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Title **Evaluation of the Ventricular Assist Device Program in the UK**

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Aim

To summarize the effectiveness and cost-effectiveness literature on ventricular assist devices (VADs); 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; construct cost-effectiveness and cost-utility models of VADs in a UK context; and investigate the factors that drive costs and survival.

Conclusions and results

Of the 70 VAD patients, 30 (43%) died pre-transplant, 31 (44%) underwent transplantation, and 4 (6%) recovered and had the VAD removed. Five (7%) were still supported for median 279 days at the end of the study. Bridge to transplant/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 30 days after implant. Commonly observed events were bleeding, infection, and respiratory dysfunction. Twenty-nine (41%) patients were discharged from hospital with VAD. For patients successfully bridged to transplant, 1-year survival after transplantation was 84%.

Seventy-one inotrope-dependent and 179 non-inotrope-dependent transplant candidates were listed. Death rates while listed were 10% and 8% and median waiting times were 16 and 87 days. For transplant recipients 1-year survival was 85% and 84%.

Symptom scores were similar in all groups pre-transplant. After transplantation all groups showed a marked and similar improvement in physical and psychosocial function. (See Executive Summary link above.)

Cognitive impairment was not found to be more common in VAD patients than non-VAD patients after transplantation.

Mean VAD implant cost, including device, was GBP 63 830, with costs of VAD support for survivors of GBP 21 696 in month one and GBP 11 312 in month two. Main cost drivers were the device, staffing, ICU stay, initial implant hospital stay and adverse events.

For the base case, extrapolating over the lifetime of the patients mean cost for VAD patients was GBP 173 841, mean survival 5.63 and mean QALYs 3.27 years. Costs for inotrope-dependent patients were GBP 130 905, mean survival 8.62 and mean QALYs 4.99 years. Non inotrope-dependent transplant candidates had similar survival rates to those on inotropes but lower costs. Compared with the worst clinical scenario the lifetime incremental cost-effectiveness ratio (ICER) for VADs was GBP 49 384 per QALY. In sensitivity analyses the mean ICER for the lifetime model, compared with the worst clinical scenario, ranged from GBP 35 121 if the device cost was zero to GBP 49 384. Since neither inotrope-dependent transplant candidates nor the worst-case scenario were considered fair controls we investigated the assumption that, in the absence of VAD technology, we would have a mixture of these situations. For mixtures considered the ICER for VADs ranged from GBP 79 212 per QALY to the non-VAD group being both cheaper and more effective.

Recommendations

Data from the published studies and the current study are insufficient to construct a fair comparison group for VADs. If the worst scenario were plausible, and we can extrapolate results to the lifetime of the patients, VAD recipients can expect improved survival and HRQoL, but VADs would not be cost effective at traditional thresholds.

Methods

See Executive Summary link above.

Further research/reviews required

- Randomized controlled trials in the UK using current second generation devices or subsequent devices (focus on long-term circulatory support or bridge to recovery)
- Modeling of the impact of VADs on the transplant program.

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