Economic and health consequences of managing bradycardia with dual-chamber compared to single-chamber ventricular pacemakers in Italy

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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.

CRD summary
The aim was to compare the cost-effectiveness of the dual-chamber versus single-chamber ventricular pacemakers for the treatment of bradycardia due to sick sinus disease and atrioventricular block. The authors suggested that, despite higher initial costs, the implantation of dual-chamber pacemaker devices was more cost-effective than the use of single-chamber ventricular pacemakers. Overall, the methodology was robust and clearly presented for both the methods and the results. The authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to compare the cost-effectiveness of the dual-chamber with the single-chamber ventricular pacemakers for the treatment of bradycardia due to sick sinus disease and atrioventricular block.

Interventions
The use of dual-chamber pacemaker devices (DDD) was compared with single-chamber ventricular pacemakers (VVI).

Location/setting
Italy/hospital.

Methods
Analytical approach:
A discrete event simulation model was developed in order to estimate, using published evidence and on the basis of individual simulations, the costs and benefits of the two interventions. The time horizon of the analysis was five years. The authors stated that the perspective was that of the Italian government.

Effectiveness data:
The main clinical evidence, such as the individual risk of developing postoperative complications and atrial fibrillation, was obtained from two long-term trials. The first was the randomised Canadian Trial of Physiologic Pacing, which included 2,658 patients with a follow-up of 6.4 years. The second was the Mode Selection Trial in Sinus-Node Dysfunction (MOST) which included 2,010 patients with published follow-up data for three years. The other clinical inputs such as the risk of stroke were derived from other studies.

Monetary benefit and utility valuations:
The utility scores used in the model were based on published data collected during the course of the MOST trial using the time trade-off approach.

Measure of benefit:
The benefit measure used was quality-adjusted life-years (QALYs). These were estimated by combining utility weights and life expectancy using the discrete-event model. A discount rate of 3% was applied for QALYs gained.

Cost data:
The economic analysis included the costs associated with the initial implantation (the procedure and the pacemaker
system) and subsequent clinical events, including anticoagulation therapy and treatment for stroke. The unit costs were reported. Hospitalisation costs were derived using data from the Italian Institute of Statistics, and other cost data were from published sources. An annual discount rate of 3% was used. All costs were expressed in 2004 Euros (EUR).

Analysis of uncertainty:
A univariate sensitivity analysis was undertaken in order to assess the robustness of the cost results to variations in key model inputs. The issue of uncertainty was handled by the use of 100 model replications in a second-order multivariate analysis.

Results
The expected discounted QALYs over a five-year time horizon were 3.07 with VVI and 3.16 with DDD.

The expected discounted mean costs per patient over a five-year time horizon were EUR 10,608 with VVI and EUR 10,631 with DDD.

The incremental cost per QALY gained with DDD over VVI was EUR 260.

The sensitivity analysis suggested that device replacement rates due to pacemaker syndrome have the biggest impact on the model results.

Authors' conclusions
The authors suggested that, despite higher initial costs, the implantation of DDD was more cost-effective than the use of VVI.

CRD commentary
Interventions:
The choice of the interventions appears to have been appropriate as they represented the current pattern of care for the medical condition under examination in the study setting.

Effectiveness/benefits:
Selected studies were used to derive the effectiveness evidence. However, it was unclear whether a systematic review of the literature had been conducted to identify these primary studies, so it is not clear if the best available evidence was used. In general, the use of data from large clinical trials should have ensured a high internal validity for the clinical estimates used in the model. The measure of benefit was appropriate and a time horizon of five years may have been adequate. The derivation of the benefit measure was appropriately reported.

Costs:
The analysis of costs was performed satisfactorily. Details of the unit costs, sources of costs and resources, price year, and discounting were reported, which enhances the possibility of replicating the analysis in other settings or time periods. The events costed and the time horizon appear to have been adequate for the study perspective. The cost estimates were applicable to the study setting.

Analysis and results:
The model was reasonably well reported. The incremental cost-utility approach was used to combine the costs and benefits. The results of both the base-case and sensitivity analyses were clearly reported. The issue of uncertainty in the model parameters was addressed explicitly by first- and second-order sensitivity analyses.

Concluding remarks:
Overall, the methodology was robust and clearly presented for both the methods and the results. The authors’ conclusions appear to be appropriate.

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