Cost-utility analysis of pacemakers for the treatment of vasovagal syncope

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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 health technology studied was dual-chamber pacemakers for treatment of vasovagal syncope.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-utility analysis.

Study population
Patients who had experienced at least 6 syncopal spells, or more than one spell in the preceding 6 months.

Setting
The setting was tertiary care. The economic study was conducted in Calgary, Alberta, Canada.

Dates to which data relate
No dates were given.

Source of effectiveness data
The effectiveness data were taken from a single study and authors' assumptions.

Link between effectiveness and cost data
The costing was carried out on the same patient sample as that used to derive effectiveness data.

Study sample
All patients who met the selection criteria in the study period were included. No power calculations were carried out to justify the size of the patient population being studied. 38 patients were included in the study. 28 patients tested positive on a tilt table for bradycardia. Baseline characteristics were also given for age, gender and syncope and drug history.

Study design
This was a before-and-after study.

Analysis of effectiveness
The analysis was based on an intention to treat. Patients were evaluated by recording the number of syncopal spells before and after pacemaker insertion, and by recording their health related quality of life, (HRQL) before and after insertion. The latter was measured using the EQ-5D. Quality adjusted life year (QALY) scores were then derived from the HRQL recordings. No statistical analysis for confounding or bias was reported. Length of follow-up was a median of 12 +/-6.5 months for HRQL data.

Effectiveness results
The patients were divided into two groups, those with greater than the median frequency of syncope (0.5 spells per month), and those with less than the median frequency. The median monthly frequency of syncopal spells was reduced from 2.0 (range: 0.9 - 20.1) to 0.18 (range: 0 - 0.8) in the high frequency group and from 0.10 (range: 0.06 - 0.2) to 0 (range: 0 - 0.34) in the low-frequency group (figures in parentheses are the inter-quartile range).

The (HRQL) (as measured by EQ-5D Visual analogue scale (VAS)) improved from 53.7+/-21.9 to 72+/-17.4 in the high frequency group. In the low frequency group it improved from 69.1+/-17.0 to 80.3+/-11.8.

The reduction in syncope frequency in all groups was significant, (p<0.0001), as was the increase in quality of life, (p<0.0001 to 0.0066). The quality of life measures showed that, after the pacemakers were introduced, there was no significant difference between the high and low frequency groups, (p=0.1) whereas before their introduction, the quality of life was significantly lower in the high frequency group, (p=0.02). The results for the 17 patients for whom there was more than one post pacemaker HRQL score were not given by time, although the authors stated they were stable.

Clinical conclusions
Dual-chamber pacemakers for patients with recurrent vasovagal syncope, statistically significantly reduced the frequency of syncope and improved health related quality of life.

Methods used to derive estimates of effectiveness
The authors made a number of assumptions.

Estimates of effectiveness and key assumptions
The pacemaker life was assumed to be 10 years. HRQL was assumed to be constant for 10 years.

Measure of benefits used in the economic analysis
QALYs were used as a measure of benefit in the economic analysis, the authors derived these from the HRQL scores obtained from using the EQ-5D Visual analogue scale (VAS) (0-100). The number of QALYs was estimated by dividing the VAS score by 100 and multiplying by 10 for 10 years extrapolation.

Patients were assessed before pacemaker implant and at 4 to 6 month intervals after implant to give the incremental QALYs gained.

A supplementary method of assessing HRQL was undertaken, but could only be used for the 25 patients who completed the entire EQ-5D. This consisted of calculating a weighted index utility score which utilised information on patients' preferences over different health states using the time trade-off method.

Direct costs
Costs were estimated using actual data. The authors estimated quantities and prices separately but details were not given in the paper.

The authors stated that they calculated the quantities and prices of the following variables (source in parentheses):
Inpatient care (Calgary Regional Health Authority (CRHA)), Day surgery (CRHA), Outpatient visit (syncope clinic), Clinic, Emergency physician & other professional services (AB Health, syncope clinic, CRHA), Lab, radiology (syncope clinic), Diagnostic tests (CRHA), Devices (syncope clinic, hospitals), and Medication (syncope clinic, hospitals).

Discounting took place at a rate of 5% a year. The following costs were included in the analysis: costs for 12 months before pacemaker insertion (drug costs, clinic costs, physician costs); cost of pacemaker insertion; and total costs (as described above) for one year after insertion. Only costs associated with vasovagal syncope and its related conditions were included. The authors did not state that costs were adjusted using a common price year, and did not distinguish between marginal and average costs. The authors did not state the date price year. Costs were only collected for 12 months, but there was an extrapolation to 10 years, although the method was not reported.

