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Safety of Pacemaker Reuse

A Meta-Analysis With Implications for Underserved Nations

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Background—A large disparity in medical health care is clearly evident between developed and underserved nations in the field of cardiac electrophysiology, specifically pacemaker implantation. This study aimed to assess the safety of pacemaker reuse.

Methods and Results—A computerized search from January 1, 1970, to September 1, 2010, identified 18 studies with outcomes of pacemaker reuse. The primary outcome was pacemaker infection or device erosion as defined by each individual study protocol. Secondary end points were device malfunction defined as a defect in the structural or electric integrity of the pulse generator. Pooled individual patient data (n=2270) from 18 trials were included in the analysis. The proportion of patients in whom an infection developed after pacemaker reuse was 1.97% (1.15% to 3.00%). There was no significant difference in infection rate between pacemaker reuse and new device implantation (odds ratio, 1.31 [0.50 to 3.40], P=0.580). The proportion of patients in whom device malfunction developed after pacemaker reuse was 0.68% (0.27% to 1.28%). Compared with new device implantation, there was an increased risk for malfunction in the reuse group (odds ratio, 5.80 [1.93 to 17.47], P=0.002). This difference was mainly driven by abnormalities in set screws, which possibly occurred during device extraction, as well as nonspecific device "technical errors."

Conclusions—This study suggests that pacemaker reuse has an overall low rate of infection and device malfunction and may be a safe and efficacious means of treating patients in underserved nations with symptomatic bradyarrhythmias and no other method of obtaining a device. However, the results also denote a higher rate of device malfunction as compared with new device implantation. Patients with highly symptomatic conduction disease may benefit from pacemaker reuse; however, they should be closely monitored for device malfunction, especially during implantation. **(*Circ Arrhythm Electrophysiol*. 2011;4:00-00.)**

Key Words: health care disparity ■ pacemaker ■ meta-analysis

AQ: 3

In the United States, roughly 250 000 pacemakers and 100 000 implantable cardioverter-defibrillators are implanted each year, and the rate has increased 20-fold in the last 15 years.[1] As a result of improvements in technology and health care, the morbidity and mortality attributed to cardiovascular disease has declined in recent decades. However, this dramatic improvement in disease burden has not been witnessed in low- and middle-income countries.[2] This great disparity in medical health care is clearly evident in the field of cardiac electrophysiology—specifically pacemaker implantation—in which the specialty is either severely underdeveloped or entirely nonexistent in many low- and middle-income countries. Countries such as Bangladesh and India average <8 new implants per million as compared with 738 new implants per million in France.[3] International aid organizations estimate that more than 1 million people die annually from a lack of access to pacemakers.[4]

Clinical Perspective on p ●●●

In an effort to promote cost savings as well as to provide care to those with no other means of acquiring a device, a number of articles in a wide variety of international settings have been published describing the safety and efficacy of pacemaker reuse (Table). These studies have shown no significant difference in outcome when comparing pacemaker reuse with a control population with new device implantation, although they were limited by sample size.[5–8] To our knowledge, this is the first meta-analysis to evaluate the current published and unpublished data regarding the safety of pacemaker reuse. T1, AQ:4

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Table. Characteristics of 18 Trials Included in Meta-Analysis

Study	Country	Year of Study Completion	No. of Pacemakers Reused		Complications Related to Device Reuse	
					Infection	Device Failure
Balachander[29]	India	1988	140	6 y	2	None
Pescariu et al[7]	Romania	2001	365	35±21 mo	6	None
Linde et al[6]	Sweden	1996	100	32±11 mo	2	Idiopathic ventricular tachycardia (n=1)
Panja et al[30]	India	1992	120	7.5±5.6 y	6	. . .
Kruse[26]	Sweden	1985	487	. . .	1	Premature battery depletion (n=1) and set screw abnormality (n=1)
Kovacs et al[31]	Hungary	1980	28	. . .	None	None
Cooperman et al[32]	Israel	1984	78	. . .	None	None
Mond et al[33]	Australia	1978	83	. . .	1	None
Amikam et al[34]	Israel	1982	132	5 y	3	None
Havia et al[35]	Sweden/Finland	1974	50	22 mo	1	None
Grendahl[5]	Norway	1993	310	. . .	14	Technical error (n=4)
Costa et al[27]	Brazil	1982	22	16 mo	1	Electromagnetic inhibition (n=1) and spontaneous reprogramming (n=1)
Rosengarten et al[8]	Canada	1987	18	29 mo	1	Set screw abnormality (n=2) and pectoral muscle inhibition (n=1)
Sedney et al[28]	Holland	1983	214	31.5 mo	1	Technical error (n=1)
Aren et al[36]	Sweden	1979	19	26 mo	None	None
Ferugilo et al[37]	Italy	1978	87	14 mo	1	None
Namboodiri et al[38]	India	2001	5	19.2 mo	None	None
Baman et al[21]	Philippines	2008	12	4 mo	None	None
Total			2270	35±25 mo*	40	13

