Re-use of explanted DDD pacemakers as VDD-clinical utility and cost effectiveness
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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 reuse of post-mortem explanted DDD pacemakers programmed to VDD mode was studied.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a sub-sample of patients who received a pacemaker in one reference hospital in India. The indications for pacing were complete heart block and second degree AV block. Those eligible for explanted DDD pacemakers went through a pre-procedural evaluation, in order to achieve optimal patient selection for VDD mode, and were poor patients who could not afford a new pulse generator.

Setting
The setting was tertiary care. The economic study was carried out in India.

Dates to which data relate
The effectiveness and resource use data were gathered between October 2000 and December 2001. It can be inferred that the costing was based on the prices for the corresponding years.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was conducted prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not conducted. Patients receiving a pacemaker in the study centre were identified and those receiving post-mortem explanted generators were noted. Patients chose the type of pacemaker according to wealth. Only patients receiving explanted programmable DDD pulse generators reimplanted in VDD mode were selected (intervention group, n=5). These were compared with patients who received new DDD pacemakers during the same period (control group, n=25). Patients who were implanted with a new pacemaker were excluded if this was a single chamber or a VDD dual chamber. Cases of pacemaker reimplantation on the same patient, or reimplantation on the DDD mode, were also excluded. Overall, there were 136 patients in the initial sample.
Study design
This was a single centre, cohort study that was carried out in one Indian hospital. The patients were followed up after one month of implantation initially and 3-monthly thereafter. No loss to follow-up was reported.

Analysis of effectiveness
All of the patients included in the study were accounted for in the analysis. The primary health outcome used in the analysis seems to have been patient quality of life, based on a questionnaire specifically designed for pacemaker-related symptoms. At analysis, the groups were not comparable in their age. The mean age was 61 years in the intervention group and 48 years in the control group. The baseline comparability in terms of severity was not discussed.

Effectiveness results
The quality of life index did not reveal any significant difference between those receiving explanted pulse generators (22.2) and those receiving newer ones (24.4; 2 patients with cardiomyopathy were excluded from the quality of life assessment in the control group). Ninety-five per cent confidence intervals and p-values were not reported.

No complications were experienced in the intervention group, but there was one case of local infection (4%) and one case of lead displacement (4%) in the control group.

Clinical conclusions
The effectiveness analysis showed that the use of explanted pacemakers reimplanted in VDD mode led to a slight improvement in complication rates, but no difference in terms of quality of life.

Measure of benefits used in the economic analysis
No summary measure of benefit used in the analysis. In effect, a cost-consequences analysis was performed.

Direct costs
The hospital costs were included in the analysis. Only the costs of the pacemakers were evaluated. No labour, drugs or other costs were included. Resource use was reported separately from the costs (number of leads required, hospital length of stay). Discounting was not relevant as the costs were incurred during less than two years, according to the average patient follow-up. The quantities and costs were estimated on the basis of actual registry patient data. The average costs per patient per treatment arm were not reported, only the cost-differences in the number of leads used. Charges were used to value resource consumption as the health care was private. It can be inferred from the paper that the costing for each year was based on the prices for the corresponding years.

Statistical analysis of costs
The costs were treated deterministically. No statistical tests were carried out.

Indirect Costs
No indirect costs were included in the economic evaluation.

Currency
Indian rupees (R).

Sensitivity analysis
No sensitivity analysis was carried out.

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

**Cost results**
The fact that the explanted DDD pulse generator was implanted in the VDD mode translated into net savings of R18,000 (i.e. 50% of the total expenditure of refurbishment per patient), since only one new VDD lead and a single lead introducer were needed (instead of two transvenous leads, as used in the DDD mode).

Further cost-savings could be inferred from the reduced time spent on fluoroscopy (8.3 minutes) and the reduced post-procedural length of stay in hospital (5.2 days) in comparison with that for DDD insertion (12.8 minutes and 7.4 days), but their cost implications were not analysed.

The costs of treating procedural complications were not included.

**Synthesis of costs and benefits**
The costs and benefits were not combined as, in effect, a cost-consequence analysis was conducted.

**Authors' conclusions**
The use of explanted DDD pacemakers programmed to VDD mode in poor patients revealed that these generators can be safely and effectively used at a significantly lower cost.

**CRD COMMENTARY - Selection of comparators**
The authors did not provide any justification for the choice of the comparator. It was unclear whether DDD or VDD are the standard implantation mode for dual chamber pacemakers. The advantages and disadvantages of both methods were not raised in the 'Discussion' section. The nature of the comparison seems to have been different modes of implantation (DDD or VDD), rather than new or explanted pacemakers, as the main cost-advantage is derived from the use of one or two leads. You should decide whether they represent valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a cohort study with a historical control. The study sample was biased, as the patients chose which intervention to have on the basis of cost considerations. There was no randomisation. Also, the patients in the intervention group were subject to a pre-procedural evaluation to guarantee an optimal patient selection for VDD implantation mode. This fact could explain why more patients in the control group suffered complications.

**Validity of estimate of measure of benefit**
The benefit measures used in the economic analysis were disease specific, thus making it difficult to compare them with the benefits of other health care interventions. The authors did not derive a summary measure of health benefit, thus the study was, in effect, a cost-consequences analysis.

**Validity of estimate of costs**
It appears that a patient perspective has been adopted for the analysis. Considering the period of follow-up (17 to 19 months depending on the treatment arm), not all of the relevant cost categories were included in the analysis as this paper only considered the differences in the cost of pacemakers. Mean costs by treatment were not provided. The costs were treated deterministically and no sensitivity analysis was carried out.
Other issues
The authors compared their findings with those from other studies and they stated clearly the nature of the problem with reused pacemakers. The real point of the analysis seems to have been to demonstrate that, for a selected group of patients previously evaluated for optimal response to VDD mode and with no other option due to their economic situation, the use of explanted DDD pacemakers used in VDD mode can be a solution. No reference was made to the potential use of explanted DDD pacemakers in the DDD mode, or its advantages and disadvantages. The authors noted some limitations of the analysis in relation to the reduced sample size, but a more detailed discussion of the validity and generalisability of the results would have been useful.

Implications of the study
The study results suggested that explanted programmable DDD pacemakers can be safely reused in VDD mode in a selected patient population, with similar efficacy and at a lower cost. However, caution is required when interpreting the authors’ conclusions because of the limitations of the analysis, mainly bias in the selection of the intervention group. This is the first study in this area that was based on an Indian setting and was undertaken from the perspective of the reality of patients in a developing country. No specific recommendations for further research were made.

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