**Indirect Costs**
No calculation of indirect costs took place.

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
A sensitivity analysis was carried out with respect to the following variables:

- the 95% confidence interval for the HRQL scores and costs was stated to have been used to assess the sensitivity of the measure of QALY to different assumptions about HRQL, although the method of calculation of these intervals was not reported;
- different assumptions were made about whether or not pacemakers would be replaced (all or none);
- different assumptions were made about the expected pacemaker life (8 or 12 years);
- different assumptions were made about the discount rate which should be used (0, 10%);
- it was assumed that the HRQL scores of the 21 subjects for whom only 1 post pacemaker score was available returned to the pre-pacemaker levels; and
- the weighted index utility score was used to measure the impact of the pacemaker, this information was only available for 25 patients.

A one-way sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The estimated benefits (mean +/- SD) were 1.02 (+/-1.42) QALYs for the whole group of patients, 1.41 (+/-1.57) for the high frequency group and 0.90 (+/-1.19) for the low frequency group. These estimates were derived from data which was collected for 12 +/-6.5 months but extrapolated to be estimates for 10 years after insertion using a 5% discount rate. No side effects of the treatment were considered.

**Cost results**
Using data collected for one year, with a discount rate of 5%, the estimated cost (mean +/- SD) of treating patients for 10 years without the pacemaker being inserted was: $11,982 +/- 4,421 per patient for the whole group of patients, $11,723 +/- 4,351 for the group with a high frequency of syncopal spells, and $12,239 +/- 4,331 for the low frequency group.
The cost per patient of treatment by pacemaker implant for ten years was estimated using data collected for 12+/−6 months after implant. A discount rate of 5% was used. The estimated costs were as follows: $25,404+/−7,368 for the whole patient group, $24,557+/−7,679 for the high frequency group and $26,241+/−7,148 for the low frequency group.

**Synthesis of costs and benefits**

The costs and benefits were combined by calculating the cost per QALY gained which was $13,159 for the whole patient group, $9,102 for the high frequency group and $15,558 for the low frequency group.

Most of the sensitivity analyses did not increase the cost of an additional QALY above $20,000. For the high frequency group it never exceeded an expected value of $16,805 with the treatment effect drop-off. It was also this scenario which produced the highest values of $22,793 for total population and $33,866 for low frequency.

Other results for the total population were:

- Using the weighted utility index to estimate cost/QALY increased it to $18,513; and
- If the pacemaker life was estimated to be 8 years the cost/QALY was $16,539, whereas if it was 12 years it was $12,512.

**Authors’ conclusions**

Dual-chamber pacing is an effective treatment for very frequent vasovagal syncope; it costs more than drug treatment, but the cost per QALY of less than $20,000 means that it will often seem a price worth paying.

**CRD COMMENTARY - Selection of comparators**

The comparator treatment consisted of drugs that reflected current medical practice at the time of the study, the authors acknowledge that these drugs may now have been superseded by florinef or paroxetine which only a few of the patients were receiving. Also, the generalisability of these results will have been impaired by the fact that the comparator was a collection of treatment with varying doses and degrees of compliance.

**Validity of estimate of measure of effectiveness**

This was a cost-utility study, and therefore the most relevant measure of effectiveness was HRQL, assuming that the method used elicits utility values. However, it was useful that the authors also showed the change in intermediate measures, which helps to validate the HRQL measure. The design of the study was weak in terms of preventing confounding by prior treatment effect, but there could be no selection bias. Some statistical controlling for prior treatment would have been useful.

**Validity of estimate of measure of benefit**

The measure of benefit was QALYs which is appropriate for this type of study. The authors identified the limitations of using one method of valuing health state, i.e. VAS, and addressed this by using a more sophisticated method, i.e. Time trade off (TTO), which did not seem to alter the final result to any great extent. The authors also acknowledged that extrapolation over 10 years, and the assumption of 10-year pacemaker life expectancy, were questionable and therefore demonstrated robustness in terms of a $20,000 threshold.

**Validity of estimate of costs**

Although the authors stated that resource data were collected separately from cost data, they did not give the information in the paper. They did not explain why the costs were higher for the low-frequency patients than for the high-frequency patients. If resource use data had been available, one would have been able to find out why. The authors did not adjust the prices to a common price year. The sensitivity analysis showed how valuable research for a
longer period after pacemaker implant could be.

**Other issues**
The authors referred to one other study dealing with the effectiveness of pacemakers. They also addressed the issue of generalisability to other settings in terms of their study population and costing. The authors did report some limitations of their study: including the fact that no indirect costs were included.

**Implications of the study**
The authors regard their study as good evidence in favour of insertion of dual-chamber pacemakers for recurrent vasovagal syncope.

However, although the authors are aware that their results were sensitive to the range of possible outcomes occurring after the one year following implant, they do not draw attention to the fact that this could have been solved by having data for a longer follow-up period. Lack of data after 1 year means that the effects of subsequent years was modelled, and not based on data from those years. Therefore further research along the lines suggested above would be very useful.

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