*Denotes mean±SD duration of follow-up.

Methods

We performed a computerized search to identify articles from January 1, 1970, to September 1, 2010, using MEDLINE (National Library of Medicine, Bethesda, MD), PubMed, the Cochrane Central Register of Controlled Trials, the ISI Web of Science, and Google Scholar. In addition, abstract lists and conference proceedings from the scientific meetings of the American College of Cardiology, European Society of Cardiology, and American Heart Association were searched. Medical subject headings and keyword searches included the terms "refurbished pacemaker," "reutilized pacemaker," "resterilized pacemaker," "reusing or reused pacemaker," and "pacemaker reutilization." Reference lists of the selected articles were reviewed for other potentially relevant citations. Authors from selected studies were contacted to obtain further information.

Study Selection

A study was included if it reported the incidence of pacemaker infection or malfunction after pacemaker reuse. In addition, we included studies examining pacemaker reuse with end points of infection or malfunction when compared with a control group with new device implantation. Data were independently abstracted by 2 reviewers (T.B., J.R.), and disagreements were resolved by consensus. Reviewers were not blinded to study authors or outcomes. Baseline demographic, clinical, and procedural characteristics including mean age, sterilization technique, and complications including infection, device malfunction, and pacemaker-related death were recorded.

Outcomes

The primary outcome was pacemaker infection or device erosion as defined by each individual study protocol. The secondary end point was device malfunction. Device malfunction was defined as a defect in the structural or electric integrity of the pulse generator as described by study authors. Ambiguous terms such as "technical error" were included as a device malfunction for the purposes of this analysis. Lead failure was not included as a device malfunction.

Statistical Methods

Data from included studies that compared used pacemaker implantation with a control group with new device implantation were combined to estimate the pooled effect (odds ratio [OR], for reimplanted pacemakers compared with controls). Pooling was done by random-effects meta-analysis using the DerSirmonian-Laird approach. If no event occurred in either or both arms of a study, the log odds ratio become undefined for comparative studies (comparing reused with new devices). Studies without an event were not included in the analysis, and for studies with zero events in one arm, a constant continuity correction was used by adding 0.5 to both study arms in the respective study.[9] To assess the influence of this approach and the risk to introduce a bias, sensitivity analyses were performed by adding different constants, instead of 0.5 (0.00001; 0.0001; 0.01; 0.1), and in addition, we also used a "treatment arm continuity correction" as an alternative approach.[10,11] In a further sensitivity analysis, we also included studies without any events in both arms.

We assessed publication bias visually (funnel plot) and by formal tests (Egger test[12] and the more recent arcsine test[13]). In addition to the inclusion of unpublished studies, we attempted to further reduce the potential impact of publication bias by the Duval and Tweedie[14] trim and fill method to statistically estimate results of unpublished studies. Funnel plot, Egger test, and the trim and fill method are closely related tests. They are based on the idea that small studies have expectedly higher between-study variations of their treatment effect (caused by the play of chance), but these estimates should be symmetrically distributed around the "true" treatment effect if there is no publication bias.

