

# Reuse of pacemakers, defibrillators and cardiac resynchronisation devices

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## ABSTRACT

**Objective** Access to pacemakers remains poor among many patients in low/middle-income countries. Reuse of explanted pacemakers is a possible solution, but is still not widespread because of concerns regarding outcomes, especially infection. Our objective was to study early outcomes with implants using reused devices and compare them with those with implants using new devices.

**Methods** We studied all patients who underwent implantation of a new or reused pacemaker, cardiac resynchronisation therapy (CRT) device or implantable cardioverter defibrillator (ICD) in the last 5 years at a single institution. We analysed outcomes related to infection, device malfunction and device-related death within 6 months after initial implantation.

**Results** During the study period, 887 patients underwent device implant, including 127 CRT devices or ICDs. Of these, 260 devices (29.3%) were reused and the others were new. At 6 months, there were three device-related infections in implants using a new device. There were no infections among patients receiving a reused device. There were no device malfunctions or device-related deaths in either group.

**Conclusions** We found no difference in rate of infection or device malfunction among patients getting a reused device as compared with those with a new device. This study reinforces the safety of reusing devices for implant including CRT and ICDs.

## INTRODUCTION

Reuse of explanted cardiac implantable electronic devices (CIED) is of great interest in an era of rising costs and declining healthcare resources. Surveys of pacemaker use have consistently found a large disparity between developed and low/middle-income countries. Numbers of pacemakers implanted per year per million population are 782, 518 and 767 in France, the UK and the USA, respectively, while they are 17, 5 and 5 in India, Bangladesh and Sudan, respectively.<sup>1</sup> While factors such as differences in population demographics and access to healthcare may contribute to this disparity, socioeconomic differences are likely to be most important, suggesting that a lot of patients who could potentially benefit from device implantation do not get the same. Outcome with reuse of pacemakers has been described in a few studies previously,<sup>2–6</sup> while there are fewer reports where reuse of complex devices has been described.<sup>7–8</sup> The uniform finding from these studies is that reuse of explanted devices is not associated with an increase in the rate of infection or mortality. There are significant cost savings with this approach and these

are especially high with complex devices because of their higher cost and potentially greater benefit.

However, reuse of explanted devices continues to be limited to a few centres in low/middle-income countries, principally because of concerns regarding infection risk. Because of the labelling of the devices by the manufacturer as single use only, regulatory agencies are wary of advocating reuse. Many of the previous reports on reuse of pacemakers suffer from limitations such as small numbers, lack of a control group, poorly defined endpoints and limited data on complex devices such as cardiac resynchronisation therapy (CRT) devices and implantable cardioverter defibrillators (ICDs).

Our institute has a large experience with refurbished pacemakers over the past 20 years.<sup>9</sup> In recent years, an increasing number of reused CRT and ICD devices are also implanted. We retrospectively studied a group of patients who received any of these devices within the last 5 years, analysing rate of infection, device malfunction and death within 6 months after implantation in patients receiving new versus reused devices.

## METHODS

This is a single centre, retrospective study. Consecutive patients undergoing implantation of a CIED (pacemaker, CRT device or ICD) in our centre from January 2010 to December 2015 were included in the study. Data were collected from review of implant registers and patient files. Cases were patients in whom a reused device was used, and controls were patients who underwent implantation of a new device. Informed consent was obtained from all patients for the procedure. In addition, patients who received a reused device were explained about the use of a reused device and consent obtained for the same.

## Reused devices

Most of the reused devices are procured from STIM développement, a French voluntary organisation based at Nancy and now Paris, France, which collects explanted and shelf-expired devices and ships them to low/middle-income countries.<sup>9</sup> Some devices are also obtained from our own institution. Pulse generators are screened and those with external signs of damage are not used. Devices are then interrogated with the appropriate programmer and those with estimated longevity <4 years or battery impedance more than 1000  $\Omega$  are excluded. Devices are washed with a soft brush with enzymatic detergent and immersed in the same solution for 48 hours. Devices with residual blood in the



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lead terminals after cleaning are excluded. The selected devices are packed with a label indicating type of device, manufacturer, model, serial number, longevity, battery impedance and date of sterilisation. After packing, the devices undergo two cycles of sterilisation with ethylene oxide 24 hours apart. Each cycle consists of preconditioning, multistage sterilisation with ethylene oxide (Steri-Gas, 3M) in a sealed chamber followed by an aeration phase for degassing. Devices are re-sterilised with ethylene oxide if they are not used within 6 months.

### Implantation procedure and follow-up

Device implantation is done by an electrophysiologist or interventional cardiologist. All patients undergoing device implantation receive a dose of ceftriaxone and ciprofloxacin intravenously at the time of implant before the skin incision. Ceftriaxone is continued for 3 days postimplant. Wound is cleaned and dressed daily for 3 days. Patients are reviewed in the pacemaker follow-up clinic 6 weeks after the procedure, when the wound is inspected and device parameters are interrogated and reprogrammed as required. Subsequently, patients are followed up at 6 months after implant and then once every 6 months to a year in the same clinic.

