2015 - EFFECTIVENESS AND SAFETY OF THE HEARTWARE® VENTRICULAR ASSIST DEVICE IN THE TREATMENT OF ADVANCED HEART FAILURE.

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Introduction: At a world-wide level, heart failure (HF) is a major health problem that generates a considerable impact on health-care costs and patients' lives. Indeed, it is estimated to affect over 23 million persons around the world. In Spain, the prevalence of HF stands at around 7% among persons aged >45 years, rising to 16% among persons aged >75 years. Furthermore, HF is the third leading cause of cardiovascular death, responsible for 11.5% and 16.8% of all deaths in men and women respectively. While cardiac transplantation is currently considered the treatment of choice for patients with advanced HF refractory to medical management, it is nevertheless limited by the availability of organs. In this context, 3rd-generation left ventricular assist devices (LVADs), such as the HeartWare® Ventricular Assist Device (HVAD), could afford an acceptable treatment option for the purpose of increasing survival among this group of patients.

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

Methods: In February 2015 we conducted a bibliographic search of the scientific literature contained both in leading computerised medical databases (Centre for Reviews and Dissemination, Cochrane Library Plus, PubMed, Embase, ISI WOK, Scopus, IME and IBECS) 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 grade-of-evidence scale developed by the Oxford Centre for Evidence-Based Medicine and another scale purpose-designed for case series by the Institute of Health Economics. Two reviewers, acting independently, selected and read the abstracts, extracted the salient information from the studies retrieved by the bibliographic search, and assessed the quality of the evidence.

Results: A total of 89 references were retrieved from the bibliographic search, and 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. The sample size in 9 studies was >100, and ranged from 10 to 1965 patients. Most of the studies indicated LVAD as a bridge-to-transplantation and used a left-ventricular support strategy. In general, safety and effectiveness results were quantified while the patient remained on mechanical assistance, whether across the pre-established follow-up period or until the end of the study (12-46 months). When it came to safety, the most frequently occurring adverse events were severe bleeding (26%-30%), right-sided heart failure requiring inotropic therapy (20%), respiratory failure (16%-20%), percutaneous driveline infection (14%-18%) and sepsis (10%-17%). Other events which occurred less frequently were stroke, device failure, liver failure, device replacement due to thrombosis, right-sided heart failure requiring VAD implantation, and mortality at 30 days. In some of the studies reviewed, the event recorded at <30 days was essentially severe bleeding, whereas other events, such as infections (percutaneous driveline or sepsis), right-sided heart failure and kidney/liver failure, occurred at >30 days. According to the compared series, the adverse event rate for the HeartWare® LVAD was similar to that for earlier generations of these devices, except in the case of percutaneous driveline infection, which was more frequent among patients

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treated with HeartMate® II. In terms of effectiveness, post-implant survival (Kaplan-Meier curve) for the HeartWare® LVAD (with data on patients who underwent heart transplantation or extraction of the device due to myocardial recovery being censored) 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). In the long term (72 months ≈6 years) no significant differences were observed in post-LVAD survival for HeartWare® vs. HeartMate® II. Similarly, no differences were seen in post-heart transplant survival between patients previously treated with the HeartWare® or HeartMate® II.

Conclusions: Despite its substantial adverse event rate, the HeartWare® LVAD registers a survival rate which is comparable to, and even higher than, the HeartMate® LVAD. Accordingly, for patients with advanced, refractory HF, the HeartWare® LVAD may be regarded as an acceptable treatment option as a bridge-to-transplantation.