Cost-effectiveness of physiologic pacing: results of the Canadian Health Economic Assessment of Physiologic Pacing


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
Patients with symptomatic bradycardia were given one of two kinds of physiologic pacing, both of which maintained AV synchrony. One was a dual-chamber pacemaker that sensed and paced both the atrium and ventricle. The other was a single-chamber atrial pacemaker for patients with isolated sinus node dysfunction. The comparator treatment was to receive a standard ventricular pacemaker.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with symptomatic bradycardia, but without chronic atrial fibrillation. Full details are given in the original effectiveness paper (Connelly et al. 2000, see 'Other Publications of Related Interest' below for bibliographic details).

Setting
The setting was secondary care. The economic study was carried out in Canada.

Dates to which data relate
The dates to which the effectiveness and resource evidence related were not given in this paper. The price year was 2004.

Source of effectiveness data
The effectiveness data were derived from a single study, the Canadian Trial of Physiologic Pacing (CTOPP).

Link between effectiveness and cost data
The costing was carried out prospectively on a sub-sample of 1,058 patients (42% of the overall CTOPP trial population) who provided effectiveness evidence.

Study sample
Sample selection, power calculations and the people excluded from the initial sample were not described in this paper. The original effectiveness paper reported that power calculations had influenced the sample size. It also gave details of the method of sample selection and individuals excluded from the initial sample. In the effectiveness analysis, there
were 1,094 patients in the physiologic group (dual-chamber or atrial pacemaker, at the discretion of the treating physician) and 1,474 in the ventricular group.

**Study design**
This was a multi-centre randomised controlled trial (RCT) in which the patients were followed up for a maximum of 5.2 years from the time of randomisation. Blinding of the outcome assessment and loss to follow-up were not reported in this study.

**Analysis of effectiveness**
The analysis was conducted on an intention to treat basis. The primary end point of the trial was the occurrence of stroke or cardiovascular death. In this study, the annual mortality and the annual rate of atrial fibrillation were used as the principal measures of effectiveness. The comparability of the groups was shown in the original effectiveness paper.

**Effectiveness results**
The annual mortality rate was 5.5% in the ventricular group and 4.9% in the physiologic group (95% confidence interval, CI: -10.5 - 25.7; p=0.33).

The annual atrial fibrillation event rate was 6.6% in the ventricular group and 5.3% in the physiologic group, (p=0.05).

**Clinical conclusions**
The authors concluded that there was no statistically significant difference in the annual mortality rate. However, there was a reduction in the rate of atrial fibrillation when physiologic pacing, rather than ventricular pacing, was used.

**Measure of benefits used in the economic analysis**
The measure of benefits used was the life-years gained. The number of atrial fibrillation events avoided was also used as a measure of health benefits. Kaplan-Meier survival curves were used to estimate the difference in mean survival times. The health benefits were discounted at a rate of 3%. The cost-effectiveness analysis was based on a sub-sample of 1,058 patients, of which 472 were in the physiologic group and 586 in the ventricular group.

**Direct costs**
The costs were estimated on the basis of actual data and were discounted at a rate of 3%. The costs measured were for pacemaker implant, care on the ward and intensive care unit, pacemaker adjustments and replacements, other tests and procedures, and follow-up. The follow-up costs consisted of hospitalisations, outpatient visits, pacemaker clinic visits, anti-arrhythmic drugs and outpatient procedures. The principal costs were broken down into prices and quantities. The resource use data were obtained directly from the clinical trial. The hospital resource prices were obtained from one of the hospitals involved in the trial. The costs of pacemaker equipment were obtained from Canadian market prices, while drug costs were from the Ontario Drug Benefits schedule. Physician costs were obtained from the Ontario Schedule of Benefits. The price year was 2004.

**Statistical analysis of costs**
The 95% CIs for the difference in mean costs were estimated by nonparametric bootstrapping. Adjustments for censoring were reported, using the method of Lin et al. (see 'Other Publications of Related Interest' for bibliographic details).

**Indirect Costs**
No indirect costs were calculated.
Currency
Canadian dollars (Can$). The conversion rate to US dollars ($) was Can$1 = US$0.76.

Sensitivity analysis
Uncertainty and heterogeneity in the estimates were explored in two analyses. In one, nonparametric bootstrap methods were used to calculate a 95% CI for the joint density of incremental costs and effects. In the other, a cost-effectiveness acceptability curve was created using alternative monetary values for life-years.

Estimated benefits used in the economic analysis
Undiscounted life expectancy after the time of randomisation was 4.40 years in the physiologic group and 4.38 years in the ventricular group. This implies a gain of 0.02 life-years in the physiologic group which, when discounted by 3%, implies a gain of 0.01 years (95% CI: -0.10 - 0.11).

