Cost-effectiveness of dual-chamber pacemaker therapy: does single lead VDD pacing reduce treatment costs of atrioventricular block?

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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
Single-lead VDD pacemakers compared to conventional DDD pacemakers with bipolar atrial leads for the treatment of atrioventricular blocks.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with symptomatic or high degree atrioventricular block and normal sinus node function were screened for the study. Patients were excluded because of signs of sinus node disease, history of intermittent atrial fibrillation, low life expectancy or because they refused to give informed consent for participation in the study.

Setting
The setting was secondary care. The economic evaluation was carried out in Germany.

Dates to which data relate
Effectiveness data were collected between 1992 and 1999. Resource use data referred to the same dates. No single price year was used, instead prices related to sources published in 1995, 1996 and an average of prices between 1992 and 1997.

Source of effectiveness data
The evidence/estimate for final outcomes was derived from a single study.

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

Study sample
Power calculations for the determination of the sample size were not reported. Patients with symptomatic or high degree atrioventricular block admitted to the University Hospital of Luebeck were screened for participation in the study. The final sample included 360 patients, 180 in each therapeutic arm. 85 patients overall were excluded from the study because of signs of sinus node disease, history of intermittent atrial fibrillation or low life expectancy. 2 patients refused to participate.
Study design
The study was a non-randomised trial with concurrent controls carried out in a single centre. Patients received the VDD or DDD devices in alternating order. Concealment of allocation from the surgeon would not have been possible due to the nature of the intervention, concealment from the patient was not discussed. The mean duration of follow-up was 42 (SD 15) months ranging from 3 to 76 months. There seems to have been no losses to follow up. Assessment of outcomes does not appear to have been blinded.

Analysis of effectiveness
The basis for the analysis of effectiveness (intention to treat or treatment completers only) was not specified. It was not specified whether it was possible to maintain the alternating order for the implantation of devices. The primary outcome used in the analysis was a combined criterion of event free survival including survival of patients, absence of complications needing re-operation and maintenance of atrioventricular synchronised pacing mode. At analysis, groups were shown to be comparable in terms of age, sex, indication for pacing, left ventricular function, and concomitant diseases.

Effectiveness results
The study reported that there was no significant difference between VDD and DDD therapy with respect to event free survival of patients. The test statistic for the log-rank test used to compare the two therapies was 0.04.

Clinical conclusions
The percentage of event-free survival did not differ between patients with VDD pacemakers and DDD devices. Both pacemaker systems showed an equal therapeutic efficacy in patients with atrioventricular block and normal sinus node function.

Measure of benefits used in the economic analysis
As the effectiveness results showed no difference in the clinical benefit between the VDD and DDD devices, the economic analysis was based on cost differences only. The analysis was therefore a cost-minimisation study.

Direct costs
Some resources (mean hospital days) were reported separately from the costs. Mean prices and fees for individual cost items were reported. The perspective of the cost analysis was that of the hospital. Direct costs included the cost of devices, leads, single-use operation material and sterilisation, fees of implanting physicians, nurses and medical technicians. Furthermore, direct primary costs of pacemaker implantation included two nights of hospital stay, antibiotic prophylaxis with three doses of cefacolin, one routine pacemaker interrogation, one 24 hour Holter ECG and one chest X-ray. If hospitalisation was prolonged due to treatment of concomitant diseases not directly associated with pacemaker implantation, a hospital stay for an uncomplicated implantation was assumed. Direct secondary costs included costs of follow-up or complications of pacemaker therapy: hospital fees due to prolonged stay or re-admission of patients, cost of laboratory examinations and antibiotic therapy, cost of additional chest X-rays, Holter recordings and pacemaker interrogations, expenses due to operative revision, device explantation and re-implantation. Costs of treatment for atrial arrhythmia’s were included as the condition could be associated with different pacemaking therapies. However, costs associated with coronary artery disease, myocardial infarction and heart failure were not included as it was considered that these were not directly associated with different dual-chamber pacing modes. Prices for devices and other materials were derived from the average price of various manufacturers calculated for a time period between 1992 and 1997. Personnel fees were taken from the standardised German hospital charges and charges for diagnostic devices were derived from the standardised German physician charges. The source of the cost of antibiotics and the day of hospital stay was not reported. The estimation of unit charges was based on standard published charges. Discounting was not conducted although the length of the study justified its use. The study reported average costs. No single price year was used. The costs were not adjusted for inflation.
Statistical analysis of costs
Resource use and unit costs were treated as point estimates. The mean costs of the two strategies and the duration of hospital stay were reported with standard deviations. A Mann-Whitney U test was used to compare the mean costs of the two different strategies, although no justification was provided for the choice of this test. Power calculations to detect a difference were not reported.

