Cost-effectiveness analysis of continuous-flow left ventricular assist devices as destination therapy

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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
This study examined the cost-effectiveness of continuous-flow left ventricular assist devices for mechanical circulatory support, compared with optimal medical management, in advanced heart failure. There was a clear improvement in the cost-effectiveness of mechanical circulatory support, and it could become cost-effective with further improvements. The cost-effectiveness methods were valid and new data for the devices were used to update an earlier analysis of mechanical circulatory support. The authors' conclusions appear to be robust.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study examined the cost-effectiveness of continuous-flow left ventricular assist devices (LVADs) for mechanical circulatory support, compared with optimal medical management, in advanced heart failure, using the latest clinical and economic data.

Interventions
LVADs were compared with optimal medical management.

Location/setting
USA/tertiary care.

Methods
Analytical approach:
The analysis was based on a Markov model with two health states (alive or dead). A time horizon of five years was considered. The authors stated that they took the perspective of a third-party payer.

Effectiveness data:
The estimates for medical management were from the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial, in which 61 patients were enrolled between 1998 and 2001. The estimates for LVADs were from the HeartMate II Destination Therapy trial, which had 134 patients, enrolled from 2005 to 2007. The survival rate was the key input. The data from the two trials were extrapolated to the long time, using specific survival curves. The probability of being in each New York Heart Association (NYHA) functional class was another key input for the analysis and was from the two trials.

Monetary benefit and utility valuations:
The utility values were from published studies and were assigned for each New York Heart Association (NYHA) functional class.

Measure of benefit:
Quality-adjusted life-years (QALYs) and life-years were the summary benefit measures and they were discounted at an annual rate of 3%.

Cost data:
The main cost categories were the device implantation and replacement costs (including hospital and professional services), re-hospitalisation costs, and out-patient costs (including professional services, laboratory tests, and drugs). The hospital costs were based on claims data from a subset of patients enrolled in the HeartMate II trial. The costs of professional services were from an analysis of Medicare claims from a random sample of patients. They included the surgical procedure and follow-up evaluation and management by cardiologists and other physicians. The quantities of resources and other items were based on trial data. Other unit costs were from Medicare reimbursement rates. All costs were in US $ and a 3% annual discount rate was applied. The price year was 2009.

Analysis of uncertainty:
Several sensitivity analyses were carried out to assess the impact of influential inputs, such as the utility values, the costs of implantation, the re-hospitalisation costs, and the long-term survival with LVADs. Alternative survival extrapolation approaches were used.

Results
The total costs were $62,856 with medical management and $360,407 with LVADs. The QALYs were 0.37 with medical management and 1.87 with LVADs. The life-years were 0.64 with management and 2.42 with LVADs.

The incremental cost per QALY gained with LVADs over medical management was $198,184. The incremental cost per life-year gained with LVADs over medical management was $167,207.

An analysis of pulsatile devices in 2002 produced estimates of $802,674 per QALY, compared with medical management, suggesting that the cost-effectiveness of newer devices had improved.

The sensitivity analysis showed that the most influential inputs were the long-term survival probabilities with the LVADs, the costs of implantation, the costs of re-hospitalisation, and the utilities for NYHA classes I and II. In general, in reasonable scenarios, the incremental cost per QALY gained remained below the threshold of $300,000, but was never lower than $122,000.

Authors’ conclusions
The authors concluded that there was a clear improvement in the cost-effectiveness of mechanical circulatory support, and it could become cost-effective with further improvements.

CRD commentary
Interventions:
The selection of the comparators was appropriate as medical management was the only alternative to the proposed devices.

Effectiveness/benefits:
The clinical evidence was from two trials, which provided up-to-date data on the efficacy of continuous-flow LVADs. Both trials were randomised and provided a good level of evidence. The authors stated that the groups in the two trials were comparable, except that patients in the LVADs group were on average six years younger and a quarter of them had less severe disease than patients in the medical management group. The trial for medical management was published 10 years before the trial for LVADs with potential changes in medical management best practice. These issues could have affected the outcomes for the two groups, as acknowledged by the authors, and the benefits of medical management might have been underestimated. Both benefit measures were appropriate as they captured the impact of the disease on survival and quality of life, which are relevant for patients with heart failure. The methods used to elicit the utility weights were not explicitly reported.

Costs:
The categories of costs and their sources reflected the perspective of the third-party payer, as stated. A clear list of the cost items was given and some unit costs and resource use were reported, but most items were presented as category totals. The sources for the costs reflected the US context and the resource use was appropriately from hospital claims. The price year was reported, allowing reflation exercises. Some cost elements were varied in the sensitivity analysis.

Analysis and results:
The results were clearly presented. The costs and benefits of the two strategies were appropriately combined, using an incremental approach. The authors pointed out that the devices had not been awarded the accepted benchmark for health technologies. Alternative scenarios were investigated in the sensitivity analyses, but the impact of simultaneous variations in the model inputs was not considered. The authors acknowledged some limitations to their analysis mainly due to the use of two trials conducted at different times. The findings appear to be specific to the US and might be difficult to transfer to other settings with different costs and clinical practice.

Concluding remarks:
The cost-effectiveness methods were valid and new data for the devices were used to update an earlier analysis of mechanical circulatory support. The authors' conclusions appear to be robust.

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