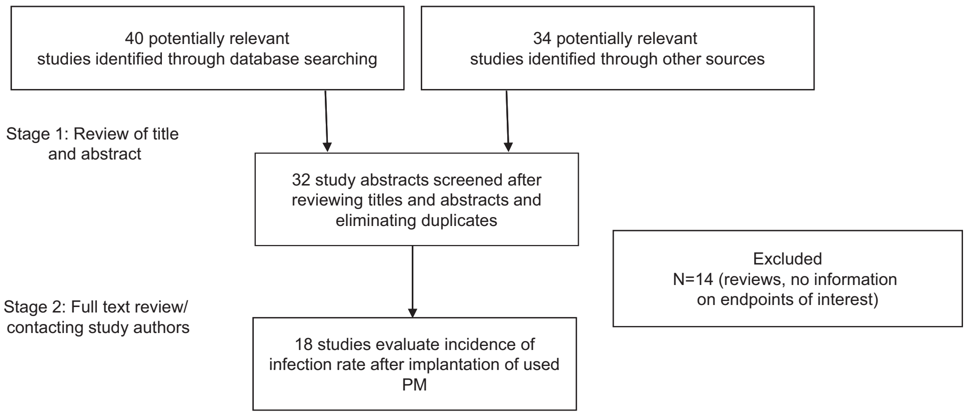

Figure 1. Outline of the search and selection strategy.

Heterogeneity among trials was quantified with the Higgins and Thompson I^2. I^2 can be interpreted as the percentage of variability caused by heterogeneity between studies rather than sampling error.

Weighted meta-analytic prevalence estimates were calculated using the variance stabilizing Freeman-Tukey Double Arcsine transformation[15,16] with a random effects model because the use of the inverse variance weight in fixed-effects meta-analysis is suboptimal when dealing with binary data with low prevalence. In addition, the transformed values of zero prevalence can be included in the analysis. The analyses are presented as point estimates, and 95% confidence intervals are shown within brackets.

All analyses were performed with R version 2.9.0[17] (packages "meta," "metaphor," and "rmeta") and SAS, version 9.2 (SAS Institute, Cary, NC) (proc mixed).[18]

Results

Of 32 articles and abstracts reviewed, 18 studies with 2270 patients met inclusion criteria (Figure 1). Five trials were controlled and directly compared pacemaker reuse with new device implantation. Of the 18 studies, 16 were based at a single center and 2 were conducted at multiple centers. All studies used sterilization protocols with ethylene oxide as a primary sterilization methodology. Average follow-up was 35±25 months (range, 2 to 76 months). The Table displays characteristics of studies included in the analysis. F1

Infection Risk

Infection data were available for 2270 patients in 18 trials. The proportion of patients who had device infection after pacemaker reuse was 1.97% [1.15 to 3.00%]; heterogeneity testing I^2=50.3% [22.6% to 75.6%] (P=0.008) (online-only Data Supplement Figure 1).

In the 5 controlled trials, a total of 913 reused devices were compared with 6679 new device implants. There was no significant difference in infection rate between pacemaker reuse and new devices (OR, 1.31 [0.50 to 3.40]; P=0.580); heterogeneity testing I^2=70.6% [25.4%; 88.5%] (P=0.009) (Figure 2). There was no suggestion of publication bias by Egger test (P=0.451) or Funnel plot (online-only Data Supplement Figure 2). F2

Device Malfunction

Device malfunction data were available for 2150 patients in 17 trials. A total of 13 events met criteria for device malfunction. Device complications included "technical errors" as described by the authors (n=5), set screw abnormalities (n=3), idiopathic ventricular tachycardia (n=1), premature battery depletion (n=1), electromagnetic inhibition (n=1), spontaneous reprogramming (n=1), and pectoral muscle inhibition (n=1). There were no reported pacemaker-associated deaths. The proportion of patients who had device malfunction after pacemaker reuse was 0.68% [0.27 to 1.28%]; heterogeneity testing I^2=38.0 (P=0.057) (online-only Data Supplement Figure 3).

In 4 controlled trials, a total of 793 reused devices were compared with 2200 new device implants. There was an increased risk for malfunction in the reuse group (OR, 5.80 [1.93 to 17.47]; P=0.002; heterogeneity testing I^2=0% [0%; 62.9%] (P=0.756) (Figure 3). There was no suggestion of publication bias according to Egger test (P=0.418). F3

Sensitivity Analyses

The overall point estimates for the OR of device malfunction ranged between 5.10 (P=0.003) and 6.39 (P=0.002). with

