Modeling payback from research into the efficacy of left-ventricular assist devices as destination therapy

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
This study evaluated implantable left ventricular assist devices (LVAD) versus optimal medical management (OMM) in patients with end-stage heart failure (ESHF). The potential benefits of newer generation LVADs were evaluated and compared with first-generation LVADs.

Type of intervention
Palliative care.

Economic study type
Cost-utility analysis.

Study population
The study involved a hypothetical population of adult patients with chronic ESHF not eligible for heart transplant, and with ongoing symptoms of New York Heart Association Class IV. This population was modelled to be similar to that included in the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure -REMATCH- trial (Rose et al. 1996 and 2001, see ‘Other Publications of Related Interest’ below for bibliographic details).

Setting
The setting was tertiary care. The economic study was conducted in the UK.

Dates to which data relate
The effectiveness evidence dated from 1996 to 2004, while the resource use data dated from 2001 to 2006. The price year was not reported.

Source of effectiveness data
Clinical parameters that were incorporated in the model included mean survival in patients with OMM, failure and success rates in those with an LVAD, and perioperative mortality. Preoperative mortality and survival with newer generation LVADs were also incorporated.

Modelling
An epidemiological model was developed in order to assess LVAD therapy based on the REMATCH experience and translated into a UK cost setting. The model began with the operation date and ended with patient death. The LVAD patients were divided in two sub-groups, successes and failures related to the operation end point. Each group as well as OMM patients had associated mean survival and costs. Model sources and assumptions were described in detail in the paper.
Sources searched to identify primary studies
Most clinical parameters were obtained from the REMATCH trial (Rose 1996 and 2001, and Anon 2004, see 'Other Publications of Related Interest' below for bibliographic details). Survival for successes, the proportion of failures and perioperative mortality were also derived from this trial. To evaluate future patient survival with newer generation LVADs, expert prior distributions were elicited.

Methods used to judge relevance and validity, and for extracting data
No systematic review appears to have been conducted. The authors stated that the REMATCH trial was the only randomised controlled trial performed to date. Bayesian prior distributions for the survival parameters were obtained from five leading experts and were adequately described in the paper.

Measure of benefits used in the economic analysis
The measure of benefits used was the quality-adjusted life-years (QALYs). The utility weights were derived from a single study (Moskowitz et al. 1997, see 'Other Publications of Related Interest' below for bibliographic details). No additional details were provided. The QALYs were appropriately discounted.

Direct costs
The costs to the health care provider were included. These covered device cost, initial hospitalisation (including operation costs), and subsequent medical care including ambulatory and inpatient settings. Resource use and costs were derived from published studies. As the device costs had higher uncertainty, a range of costs was evaluated. Discounting of the long-term costs was adequately performed. The price year was not reported. The unit costs and the resource quantities were not reported separately.

Statistical analysis of costs
The cost data were deterministic.

Indirect Costs
Productivity costs were not included.

Currency
UK pounds sterling ().
Synthesis of costs and benefits
The study results were tabulated and depicted graphically. The authors presented the cost-effectiveness thresholds under different assumptions about device cost and QALY valuations in the form of a figure, with contours of the joint prior distribution superimposed. The figure showed combinations of survival parameters under which LVAD would be cost-effective compared with OMM at 30,000 per QALY and 40,000 per QALY. Similar results were presented in a table reporting, for each combination of QALY value threshold and device cost, the expected net benefits of the intervention, the expected value of perfect information and the probability of being cost-effective.

Cost-effectiveness probabilities under the study priors were found to be low (0.2%) for devices costing as much as 60,000, and would be no more than 84% even in the (implausible) case that the device costs nothing at all. Nevertheless, the figures are not inconsistent with an ultimately favourable assessment of LVAD therapy if the cost of the device were to fall in the future.

Taking into account the estimated 15,000 annual ESHF patients in the UK, the expected value of perfect information suggested that the costs of a future LVAD trial could not be recouped over any reasonable period unless the cost of the device were substantially less than 60,000.

Authors' conclusions
The future cost-effectiveness of the left ventricular assist device (LVAD), as well as the value of future information, depends on substantial improvements in survival being achieved by later generations of devices, as well as on a reduction in current device costs.

CRD COMMENTARY - Selection of comparators
The comparator, OMM, was justified on the grounds of it being the only intervention to be compared with LVADs in randomised controlled trials. It was chosen to represent current practice.

Validity of estimate of measure of effectiveness
The baseline survival of the two comparators was modelled after the single randomised trial that compared them, which seems to have been the best evidence available. Bayesian prior distributions for the survival parameters for newer generation LVADs were obtained from expert opinion and were adequately described.

Validity of estimate of measure of benefit
Survival was extrapolated to quality-adjusted life survival using utility weights from a single study, but the valuation method and patient sample were not described further. Considering the long-term horizon of the study, the benefits were appropriately discounted.

Validity of estimate of costs
The cost analysis was performed from the perspective of the health care provider, who may reimburse the cost of the device or decide to fund new research. Most of the relevant cost categories appear to have been included. Some exceptions included ambulatory drug costs and, possibly, any maintenance device costs or battery replacement. However, it is unlikely that these costs, which seem relatively small, would have greatly influenced the study results. A price year was not reported, which could limit future reflation exercises. The quantities and the costs were reported mainly in an aggregate fashion, which could also limit the extrapolation of the study results to other settings. Resource use and unit costs were obtained from published sources. The costs were appropriately discounted given the long-term horizon of the study.

Other issues
The authors did not compare their findings with those of other studies or discuss generalisability issues. The study results were not presented selectively and the conclusions clearly reflected the scope of the analysis, mainly focusing on
the future cost-effectiveness and value of information related to LVADs.

**Implications of the study**
Given the best available current evidence and clinical opinion, a new trial of second-generation LVADs would represent value for money in a UK setting at a plausible device cost of around 40,000.

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**Bibliographic details**

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**Other publications of related interest**
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