INAHTA Brief

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Title **Effectiveness and safety of the HeartWare® ventricular assist device in the treatment of advanced heart failure**

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Aim

To assess the effectiveness and safety of the HVAD in the treatment of adult patients with advanced heart failure.

Conclusions and results

Despite its substantial adverse event rate, the HeartWare® LVAD registers a survival rate which is comparable to, and even higher than, the HeartMate® LVAD.

A total of 14 primary studies, all case series, were included in accordance with the selection criteria. Five of these compared HeartWare® and HeartMate II® LVADs, or, in one instance, other pulsatile- or continuous-flow devices. Most of the studies indicated LVAD as a bridge to transplantation and used a left ventricular support. Regarding safety, the most frequently adverse events were severe bleeding (26%-30%), right heart failure requiring inotropic therapy (20%), respiratory failure (16%-20%), percutaneous driveline infection (14%-18%) and sepsis (10%-17%). According to the comparative case series, the adverse event rate for the HeartWare® LVAD was similar to that for earlier generations of these devices. In terms of effectiveness, post-implant survival (Kaplan-Meier curve) for the HeartWare® LVAD was 70% at 12 and 24 months vs. 46%-48% at 12 months and 33% at 24 months for other pulsatile- or continuous-flow VADs (p: 0.013).

Recommendations (if any)

Accordingly, for patients with advanced, refractory HF, the HeartWare® LVAD may be regarded as an acceptable treatment option as a bridge to transplantation.

Methods

In February 2015, a bibliographic search of the scientific literature was conducted both in leading computerised medical databases (CRD, Cochrane, PubMed, Embase, ISI WOK, etc.) and in databases of clinical trials and ongoing studies (ClinicalTrial.gov, The Cochrane Central Register of Controlled Trials, Prospero, POP Database and NIH Reporter). The quality of the scientific evidence was assessed using a general (Oxford Centre for Evidence-Based Medicine and specific (Institute of Health Economics) scale. Two independent investigators selected and review the abstracts, extracted the main information from the studies retrieved by the bibliographic search, and assessed the quality of the evidence.

Further research/reviews required

The review update is recommended within two years in order to analyze the results of ongoing studies about clinical utility of HeartWare® as destination therapy.

Written by

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