

# Evaluation of the ventricular assist device programme in the UK

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## *Executive summary*

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## Executive summary

### Background

Medical management of patients with mild to moderate heart failure has substantially improved survival and quality of life in recent years owing to the increased use of angiotensin-converting enzyme inhibitors and  $\beta$ -blockers. For severe heart failure, transplantation is widely accepted as the most effective surgical treatment for suitable patients. However, heart transplantation is rationed by the availability of suitable donor hearts and there has been a steady decline in donor hearts over time.

Ventricular assist devices (VADs) were first used to support transplant candidates with rapidly failing circulation who were considered unlikely to survive until a suitable organ could be found. This situation is described as bridge to transplantation (BTT).

The National Specialist Commissioning Advisory Group (NSCAG) has agreed to support a new national service providing VAD therapy in three centres in the UK. A standard requirement of NSCAG is that such new services should be subject to an appropriate evaluation. Thus, this integrated but independently led health technology assessment was conducted, focusing on the clinical and cost-effectiveness of the use of VADs in the context of bridging to either transplantation or recovery in patients who are appropriate candidates for heart transplantation.

### Objectives

This study had four key objectives:

- to summarise the relevant effectiveness and cost-effectiveness literature
- to collect data on survival, transplantation rates, health-related quality of life (HRQoL) and resource use for VAD and non-VAD transplant candidates in the UK
- to construct cost-effectiveness and cost-utility models of VADs in a UK context
- to investigate the factors that drive costs and survival.

### Methods

#### Setting

NSCAG-funded VAD implantation was carried out at the Freeman, Harefield and Papworth transplant centres in the UK.

#### Participants

The study involved 70 patients implanted with a VAD as a BTT between April 2002 and December 2004. The construction of a fair comparison group was not feasible. To provide bounds on effectiveness/cost-effectiveness of VADs three other groups were studied. The first and second groups consisted of non-VAD-supported transplant candidates ( $n = 250$ ), listed at the three centres between April 2002 and December 2004. They were divided into an inotrope-dependent group ( $n = 71$ ) and a non-inotrope-dependent group ( $n = 179$ ). Although patients in the inotrope-dependent group were closest to the VAD group they were less sick. The final group comprised a hypothetical worst case scenario, which assumed that all VAD patients would die in the intensive care unit (ICU) within 1 month without VAD technology.

#### Interventions

Patients were included who were implanted with a VAD designed for circulatory support for more than 30 days, with intention to BTT. A multistate model of VAD and transplant activity was constructed; this was populated by data from the UK.

#### Main outcome measures

The main outcome measure was survival from VAD implant or from transplant listing for non-VAD patients to 31 March 2005. VAD support was considered successful if the patient survived to transplantation or recovered myocardial function to allow removal of the device. Serious adverse events during VAD support and after transplantation were recorded. Pre- and post-transplantation HRQoL for VAD and non-VAD transplant candidates was assessed by the EuroQoL, Short Form 36, Functional Limitations Profile, Physical Symptoms Checklist, Hospital Anxiety and Depression Scale and a VAD-specific questionnaire. Cognitive functioning was also

assessed. Utility weights were derived from EuroQoL responses to estimate quality-adjusted life years (QALYs). Incremental cost-effectiveness ratios (ICERs) were defined as the additional cost of VADs divided by additional QALYs. Time-horizons were 3 years, 10 years and the lifetime of the patients.

## Results

Of 70 VAD patients, 30 (43%) died pretransplant, 31 (44%) underwent transplantation and four (6%) recovered and had the VAD removed. Five patients (7%) were still supported for median of 279 days at the end of March 2005. Successful BTT/recovery rates were consistent with published rates. Survival from VAD implant was 74% at 30 days and 52% at 12 months. There were 320 non-fatal adverse events in 62 patients during 300 months of VAD support, mostly in the first month after implant. Common observed events were bleeding, infection and respiratory dysfunction. Twenty-nine (41%) patients were discharged from hospital with a VAD. The 1-year survival post-transplant was 84%.

For the 71 inotrope-dependent and 179 non-inotrope-dependent transplant candidates, death rates while listed were 10% and 8% and the median waiting times were 16 and 87 days, respectively. For transplant recipients 1-year survival was 85% and 84%, respectively.

Both VAD and non-VAD patients demonstrated similar significant improvements in their New York Heart Association class after transplantation.

All patients had poor EQ-5D pretransplantation; after transplantation the groups had similar EQ-5D of 0.76 irrespective of time after surgery. HRQoL was poor in the first month for VAD patients, but better for those who waited longer in all groups. VAD patients reported more problems with sleep and rest and with ambulation in the first month. Symptom scores were similar in all groups pretransplantation. After transplantation all groups showed a marked and similar improvement in physical and psychosocial function.

Mean VAD implantation cost, including device, was £63,830, with costs of VAD support for survivors of £21,696 in month 1 and £11,312 in month 2. Main cost drivers were device itself, staffing, ICU stay, hospital stay and events such as bleeding, stroke and infection.

For the base case, extrapolating over the lifetime of the patients the mean cost for a VAD patient was £173,841, with mean survival of 5.63 years and mean QALYs of 3.27. Corresponding costs for inotrope-dependent patients were £130,905, with mean survival 8.62 years and mean QALYs 4.99. Since inotrope-dependent patients had lower costs and higher QALYs than VAD patients, this group is said to be dominant. Non-inotrope-dependent transplant candidates had similar survival rates to those on inotropes but lower costs, also dominant. Compared with the worst case scenario the mean lifetime ICER for VADs was £49,384 per QALY. In a range of sensitivity analyses this ranged from £35,121 if the device cost was zero to £49,384. Since neither inotrope-dependent transplant candidates nor the worst case scenario were considered fair controls the assumption was investigated that, without VAD technology, there would be a mixture of these situations. For mixtures considered the ICER for VADs ranged from £79,212 per QALY to the non-VAD group being both cheaper and more effective.

## Conclusions

There are insufficient data from either published studies or the current study to construct a fair comparison group for VADs. Overall survival of 52% is an excellent clinical achievement for those young patients with rapidly failing hearts. However, if the worst case scenario were plausible, and one could reliably extrapolate results to the lifetime of the patients, VADs would not be cost-effective at traditional thresholds.

## Implications for the health service

More reliable information on the effectiveness of VADs compared with alternative treatments is required before robust recommendations can be made. Observational data suggest that VADs are not yet cost-effective for current patients and that there is no cost-effectiveness argument for widespread dissemination of the technology. However, VAD implantation can be justified for selected current cases based on survival, and for future patients on the grounds of maintaining the understanding and skills required for implantation and management.

## Recommendations for research

The following areas for further research are suggested. ►

- Further randomised controlled trials are required, using current second generation devices or subsequent devices and conducted in the UK. Studies could include randomised comparisons with optimal medical management for stable ambulatory patients and/or head-to-head comparisons of different devices for patients with acute-onset severe heart failure.
- Until trials can be conducted, UK activity and results should be carefully monitored and the NSCAG service structured and managed to

maximise understanding and skills base for future patients.

- The impact of VADs on the transplant programme requires further modelling work.

## Publication

Sharples L, Buxton M, Caine N, Cafferty F, Demiris N, Dyer M, *et al.* Evaluation of the ventricular assist device programme in the UK. *Health Technol Assess* 2006;**10**(48).

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The research reported in this monograph was commissioned by the HTA Programme as project number 01/19/01. The contractual start date was in March 2002. The draft report began editorial review in August 2005 and was accepted for publication in April 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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