Re-used pacemakers — as safe as new?

A retrospective case-control study

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Abstract Re-use of pacemakers is of interest in an era of declining health care resources if it is proven safe and without risks to the patients. In order to investigate the safety of re-use of pacemakers we performed a retrospective case-control study. One hundred patients, who received a re-used pacemaker, were matched for date of implantation and mode (AAI; VVI; DDD) to 100 others who received a newly manufactured pacemaker and were followed for a mean of 32 ± 11 months for complications defined as infections and signs of pacemaker malfunction and pacemaker replacement earlier than anticipated due to battery depletion. Patients who received re-used pacemakers were significantly older than those who received new units (79 ± 9 vs 68 ± 21 years; P < 0.0001). The number of complications did not differ significantly between groups. There were no early replacements due to battery depletion in either of the two groups. A cost-benefit analysis revealed a substantial economical advantage.

Conclusions The re-use of pacemakers can be carried out without increased risk to the patients provided a proper routine for technical control and sterilization is followed. Re-use means substantial savings which possibly could make advanced pacemaker treatment available to all eligible patients irrespective of age. Whether re-use is feasible with implantable defibrillators remains to be determined.

Key Words: Cardiac pacing, pulse generators, re-use, safety, health economy.

Introduction

In Sweden pacemakers have been re-used for decades. Previous studies indicate that this tradition can be practised without untoward risks for the patient[1,2]. The re-use of pacemakers was the theme of a NASPE policy conference in 1985 with the following recommendations: (a) national legislation should not prohibit re-use, (b) re-use should be proven free from any additional risk or adverse effects for the patient compared to the use of a new pacemaker (c) a cost-benefit analysis should document that the re-use results in substantial economic advantages[3].

By Swedish law, all implanted pacemakers and defibrillators must be explanted when the recipient dies to avoid device explosion during cremation. Extraction of a pacemaker is not defined as an autopsy and can be performed by any physician or technician in a pathology department. Moreover, the patient is not the owner of the implanted pacemaker, which belongs to the implanting centre. Thus, the implanting centre has the right to retrieve explanted pacemakers and defibrillators from the institution where the patient died or from the pathologist. These factors probably contribute to the tradition to re-use pacemakers in Sweden.

When Sweden became a member of the European Common Market in 1994, the Medical Board of Health elaborated rules for the use of medical–technical products in concurrence with those in the Common Market. According to these rules, only pacemakers with CE labelling can be accepted for implantation. CE labelling signifies that the manufacturer takes full responsibility for the use and safety of a product as long as the user follows their instructions. The new rules worried the medical profession as to whether the tradition to re-use pacemakers could still be continued. Figures from the Swedish Pacemaker Register reflect this hesitance and indicate a drop in the re-use of pacemakers from 14% of all primary implantations and replacements in 1991 to 8% in 1994–5. In an inquiry regarding re-use of pacemakers, reasons given for non-re-use were uncertainty about legality and ethics as well as a lack of established routines for re-use.

Re-use of pacemakers and possibly of other devices should be of common interest in an era of declining health care resources. If, as indicated by previous studies[1,2], re-use is safe and without risks to the patients, it should be applied more widely granting
accessibility of treatment to all patients in need of cardiac pacing irrespective of age. Moreover, the safe re-use of defibrillators and, for example solid electrophysiology catheters would allow additional savings.

In order to investigate if re-use of pacemakers carries possible risks for complications for the patient compared to a newly manufactured pacemaker, we performed a retrospective case-control study. In addition, a cost–benefit analysis was carried out to prove a possible economical advantage.

### Material and methods

#### Criteria for re-use

At our hospital, a pacemaker can be re-used once the criteria for re-use are fulfilled (Table 1). The heads of the departments of Thoracic Surgery and Cardiology have given the responsibility for recycling of pacemakers to one nurse and one assistant. The assistant collects explanted pacemakers from the institution where the patient died or from the Department of Pathology. The nurse cleans the pacemaker with a brush, soap and water and inspects it. All generators with signs of damage are excluded from re-use. The assistant checks the pacemaker with a PSA (Pacemaker System Analyser, Medtronic, Minneapolis, USA) for battery current, cell-impedance, and programmed values. The pacemaker is programmed to nominal values and put in Lysetol solution (Schülke & Mayr, Germany), which contains phenoxypropanol and benzalconiumchloride. The pacemaker is immersed for 12 h, then rinsed under running water and dried. It is subsequently wiped with 70% ethanol and air-dried. Finally it is packed, labelled and sterilized in ethylene oxide. The recycled pacemakers are used in our institution only and can never be sold to another hospital. Patients eligible for re-used pacemakers are only those in whom the life-expectancy of the patients is estimated to be lower than that of the pacemaker.

### Case-control study

We performed a retrospective case-control study of consecutive 100 patients who between 1 January 1992 and 1 January 1994 received a re-used pacemaker at primary implantation or replacement. These patients were matched for date of implantation and stimulation mode (AAI, VVI, DDD) to 100 other patients who had received newly manufactured pacemakers. All files were reviewed for complications by two investigators (C.L., A.B.). The follow-up ended on 1 August 1996. Since 1 August 1993 all patients were administered cloxacillin sodium 2 g intravenously prior to implantation as part of a routine to prevent infection.[4]

Complications related to the re-use of pacemakers were defined as infections that required antibiotics and/or re-operations, suspicion of pacemaker-malfunction described in the file or causing replacement and replacements due to battery depletion. Lead-related complications as well as those associated with an inappropriate choice of pacing mode, i.e. pacemaker syndrome, were not defined as related to the choice of a re-used or newly manufactured pacemaker. Such problems were therefore excluded from this study.

