Re-used pacemakers: as safe as new? A retrospective case-control study

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The re-use of pacemakers in patients requiring cardiac pacing.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients who received a re-used pacemaker or a new pacemaker. Patients, receiving a re-used pacemaker, had a life expectancy of less than that of the patients, receiving new pacemakers.

Setting
Hospital. The economic analysis was conducted in Stockholm, Sweden.

Dates to which data relate
Effectiveness data were collected between 1st January 1992 and 1st August 1996. Resource data were collected between 1st January 1989 and 1st January 1993. The price year used were not clearly stated, but seems to be 1995.

Source of effectiveness data
Effectiveness data were taken from a single study.

Link between effectiveness and cost data
The costing was undertaken on a different patient sample to that in the effectiveness analysis. Data for both effectiveness and costings were collected retrospectively.

Study sample
Power calculations were not used to determine the sample size. There were 100 patients in both the re-used and new pacemaker cohorts. The average age of patients in these two groups was 79 (+/- 9) years and 68 (+/- 21) years, respectively and 39% and 50% of patients were male.

Study design
This was a single centre retrospective matched cohort study. The duration of follow up was up to a maximum of 55 months after implantation (mean 32 months, +/- 11 months)
Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes used in the analysis were the incidence of complications and pacemaker malfunctions. At analysis the age of the two cohorts were significantly different with the re-use cohort being older than the new cohort (79 years versus 68 years, P<0.0001). No adjustment was made for this as reused pacemakers are only suitable for those with shorter life expectancies.

Effectiveness results
In the reused pacemaker cohort there were 2 cases of infection and one malfunction (3%) compared with 7 infections (7%) in the new cohort. These differences were not significant and, additionally, there were no cases of early replacement due to battery depletion.

Clinical conclusions
The authors concluded that pacemakers could be reused without increased risk of complication or technical malfunction.

Measure of benefits used in the economic analysis
Since the effectiveness analysis demonstrated no difference in effectiveness between re-use and new pacemakers the economic analysis was based on the difference of costs only.

Direct costs
The costs of pacemakers were estimated from the National Swedish Pacemaker Registry in 1995. A cohort of 129 patients who received reused pacemakers between 1989 and 1993 were followed up until August 1996. Costs were estimated from the perspective of the Swedish National Health Service. The price year used was not stated and costs were not discounted.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
Of the 129 patients studied only 12 had required a replacement pacemaker, 73 patients died before a replacement was required and 44 were alive without need for replacement. The total number of pacing months with the re-used pacemaker was 5,567. The cost of a new pacemaker was estimated to be $3,000 whilst that for the reused pacemaker was $100. In 1995 using the 317 reused units led to a reduction in costs compared with the use of new pacemakers of $919,300.

Synthesis of costs and benefits
Not applicable.
Authors' conclusions
The authors concluded that the re-use of pacemakers in eligible patients would lead to a substantial reduction in costs and would increase the number of patients for whom the use of pacemakers would appear to be a viable option.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used. Pacemakers have historically been explanted and re-used in Sweden and studies in the literature have reported that this practice is not associated with increased risks if strict standards are used.

Validity of estimate of measure of benefit
The estimate of benefits was based on a retrospective matched cohort analysis. As the study lacked randomisation and sensitivity analysis, the results need to be treated with some caution. Moreover, the two patient groups were shown to be different and, therefore, the results may be subject to bias.

Validity of estimate of costs
Insufficient information was provided on the source and nature of costs or the price years and exchange rate used. In addition costs were not estimated for the same patient sample as that used in the effectiveness analysis. It is not clear if the costs of reused pacemakers include the costs associated with the explanation and preparation of these pacemakers. Costs were estimated from the perspective of the heath service and other costs such as those to society were excluded.

Other issues
The costs identified in the study may not be applicable outside Sweden.

Implications of the study
There is a need for further, well designed, economic evaluations to compare, in particular, the costs associated with new and reused pacemakers. As noted by the authors there is a need also to examine further the efficacy and effectiveness of re-use of defibrillators.

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