 95% 1.10 - 3.75)

**Unexpected Battery Depletion**
RR 2.12, $p = 0.116$ (CI 95% 0.75 - 6)

**Procedure related infection**
RR 0.87, $p = 0.466$ (CI 95% 0.38 – 2.03)

**PM Explanted for the Primary Endpoint**
RR 1.31, $p = 0.794$ (CI 95% 0.70 - 2.45)

---

**All explanted devices**
RR 1.68, $p=0.02$ (CI 95% 1.1 – 2.5)

---

**Figure 1**

*New Pacemakers*  
*Resterilized Pacemakers*
Figure 2

A. PM explanted for the primary endpoint.

B. All PM explanted for any reason

Log Rank $p = 0.340$

Log Rank $p = 0.048$
Figure 3

<table>
<thead>
<tr>
<th></th>
<th>Study Group n = 307</th>
<th>Controls n = 296</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working at last visit (%)</td>
<td>264 (86%)</td>
<td>276 (93%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Expected battery depletion</td>
<td>32 (10%)</td>
<td>15 (5%)</td>
<td>0.031</td>
</tr>
<tr>
<td>Unexpected BD</td>
<td>11 (3.6%)</td>
<td>5 (1.7%)</td>
<td>0.116</td>
</tr>
<tr>
<td>Early UBD</td>
<td>5 (1.6)</td>
<td>1 (0.3%)</td>
<td>0.198</td>
</tr>
<tr>
<td>Premature UBD</td>
<td>6 (2%)</td>
<td>4 (1%)</td>
<td>0.399</td>
</tr>
</tbody>
</table>

Average battery voltage: 2.76 V
Average battery impedance 1.3 KΩ

Assumed energy wasted
On first implant
Overall infection rate $P = 0.466$

Time

Early (days) 2 4 6 8 10 12
Late (months)

Figure 4
Re-Use of Pacemakers: Comparison of Acute and Long Term Performances
Santiago Nava, José L. Morales, Manlio F. Márquez, Fausto Barrera, Jorge Gómez, Luis Colín, Josep Brugada and Pedro Iturralde

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