When patients with a heart rate of 60 beats per minute (bpm) or lower were analysed, the discounted life expectancy was 4.44 years in the physiologic group and 4.19 years in the ventricular group (difference 0.25, 95% CI: 0.09 - 0.36). Patients with a heart rate greater than 60 bpm had life expectancies of 4.21 years (physiologic group) and 4.32 years (ventricular group), respectively, a difference of -0.11 (95% CI: -0.25 - 0.05).

The mean number of atrial fibrillation events was 0.20 in the physiologic group and 0.24 in the ventricular group, a difference of 0.04 events avoided (95% CI: 0.0 - 0.08).

For patients with a heart rate of 60 bpm or lower, the mean number of atrial fibrillation events was 0.24 in the physiologic group and 0.28 in the ventricular group, a difference of -0.04 (95% CI: -0.10 - 0.02). For patients with a heart rate greater than 60 bpm, the mean numbers of atrial fibrillation events were 0.18 (physiologic group) and 0.22 (ventricular group), respectively, a difference of -0.04 (95% CI: -0.10 - 0.02).

The patients were followed up for a mean of 3.1 years (maximum 5.2 years).

The side effects of treatment were not considered in the analysis.

Cost results
The total cost per patient over 5.2 years was Can$16,833 in the physiologic group and Can$13,857 in the ventricular group. The difference was Can$2,976 (95% CI: 926 - 5,442).

The costs of adverse effects were dealt with in the analysis.

Synthesis of costs and benefits
The incremental cost per life-year gained was Can$297,600. Among patients with a heart rate of 60 bpm or lower, the incremental cost per life-year gained was Can$16,004, and for patients with a heart rate greater than 60 bpm, the ventricular pacemaker was dominant (both less costly and more effective).

The incremental cost per atrial event avoided was Can$74,400. This incremental cost was Can$102,275 among patients with a heart rate of 60 bpm or lower and Can$40,400 among patients with a heart rate greater than 60 bpm.

The cost-effectiveness acceptability curve showed that the probability that physiologic pacing was cost-effective was less than 50% if decision-makers were willing to pay $300,000 per life-year. However, for patients with a heart rate of less than 60 bpm, if the willingness to pay for a life-year gained was $50,000, then the probability that physiologic pacemakers were cost-effective was 98%.

Authors' conclusions
The cost of an extra life-year gained for the patients as a whole was more expensive than is currently considered...
reasonable. However, when patients with a hear rate of less than 60 bpm are studied, the lower cost of a life-year gained (i.e. $16,004) represents good value for money. Therefore, "the widespread use of physiologic pacemakers is not an economically attractive strategy. The selective use of these devices in patients who are likely to be pacemaker dependent may be more attractive but requires prospective evaluation".

CRD COMMENTARY - Selection of comparators
The choice of the comparator (i.e. ventricular pacing) was justified by it having been current practice in many settings before the introduction of physiologic pacing. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The analysis was based on a RCT, which was appropriate for the study question. Full details of the study sample and comparability at the baseline were not given in this paper but in the parent effectiveness paper (Connelly et al. 2000). The internal validity of the analysis would have benefited from more information on methods of randomisation and the sample of patients.

Validity of estimate of measure of benefit
The main measure of benefits used was the life-years gained. The authors also used the number of atrial events avoided. Both measures of benefit were obtained directly from the effectiveness analysis.

Validity of estimate of costs
From the cost perspective adopted (i.e. the health care system), all the costs appear to have been included. The costs were reported separately from the quantities, which enhances the reproducibility of the results. The resource use quantities were taken from a single study and, to account for uncertainty around the input parameters, a probabilistic cost-effectiveness analysis was performed. The prices were taken from the authors’ setting and published sources, and a conversion rate was reported. No statistical, sensitivity or other kind of analysis of the quantities or prices was carried out. These limitations may well influence the internal validity of the cost analysis. The year to which the prices referred was stated, and this improves the generalisability of the results.

Other issues
The authors did not clearly compare their results with the findings from other studies, merely providing bibliographic references on the same topic. The issue of generalisability to other settings was not addressed. The authors did not present their results selectively and their conclusions reflected the scope of the analysis. The authors reported certain limitations of their study. First, the study did not examine the impact of the treatment on the quality of life, but simply looked at life-years gained. Second, the authors suggested that additional data that incorporated the impact of reducing nonfatal cardiac events may provide a more accurate assessment of the cost-effectiveness of physiologic pacing. Third, the economic data were obtained from a sub-sample of centres participating in the whole trial, and it is possible that they were not representative of all the centres: there was evidence that they were not representative in terms of their effectiveness results. Finally, the short period of follow-up failed to capture the effect of pulse generator replacement on the follow-up costs.

Implications of the study
The authors recommended a study be conducted that considers the effect of a pacemaker on quality of life and has a follow-up period of sufficient duration to account for the replacement costs of pacemakers. They suggested that physiologic pacemakers for patients who are more likely to be pacemaker dependent (heart rate \( \leq 60 \) bpm) are likely to be cost-effective, but should be studied prospectively.

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Other publications of related interest


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