TITLE: HeartWare® Ventricular Assist System for end stage heart failure: Clinical effectiveness

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RESEARCH QUESTIONS

1. What is the clinical effectiveness and safety of HeartWare Ventricular Assist System for patients with end stage heart failure eligible for cardiac transplantation?

2. What is the comparative effectiveness and safety of HeartWare Ventricular Assist System as compared to the Berlin Heart for patients with end stage heart failure eligible for cardiac transplantation?

3. What are the guidelines for the use of the HeartWare Ventricular Assist System for patients with end stage heart failure eligible for cardiac transplantation?

KEY MESSAGE

The current literature on the clinical effectiveness and safety of the HeartWare device is limited to two case series and three retrospective analyses. In three of these studies, the mortality rate was 14% one-year post HeartWare implantation. No studies that compared the HeartWare device to the Berlin Heart or evidence-based guidelines for use of the HeartWare system in patients with end stage heart failure were identified.

METHODS

A limited literature search was conducted on key health technology assessment resources, including PubMed, Ovid EMBASE, the Cochrane Library (Issue 12, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between January 1, 2006 and January 5, 2011. No filters were applied to limit the retrieval by study type. Internet links were provided, where available.
The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

**RESULTS**

No relevant health technology assessment reports, systematic reviews, meta-analyses, randomized controlled trials, or evidence-based guidelines were identified. Five non-randomized studies in patients with heart failure were identified, but none of these compared the HeartWare Ventricular Assist System to the Berlin Heart. Other articles of potential interest are included in the appendix.

**OVERALL SUMMARY OF FINDINGS**

One retrospective study\(^1\) (45 patients) compared the HeartWare device to two types of HeartMate left ventricular assist devices (LVAD) for the outcome of infection. Infection rates per 100 device days were 0.21 for the HeartWare compared to 0.26 and 1.11 for the two HeartMate LVAD.

Two case series\(^2,3\) and two retrospective studies\(^4,5\) measured survival and outcome post-implantation of the HeartWare device. The first case series\(^2\) (23 patients in five centres) found that two patients subsequently required heart transplants, two patients died, and nineteen patients were still using the device after 180 days. Actuarial survival was 91% at six months and 86% at one year.

The second case series\(^3\) (43 patients in five centres) found that 24 patients still used the HeartWare device after 180 days following implantation. At the end of the study period (> two years), eight patients had received heart transplants, three patients had recovered left ventricular function and were weaned of the HeartWare, 27 patients still required support, and five patients died. Actuarial survival was 90% at six months and 86% at one year following implantation of the HeartWare device.

One retrospective study\(^4\) evaluated HeartWare (21 patients), HeartMate (73 patients), and Circulite (6 patients). No comparative results were provided in the abstract. The overall perioperative mortality rate was 19%. A total of 78% of patients were discharged from hospital after an average (± standard deviation) of 48 ± 36 days. Two years post-implantation, the overall mortality rate was 14%.

The other retrospective study\(^5\) evaluated elective, LVAD, and urgent patients post cardiac transplantation. Actuarial survival, incidence of rejection, incidence of severe infections (including cytomegalovirus disease), and graft vasculopathy were comparable for the three groups at one, three, and five years post-transplant.

No studies that compared the HeartWare device to the Berlin Heart or evidence-based guidelines for use of the HeartWare device in patients with end stage heart failure were identified.
REFERENCES SUMMARIZED

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses
No literature identified.

Randomized controlled trials
No literature identified.

Non-randomized studies


Guidelines and recommendations
No literature identified.

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APPENDIX – FURTHER INFORMATION:

Review article


Case report


Other non-randomized studies (not specific to heart failure)


Additional references


13. HeartWare—controllers used with HeartWare ventricular assist systems: audible alarm may have reduced volume, potentially compromising patient safety [Internet]. Plymouth Meeting (PA): ECRI Institute; 2010. [cited 2011 Jan 04]. Available from: www.ecri.org Subscription required.


