Mechanical ventricular assistance: an economical and effective means of treating end-stage heart disease

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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
Mechanical ventricular assistance device (VAD) as a bridge to transplantation versus medical treatment with inotropic agents or an intraaortic balloon pump before heart transplantation in the management of patients with a chronically failing heart.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with end-stage heart failure classified as status I at the time of transplantation or death by United Network for Organ Sharing criteria.

Setting
Hospital. The economic study was carried out in Pennsylvania, USA.

Dates to which data relate
The effectiveness analysis data and resources used were collected during the years 1991-1994. The fiscal year was not reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not reported as determinants of the sample size chosen. From 65 patients on the cardiac transplant waiting list, 43 were classified as status I according to the United Network for Organ Sharing criteria entered the study. Of those, 12 were assisted by the VADs (intervention group) and 31 were treated medically (the control group). The remaining 22 patients, were classified as Status II and were excluded from the study (34%).
Study design
This was a retrospective cohort study carried out in a single centre. The mean duration of follow up for the intervention group was 11.2 months (range: 2 - 32 months), and for the control group was 12.4 (range: 2 - 35 months). No loss to follow up was reported but 1 death occurred in the intervention group (8.3%) and 10 deaths occurred in the comparator group (33%).

Analysis of effectiveness
The clinical analysis was based on intention to treat. The primary health outcomes used were survival to transplantation, discharge rate, survival rates at follow-up intervals (using Kaplan-Meier actuarial survival from time of transplantation), and time spent between transplantation and discharge. Groups were shown to be comparable in terms of age, sex, pre-transplantation diagnosis, blood types and average total waiting time for transplantation.

Effectiveness results
92% of the VAD group survived to be transplanted versus 68% in the medical group, (P=0.107). The discharge rate for the VAD group was 92% (100% of patients who underwent transplantation) versus 55.4% for the medical group, (P=0.023). The survival rates at 1, 6 and 36 months for the VAD group were 100%, 81.8%, and 81.8%, respectively. The corresponding values for the medical group were 91.7%, 83.3%, 69.4%. A log rank comparison made between the groups in terms of survival rates at follow-up intervals showed no significant differences. A further evaluation of time spent between transplantation and discharge showed no significant difference between strategies with an average of 17.8 days for intervention and 22.2 days for comparator, (p=0.28).

Clinical conclusions
Although transplantation rates did not reach significance, the results clearly demonstrated the similarity between these modalities in supporting patients to transplantation. Further, the patients who underwent implantation of an LVAD had significantly improved rates of discharge from the hospital. The findings of equal long-term survival show the success associated with mechanically assisted patients and emphasize the role of this treatment modality in the care of these critically ill patients.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic study, and only separate clinical outcomes were reported.

Direct costs
Quantities were not reported in detail separately from the costs. The cost items were not reported separately. The cost items included in the cost analysis (patient charge costs and hospital costs) were not specified. The boundary adopted was not explicitly specified. The costs were obtained from the records provided by the Department of Clinical Cost Accounting of the authors own institution. The quantity of resources was measured from July 1991 to July 1994. The date of the price data was not explicitly specified.

Statistical analysis of costs
Student’s t test were performed with p<0.05 being statistically significant.

Indirect Costs
Not reported.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The patients in the intervention group had a cost per day and charge per day of $2,859 and $1,808, respectively. The comparator group presented corresponding figures of $3,371 and $2,071. The implied differences were insignificant with p=0.24 and p=0.16, for cost and charge per day differences, respectively.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors’ conclusions
When costs are normalized to admission length, patients who are assisted mechanically and subsequently undergo transplantation have decreased daily costs/charges when compared with those treated medically. These differences will likely become significant as the mechanically assisted patients are discharged to outpatient care facilities. Discharging these patients increases the possibility of their returning to work while awaiting transplantation. Therefore, these devices with equal transplantation rates and increased discharge rates, may be associated with decreased maintenance expenses before transplantation, particularly as this therapy is instituted earlier during the course of progressive heart failure.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of effectiveness
The internal validity of the results may be weakened due to the lack of a randomised design and the small sample size.

Validity of estimate of costs
The resource utilisation and cost items were not reported separately and insufficient details were given of the methods of cost estimation.

Other issues
In view of the lack of randomisation and sensitivity analysis, the results need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

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