### Cost-benefit analysis

The cost benefit analysis comprised 129 patients who received a re-used pacemaker between 1 January 1989 and 1 January 1993. They were analysed for survival and time to pacemaker replacement.

### Results

#### Case-control study

All files could be retrieved. The clinical data are presented in Table 2. The complication rate was 3% in patients receiving re-used pacemakers and 7% in those given newly manufactured units (Table 3). Eight of the complications occurred in connection with primary implants (re-used pacemakers n=1, newly manufactured...
pacemakers n=7) and two after replacements (re-used pacemakers n=2). One case of possible pacemaker malfunction was observed during implantation of a re-used pacemaker. This occurred in a 92-year-old man who underwent a primary implant of a VVIR pacemaker owing to high degree atrioventricular block. He developed attacks of ventricular tachycardia when the re-used pacemaker was connected to the ventricular lead. There were no signs of pacemaker-mediated tachycardia. When the unit was exchanged for a newly manufactured unit, the ventricular tachycardia subsided. It cannot be excluded that the arrhythmia was related to the positioning of the ventricular lead rather than to the generator. There were slightly more infections in the group receiving newly manufactured pacemakers than in the group receiving re-used pacemakers. All but one of these nine infections occurred before the introduction of the routine to give prophylactic intravenous antibiotics prior to implantation. There were no early replacements due to battery depletion during the 32 ± 11 months follow up.

Cost–benefit analysis

There were 55 women and 74 men in the study. Two patients were lost to follow up. Seventy-three of the 129 patients (56%) died after an average implantation time of 3.1 years and before a need of replacement. The 44 patients who are still alive have had the re-used pacemaker implanted for a mean of 5.4 years. Only 12/129 (9%) underwent replacement (mean time=4.3 years). This signifies a saving of 73 patients x 3.1 years + 44 patients x 5.4 = 463.9 patient years, or 5567 pacing months with a re-used pacemaker. This corresponds to an average of 7 years per pacemaker. The estimated cost for a pacemaker is 3000 USD/unit (USD = United States dollars). The comparable cost for a re-used pacemaker is 100 USD/unit. Calculated from figures in the National Swedish Pacemaker Registry, the national expenditure of the 4023 pacemakers that were implanted in Sweden in 1995 was 12.1 million USD. The corresponding cost for the 317 re-used units was 31.700 USD. This amounts to an estimated national saving of 919 300 USD.

Discussion

In Sweden, pacemakers have been re-used for decades. Our study indicates that re-use, providing proper standards are strictly followed, does not cause additional risk for complications to the patients. These findings agree with two previous Swedish studies. Havia and Schüller in 1976 reported no complications in 50 patients receiving re-used pacemakers. Munksgaard-Kruse in 1984 described a 17 year experience of re-use of pacemakers in 498 patients who had received a re-used unit compared to 1197 who were implanted with newly manufactured pacemaker. The complication rate was comparable in the two groups (5.9%; newly manufactured pacemaker vs 4.8%; re-used pacemaker). Moreover, a substantial cost–benefit with a gain of 11 000 pacing months could be demonstrated.

In our institution, patients eligible for re-used pacemakers were those in whom their life-expectancy was estimated to be lower than that of the pacemaker. The cost–benefit analysis in the current study shows that a correct approximation was made in most cases since only 9% of the patients receiving re-used units underwent replacements.

If there is an established routine for sterilization and technical control, the re-use of pacemakers can provide substantial economical benefits. With restrictions in economic frames, doctors might choose to implant elderly patients with less expensive and thus less sophisticated modes, such as fixed rate ventricular inhibited pacemakers. Re-use of pacemakers makes it possible to implant advanced pacing systems irrespective of the patients' age. It will, according to our experience, provide no additional risk for the recipient.

It has been widely established that atrioventricular synchronous pacing provides a superior quality of life, exercise tolerance and haemodynamics compared to fixed rate ventricular inhibited pacemakers[5–7]. Therefore, it could be argued that it is unethical not to re-used pacemakers if costs determine which pacing mode can be applied.

This argument could also encompass the re-use of implantable defibrillators and solid catheters used in invasive electrophysiology. The annual implantation rate of implantable defibrillators varies between European countries and is generally lower than in the United States. At the same time, the indications for defibrillators are expanding[8]. Therefore, it may seem unethical to withhold life-saving treatment from patients who might benefit from implantable defibrillators by economical necessity. With this in mind studies on the safety in the re-used of defibrillators are clearly needed.

Finally, it would seem that the regulation of device implantation and re-use should to a greater extent than at present, be influenced by members of the medical profession rather than as presently more commonly by the manufacturer.

Conclusion

The re-use of pacemakers can be carried out without increased risk to the patients provided a proper routine for technical control and sterilisation is followed. Re-use means substantial savings and such a system would possibly make advanced pacemaker treatment available to all eligible patients. Whether re-use is feasible with implantable defibrillators remains to be determined.

References