### Follow-up and definition of end points

Events occurring within the first 6 months after device implant were included for analysis of outcomes.

#### Device-related infection

Infection of the device in situ and its pocket usually requiring explantation of the device. Device-related infections were classified based on the timing of its occurrence from the date of implant as early infection when it occurs in the first month of the implant and late infection when it occurs in the first 6 months of the implant.

#### Device malfunction

Failure of the device to perform its intended function (pacing, sensing or defibrillation) which is not due to lead-related problems and may be because of loss of mechanical or electric integrity during the extraction and/or sterilisation process.

#### Device-related death

Mortality due to device infection or device malfunction within 6 months of the implant.

### Statistical analysis

Continuous variables are reported as mean $\pm$ SD and compared between groups using an unpaired t-test. Categorical variables

are reported as percentages and were compared using a  $\chi^2$  test. All comparisons were two tailed and p value <0.05 was considered significant.

### RESULTS

A total of 887 patients underwent implantation of a device between January 2010 and December 2015 and were included in this analysis. Single or dual-chamber pacemakers comprised 760 (85.7%) of these while the remaining were CRT devices or ICDs. A total of 260 devices (29.3%) were reused and the rest were new devices. Among the 760 pacemaker implant procedures, 565 (74%) were new implants and 195 (26%) were device replacements. For the 127 complex devices, 116 were new implants (91%) and 11 (9%) were device replacement procedures. The details of the devices are shown in table 1. Demographic and clinical characteristics of the patients undergoing implantation of reused or new pacemakers are summarised in table 2, while demographics of patients with complex devices are listed in table 3.

Follow-up data for the first 6 months after implant were available for all the patients. Three patients in the entire group developed pocket infection and required explantation of the pacing system. Two of these occurred after implantation of a new pacemaker. One was a 65-year-old female with diabetes who had a temporary wire inserted before the implantation of a single-chamber ventricular pacemaker. The second was a 29-year-old male who had no risk factors and underwent a dual-chamber pacemaker implant for congenital atrioventricular block. Both presented as pocket infection within a month of implant with no bloodstream infection or endocarditis and were successfully managed with device explant and subsequent implantation of a new device. The third was a young male with dilated cardiomyopathy who underwent a CRT device implant for dilated cardiomyopathy, heart failure and left bundle branch block. He presented with a pocket infection 40 days after implantation of a new CRT device and was also treated by explanting the device and leads. No infections were seen in patients who received a reused device. No device malfunction was noted in either group throughout the study period. No device-related mortality was seen in either group. Three deaths occurred, all due to heart failure: two in patients with an Automatic Implantable Cardioverter Defibrillator (AICD) and one in a patient with a CRT device.

The short duration of follow-up (6 months) is not sufficient to determine decrease in device longevity, if any, with reused devices. Among the pacemakers, estimated battery longevity as reported during device interrogation before implant was available for 159 refurbished pacemakers (70.7%) and was 10.5  $\pm$  2.5 years.

### DISCUSSION

Among all patients who underwent implantation of a CIED at a single centre over a 5-year period, we found that the rate of

**Table 1** Device types

Device type	Device subtype	Refurbished	New
Pacemakers n=760 (85.7%)	AAI	14	77
	VVI	132	275
	VDD	8	33
	DDD	71	150
	Total	225 (29.6%)	535 (70.4%)
Complex devices n=127 (14.3%)	Single-chamber ICD	22	46
	Dual-chamber ICD	1	8
	CRT-P	11	34
	CRT-D	1	4
	Total	35 (27.6%)	92 (72.4%)

CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy - defibrillator; CRT-P, cardiac resynchronisation therapy - pacemaker; ICD, implantable cardioverter defibrillator.

**Table 2** Pacemaker implants: demographics and clinical data

	Refurbished (n=225)	New (n=535)	p Value
Age	62.3 $\pm$ 12.9	54.7 $\pm$ 17.1	<0.001
Male sex	108 (48%)	272 (50.8%)	0.5
Indication—AV block	193 (85.8%)	411 (76.8%)	0.006
Indication—SND	31 (13.7%)	119 (22.2%)	0.007
Indication—others	1 (0.4%)	4 (0.7%)	—

AV, atrioventricular; SND, sinus node dysfunction.

**Table 3** Complex device implants: demographics

	Refurbished (n=35)	New (n=92)	p Value
Age	45.3±14.5	48.9±13.4	0.19
Male sex	26 (74.3%)	76 (82.6%)	0.29

infection, device malfunction or device-related death was small and not different between those receiving a new and a reused device. Our study reinforces the evidence from previous reports on the safety of reused pacemakers and in addition, extends this to complex devices like ICD and CRT devices.

This was not a prospective study and allocation of devices to patients was not randomised. Our institute caters to a wide spectrum of patients from different socioeconomic backgrounds. Limited number of free devices is provided to eligible patients with a poor socioeconomic status. The limit on the number of devices that can be provided results in selection of younger patients and patients without significant comorbidities. Some patients opt to pay for a new device and these patients are again likely to be younger. Because of these reasons, patients receiving a new device were more likely to be younger and have sinus node dysfunction as the diagnosis as seen in table 2. Most of the devices were pacemakers with complex devices comprising about 14%. In all categories, about 30% of the devices were reused.