Indirect Costs
Indirect costs were not included in the study. No justification for their exclusion was provided.

Currency
Costs were assessed in Euros. A conversion rate between Euros and Deutschmarks was provided (1.95 DM = 1 Euro), although no date was provided.

Sensitivity analysis
No sensitivity analyses were conducted.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
To make comparisons between the two strategies, the authors defined 1000 virtual cost-units (CU) as the primary costs of an uncomplicated DDD pacemaker implantation (5800 Euros) and reported the results using this method.

The cumulative costs after a mean (SD) follow-up of 42 months was 1,004 CUs (71) for VDD and 1,108 CUs (87) for DDD. The costs of an uncomplicated implantation of a DDD pacemaker were defined as 1,000 cost units (CU). Cumulative costs of DDD pacing were significantly higher compared with VDD pacing, (p<0.001).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors concluded that the use of single-lead VDD pacemakers achieved significant reduction of implantation and follow-up costs without loss of therapeutic efficacy compared to conventional DDD systems.

CRD COMMENTARY - Selection of comparators
The choice of comparator, namely DDD devices was justified as being the conventional device used. However, the authors should have provided the full name of the two devices, rather than simply using the acronyms. You, as a user of the database, should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
This analysis was based on a non-randomised trial with concurrent controls, which was appropriate for the study question, although the authors could have provided more explanation of this choice in preference to a more rigorous randomised trial. The study sample, namely patients with atrioventricular block, was representative of the study population. The patient groups were shown to be comparable at analysis. Some of the problems with the analysis of effectiveness were that the study design did not conform to the strict requirements of controlled and blinded randomisation. However, the authors reported that selection bias was minimised by ensuring that VDD and DDD
pacemakers were implanted in alternating order. One weakness of the analysis was the lack of blinding of the investigators to the device implanted; blinding could have increased the reliability of the results.

**Validity of estimate of measure of benefit**
No summary measure of benefit was estimated, since the devices were shown to be therapeutically equivalent.

**Validity of estimate of costs**
The strengths of the analysis of costs were that, for the cost perspective adopted, all relevant categories of cost were included in the analysis and for each category of cost, all relevant costs were included. Conditions requiring treatment post-implantation were carefully reviewed and only those likely to be associated with the intervention were included in the cost analysis. Some resources (hospital stay) were reported separately from costs and unit costs were reported. However there were some weaknesses in the analysis of costs. Charges were used rather than costs and this can be problematic since it can affect the generalisability of the results. No single price year was used and conversions were not made. Sensitivity analyses were not conducted. A Mann-Whitney-U test was used for the statistical comparison of costs, but no justification was provided for the use of this test. The authors used Cost Units (CU) to compare the costs of interventions, which was not really helpful to the analysis and indeed added some confusion. Discounting was not conducted although the time horizon was greater than one year.

**Other issues**
Comparisons were made with other clinical studies and the authors stated that no cost-effectiveness studies had yet been conducted comparing the two interventions. The authors addressed the issue of generalisability in that they warned that it was difficult to determine true costs of hospital treatment in Germany, due to the social health insurance system. The authors do not appear to have presented their results selectively. The study considered patients with high degree atrioventricular block and normal sinus mode function and this was reflected in the authors' conclusions.

**Implications of the study**
The findings of the study support the use of single-lead VDD pacemakers. The authors recommended addressing the impact of the longevity of pacemaker systems in further studies.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
11161919

**DOI**
10.1053/euhj.2000.2126

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Aged; Aged, 80 and over; Cardiac Pacing, Artificial /economics; Cost-Benefit Analysis; Female; Follow-Up Studies; Heart Block /economics /therapy; Humans; Male; Middle Aged; Pacemaker, Artificial /economics
AccessionNumber
22001000293

Date bibliographic record published
30/11/2001

Date abstract record published
30/11/2001