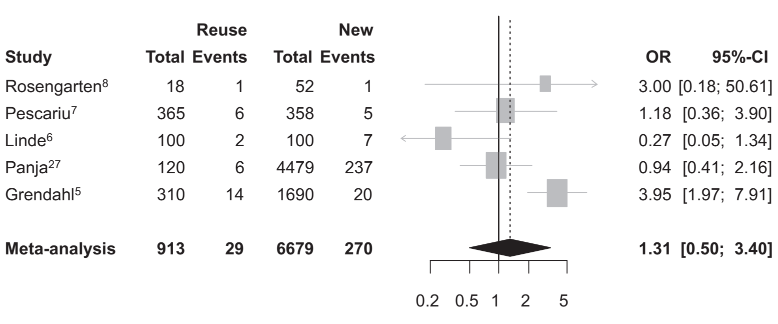

Figure 2. Forest plot of ORs of patients in whom an infection developed after implantation of reused pacemakers versus implantation of new pacemakers. Horizontal bars indicate 95% confidence intervals.

Study	Reuse Total	Reuse Events	New Total	New Events	OR	95%-CI
Rosengarten[8]	18	3	52	2	5.00	[0.76; 32.77]
Pescariu[7]	365	0	358	0		
Linde[6]	100	1	100	0	3.03	[0.12; 75.28]
Grendahl[5]	310	4	1690	3	7.35	[1.64; 33.01]
Meta-analysis	**793**	**8**	**2200**	**5**	**5.80**	**[1.93; 17.47]**

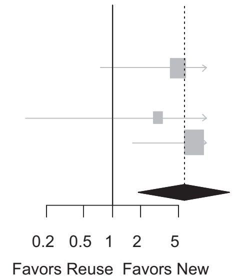

Figure 3. Forest plot of ORs of risk for device malfunction after implantation of reused pacemakers versus implantation of new pacemakers. Horizontal bars indicate 95% confidence intervals.

the different approaches of continuity correction for zero values (online-only Data Supplement Table).

Discussion

This meta-analysis including 18 studies and 2270 patients revealed an overall low rate of adverse effects with pacemaker reuse, specifically infection (1.97%), and device malfunction (0.68%). However, our study also suggests that pacemaker reuse may be associated with a higher rate of device malfunction as compared with new device implantation.

A great disparity in the distribution of electrophysiological devices clearly exists. The risks of pacemaker reuse must be weighed against the obvious benefit patients with no other options may receive with device implantation, especially for those with complete heart block, which is the primary indication for device implantation in underserved countries.[19,20]

Approximately 20 years ago, pacemaker reuse was routinely performed in many countries (Table). In 1996, 5% of all devices implanted in Sweden were from a previous recipient; there is no evidence that this practice resulted in any increased patient risk.[21] Moreover, governing bodies such as the European Society of Cardiology and the American College of Cardiology/American Heart Association/North American Society of Pacing and Electrophysiology published proceedings stating that "reuse of pacemakers may be considered"[21] and pacemaker reuse "may eventually add significantly to the cost-effectiveness of cardiac pacing,"[22] respectively. However, due to liability and ethical concerns, the practice of pacemaker reuse was abandoned.

Patients receiving reused devices have no difference in actuarial survival when compared with those receiving new devices at 10-year follow-up.[23] Moreover, none of the controlled trials in the medical literature found a higher risk of infection or device malfunction in the reused device cohort.[5–8] Our pooled analysis did show a higher rate of device malfunction (OR, 5.8 [1.93 to 17.47]) when compared with new device implantation, although the absolute numbers of device malfunction were very low (0.68%, [0.27% to 1.28%]) and did not include mortality. This higher rate of malfunction may be attributable to a greater sample size, thus accounting for increased mechanical abnormalities such as loose set screws. In this perspective, one must evaluate whether a higher rate of device malfunction outweighs the baseline risk of morbidity and mortality that patients with symptomatic bradycardia encounter on a daily basis. We submit that patients with symptomatic bradycardia will, on average, gladly accept such risk if this is the only opportunity to receive a device. Moreover, the dependability of pacemakers has significantly improved in recent decades, with studies showing a malfunction rate of 0.04%.[1] Thus, the low rate of device malfunction seen in our study may actually be lower, with current pacemaker manufacturing standards. We must not forget that at the foundation of each technological breakthrough is the need to improve humanity in all corners of our society. Whenever possible, medical therapies should be offered to every individual who may derive overall benefit.