We observed three infections within 6 months of implant among the total of 887 devices (0.34%), which is consistent with rates reported in other studies.<sup>10–12</sup> All the infections occurred in patients receiving a new device and there were no infections among the 260 implants where patients received a reused device. All device-related infections were confined to the pocket without involving the right heart and with no evidence of sepsis or extrusion of wires and generator. During the study duration of 5 years, no other patient underwent a procedure related to pocket infection. The finding of a low infection rate is consistent with previous studies that have found no significant difference in infection rates between refurbished and new pacemakers.<sup>13–15</sup> In a meta-analysis<sup>16</sup> including 18 studies and 2270 patients, the overall rate of infection with a reused device was low (1.97%).

There were no device malfunctions noted in our study. During one implant with a reused device, loss of capture due to a loose set screw was noted and rectified before completion of the procedure. In the meta-analysis by Baman *et al*,<sup>16</sup> device malfunction was more common with reused devices, but the incidence was low (0.68%). Malfunction in reused devices is often due to issues with the screw mechanism and can be avoided by taking care during device retrieval and cleaning and screening of the devices before implant. Kantharia *et al*<sup>17</sup> found that refurbished devices donated by funeral homes in the USA when reused in the poor needy patients in India were safe besides improving their quality of life.

Most of the reused devices were obtained from STIM développement (<http://www.stim-developpement.org>), an organisation based in France, while some of the devices were obtained from our institute itself. The most common sources of reused devices is device explantation following death of patients with an implanted device. Device upgrades and device-related infection are other, less common sources of reused devices. Device upgrades have continued to increase over the last 15 years and are a growing contributor to device

explants. Infections are mainly early device-related infections, which means that sufficient battery life is still present. This early device infection warranting device explantation was addressed in one study, where mean time period between device implantation and explantation was 52 days.<sup>18</sup> Patients over 80 years of age comprise 32% of pacemaker implants in developed countries.<sup>19</sup> Although survival rates after implant vary with population characteristics, the 5-year mortality rate for patients with pacemakers can reach 40%.<sup>20</sup> Depending on patterns of use, most pacemakers can thus have sufficient battery left when patients die.

Death of the patient with sufficient residual battery longevity is more common with complex devices like ICD and CRT because these patient groups are sicker with a higher mortality rate. The higher cost of these devices and the greater benefits they carry make the cost-effectiveness of reuse of these devices higher. Risk of infection is higher with implantation of complex devices<sup>10–21</sup> and therefore our data showing no increase in risk with reused devices are reassuring. There is limited previous literature on reuse of complex devices.<sup>7–8–22</sup> Our data are a significant addition to this literature.

The potential benefits of refurbished devices in cardiac electrophysiology should be explored to benefit many patients in need of them in low/middle-income countries across the globe. Legal restrictions to access such device therapy should be eased and standard protocols developed to ensure safe and ethical practice.<sup>23</sup> In the light of evidence provided by this study, in addition to those from previous such studies, it is unethical and unscientific to deny this life-saving therapy to patients in need.

## LIMITATIONS

This is a retrospective study, and the allocation of patients was not randomised. This inevitably leads to selection bias and explains the higher age of patients in the reused devices group since the treating cardiologists preferred to use the limited new devices for younger patients. However, the older population with more comorbidities would have been expected to have more infections, if at all, which we did not see. Second, our study has limited follow-up of 6 months only. Previous studies have reported infections even years after pacemaker implant. However, most infections occur within the first 6 months to 1 year, and early infections are most reliably related to surgical factors. Finally, reuse of devices also incurs some cost related to

## Key messages

### What is already known about this subject?

Reuse of pacemakers is feasible and is not associated with a higher infection rate.

### What does this study add?

This study reinforces this knowledge and extends this information to complex devices (implantable cardioverter defibrillators and cardiac resynchronisation therapy devices).

### How might this impact on clinical practice?

The results of this study should encourage cardiologists to consider reused devices as an option for patients who need a pacemaker or complex device and are not able to afford a new device.

collection, processing, shipping and sterilisation. A formal analysis has not been performed to calculate the costs incurred per device and thus calculate the cost savings, but rough calculations suggest that the cost of reuse would only be a fraction of the cost of a new device.

## CONCLUSION

Our retrospective analysis of implants with reused pacemakers, CRT devices or ICDs shows that these are not associated with a higher risk of infection or device malfunction during a medium term follow-up as compared with implantation of new devices. In concert with evidence from previous studies, these results should allay fears of infection risk with device reuse and promote more widespread use of this cost-effective and potentially life-saving therapy.

**Contributors** RJS designed the study, performed the data analysis, drafted the manuscript and coordinated the revisions. RS was responsible for data collection and assisted with drafting the manuscript. SS, AAP and JB were involved in the management of the patients and provided substantial critical revisions of the manuscript. PS, XJ and BD, as members of STIM développement, were instrumental in setting up the system for collection and transport of the devices. They wrote the sections about the organisation and assisted with revisions. All authors agree to be accountable for all aspects of the work.

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