Analysis of charges and complications of permanent pacemaker implantation in the cardiac catheterization laboratory versus the operating room
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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
Permanent pacemaker implantation, conducted in a cardiac catheterisation laboratory (CCLAB) by electrophysiologists, was studied.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
The study population comprised patients aged older than 16 years who required pacemaker implantations.

Setting
The setting was an academic hospital. The economic study was performed in Miami (FL), USA.

Dates to which data relate
The dates to which the effectiveness evidence and resource use data related were not given. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed on the same sample of patients as that used in the effectiveness study. It was unclear whether the costing was performed retrospectively or prospectively (or both).

Study sample
Power calculations, if performed, were not reported. A total of 254 consecutive patients requiring pacemaker implantations were included in the analysis. Of these, 122 patients received their pacemaker implant in the OR and 132 received their implant in the CCLAB. The mean age in the OR group was 64 (+/- 21) years and 64% were men. The mean age in the CCLAB group was 65 (+/- 17) and 34% were men. Indications were similar between the two groups, with the majority of patients suffering from second or third degree atrioventricular block or atrioventricular node ablation. The patient groups were matched in terms of the type of pacemakers implanted, with the majority of the patients receiving dual chamber devices. No patient refused to participate or was excluded from the initial sample.
Study design
This was a cohort study that was carried out in a single centre (Department of Medicine, Division of Cardiology, University of Miami, Florida). It was unclear whether the study was prospective or retrospective. The authors stated that the patients were allocated to each group independently. Only a few high-risk patients referred to the CCLAB crossed over to the OR. The follow-up was 2 years. No loss to follow-up was reported.

Analysis of effectiveness
All of the patients included in the initial study sample were taken into account when estimating the effectiveness. The primary health outcomes included in the analysis were the rate of procedural and infectious complications, and the hospital length of stay. Infectious complications were defined according to the criteria of Choo et al. (see Other Publications of Related Interest). These included abscess formation in the pacemaker pocket, fever and sepsis in a patient with no other source of infection, and erosion of part of the pacing system through the skin with secondary infection. The authors stated that there were no differences among the two study groups, but no statistical analysis of these differences was performed. The differences in the percentage of men in the two groups and in some of the indications appear to have been substantial. Moreover, the statistically significant difference in the average hospital days spent prior to implantation, 5.65 (+/- 9.54) days for the OR group versus 3.16 (+/- 12.40) days for the CCLAB group, (p<0.05), might suggest a higher percentage of high-risk patients in the OR group.

Effectiveness results
There were 14 procedural complications in the OR group (5 pneumothorax, 8 lead dislodgements, 1 cardiac arrest) versus 7 in the CCLAB group. This difference was not statistically significant.

All of the complications were minimal.

No deaths or infectious complications occurred in the two groups.

The average hospital stay did not differ significantly between the two groups, 9.22 (+/- 11.72) days for the OR group versus 7.22 (+/- 12.49) days for the CCLAB group.

In particular, no statistically significant difference was found in the post-implant days, 4.06 (+/- 5.50) days for the OR group versus 4.00 (+/- 8.38) days for the CCLAB group.

Clinical conclusions
The effectiveness analyses showed that permanent pacemaker implantation in an OR, as performed by surgeons, and in a CCLAB, as performed by electrophysiologists, presented no statistically significantly different results in terms of complications and hospital length of stay.

Measure of benefits used in the economic analysis
No summary benefit measure was used. No difference was found between the two alternatives in terms of the effectiveness outcomes. The study should therefore be classified as a cost-minimisation analysis.

Direct costs
Discounting was not carried out as it was not relevant to the analysis (although the patients were followed up for 2 years, the costs were incurred in a short time period). The unit costs were not reported separately from the quantities of resources used. The quantity/cost boundary adopted was that of the hospital. The costs included were those related to the implantation during the day of the procedure, such as pacemaker implant, fluoroscopy and anaesthesia. A detailed breakdown of the costs was reported. The costs of pacemaker generators and professional charges were excluded from the analysis because they were common to both groups. The costs were estimated from hospital charges. Resource use was derived using actual data obtained from the patients included in the study. Information about when the resource use
occurred was not given and the price year was not reported.

Statistical analysis of costs
Student's t-test was used to estimate the statistical significance of differences in the costs of the two alternatives.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not conducted.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average hospital cost per patient for permanent pacemaker implantation was $5,465 (+/- $1,670) in the OR and $2,682 (+/- $8) in the CCLAB. The difference was statistically significant, (p<0.001).

Synthesis of costs and benefits
Not relevant because a cost-minimisation study was performed

Authors' conclusions
Pacemakers could be implanted in the cardiac catheterisation laboratory (CCLAB) by non-surgeons, without any increase in complications and with a decrease in hospital costs.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The traditional approach for pacemaker implantation was compared with the more recent procedure. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a cohort study, which seems to have been appropriate for the study question. However, it was unclear whether the study was carried out prospectively or retrospectively. The main limitation of the study appears to have been the possible selection bias. Some characteristics were different between the two study groups and there was a statistically significant difference in pre-implant hospital length of stay in the two groups. Although the authors stated that this difference is likely to be due to the ease with which the patients could be scheduled in the CCLAB, compared with the OR, it could also be due to differences in the patients' level of risk. Moreover, no statistical analyses were performed to compare the patients' characteristics. No power calculations were performed, but the sample appears to have been of sufficient size to detect differences in the results.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was categorised as a cost-minimisation
study.

**Validity of estimate of costs**
The analysis of the costs was conducted from the perspective of the hospital. All of the relevant categories of costs seem to have been included, whereas some categories were excluded because they were common to both groups. However, the unit costs and the quantities of resource use were not reported separately and few details of the cost calculations were given. Information about when the resource use occurred was not given and the price year was not reported. The authors performed statistical analyses to estimate the statistical significance of the difference in the observed costs, but no sensitivity analyses were performed.

**Other issues**
The authors compared the effectiveness results of their analysis with those from other published studies in order to validate their results and address, in part, the issue of the generalisability of the findings. However, no sensitivity analyses were performed, which could limit the generalisability of the study results. The authors stated that this was the first study comparing pacemaker implantation in the OR and CCLAB, not only in terms of effectiveness, but also in terms of costs.

**Implications of the study**
The study results suggest that pacemakers implantation in a CCLAB could substantially reduce the hospitalisation costs and have an impact on health care expenditure, given the wide use of these medical devices.

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**Other publications of related interest**

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