This study suggests that pacemaker reuse has an overall low rate of infection and device malfunction and may be a safe and efficacious means of providing health care to those with symptomatic bradycardia and no other means of obtaining a device. These findings have significant implications to any pacemaker reuse initiative to help alleviate the burden of symptomatic bradycardia in our world.[24,25] Although the results of this meta-analysis describe a higher rate of device malfunction compared with new device implantation, many of the noted complications may be discovered and replaced with another device during the implantation process. Adequate training of funeral directors during device explantation may be the most efficacious method to significantly reduce device malfunction because many of the defects were secondary to mechanical header malfunction, possibly during extraction. Finally, rigorous patient selection and adequate training of implanting physicians are paramount to provide reuse pacemakers to those only with debilitating bradycardia as well as those able to have close monitoring for device malfunction.

Limitations

This study has several limitations. First, 3 of the 18 studies have only been presented as abstracts and did not undergo a rigorous peer-review process. Detailed information on study protocols, definitions of end points, and loss to follow-up of patients is limited. Second, the direct comparison of outcomes of pacemaker reuse versus new pacemakers is based on nonrandomized, controlled trials. Nonrandomized treatment assignment introduces a significant risk for selection bias. The population of patients in whom reused pacemakers have been implanted may differ from patients with implantation of new devices. Third, failure to truly understand the details of device malfunction in the reused pacemaker group is a significant limitation of this meta-analysis. Complications such as set screw malfunction (n=3),[8,26] premature battery depletion (n=1),[26] electromagnetic inhibition (n=1),[27] spontaneous reprogramming (n=1),[27] and pectoral muscle inhibition (n=1)[8] can be clearly attributable to loss of mechanical or electric integrity during the extraction and/or sterilization process. Moreover, 2 of the authors described complications simply as "technical errors" (n=5)[5,28] thus limiting further clarification. However, other reported complications such as incessant ventricular tachycardia (n=1)[6] that resolved on device extraction may be secondary to lead placement rather than device malfunction. The fourth limitation of our study is the lack of available data regarding implanter experience and a possible association with complications. Also, the duration of follow-up varied considerably among the studies; however, we found no significant influence of follow-up duration on study conclusions.

Implications

In our meta-analysis of 2270 patients, pacemaker reuse was associated with an overall low rate of infection (<2%) and device malfunction (<1%) and may represent a viable option for patients in underserved nations with symptomatic bradycardia and no other means of obtaining a device. However, the incidence of device malfunction was significantly higher when compared with new device implantation. This difference was mainly driven by abnormalities in set screws, which possibly occurred during device extraction as well as nonspecific device "technical errors," as reported by 2 authors. Patients with highly symptomatic conduction disease may benefit from pacemaker reuse but should be closely monitored for device malfunction. Large controlled trials are necessary to better understand the role of pacemaker reuse for medically underserved individuals who otherwise would not have access to bradyarrhythmia therapy.

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Dr Oral was a founder of Ablation Frontiers, Inc, and is now a consultant for Medtronic Ablation Frontiers.

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CLINICAL PERSPECTIVE

A great disparity in medical health care is clearly evident in the field of cardiac electrophysiology—specifically pacemaker implantation—in which the specialty is either severely underdeveloped or entirely nonexistent in many low- and middle-income countries. In an effort to promote cost savings as well as to provide care to those with no other means of acquiring a device, a number of articles in a wide variety of international settings have been published describing the safety and efficacy of pacemaker reuse. The aim of this meta-analysis is to assess the safety of pacemaker reuse. Pooled individual patient data (n=2270) from 18 trials were included in the analysis. The results demonstrate that there is no significant difference in infection rate between pacemaker reuse and new device implantation ($P=0.58$); however, there was an increased risk for malfunction in the reuse group ($P=0.002$). This difference was mainly driven by abnormalities in set screws, which possibly occurred during device extraction as well as nonspecific device "technical errors." Overall, pacemaker reuse was associated with an overall low rate of infection (<2%) and device malfunction (<1%) and may represent a viable option for patients in underserved nations with symptomatic bradycardia and no other means of obtaining a device. We believe that postmortem pacemaker reuse is a safe, feasible, and ethically responsible means of delivering electrophysiological health care to those in great need.