Eficacia y Seguridad de los Dispositivos de Asistencia Ventricular

Efficacy and Safety of Ventricular Assist Devices. *Executive summary*

INFORMES DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS
AETSA

INFORMES, ESTUDIOS E INVESTIGACIÓN

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN
DE TECNOLOGÍAS Y PRESTACIONES DEL SISTEMA NACIONAL DE SALUD

JUNTA DE ANDALUCIA
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

Eficacia y seguridad de los dispositivos de asistencia ventricular

Efficacy and safety of ventricular assist devices. *Executive summary*

INFORMES DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS
AETSA

INFORMES, ESTUDIOS E INVESTIGACIÓN

Molina Linde, Juan Máximo

Eficacia y seguridad de los dispositivos de asistencia ventricular. Juan Máximo Molina Linde, Ana María Carlos Gil, Rebeca Isabel Gómez y Carmen Beltrán Calvo — Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, 2013.

77 p; 24 cm. (Colección: Informes, estudios e investigación. Ministerio de Sanidad, Servicios Sociales e Igualdad. Serie: Informes de Evaluación de Tecnologías Sanitarias)

1. Corazón artificial 2. Insuficiencia cardiaca / terapia 3. Trasplante de corazón I. Carlos Gil, Ana María II. Isabel Gómez, Rebeca III. Beltrán Calvo, Carmen IV. Andalucía. Agencia de Evaluación de Tecnologías Sanitarias V. España. Ministerio de Sanidad, Servicios Sociales e Igualdad VI. España. Ministerio de Economía y Competitividad

Autores: Juan Máximo Molina-Linde, Ana María Carlos-Gil, Rebeca Isabel-Gómez y Carmen Beltrán-Calvo.

Este documento se ha realizado al amparo del convenio de colaboración suscrito por el Instituto de Salud Carlos III, organismo autónomo del Ministerio de Economía y Competitividad, y la Fundación Progreso y Salud de la Consejería de Igualdad, Salud y Políticas Sociales de la Junta de Andalucía, en el marco del desarrollo de actividades de la Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del SNS, financiadas por el Ministerio de Sanidad, Servicios Sociales e Igualdad

Edita: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía
Consejería de Igualdad, Salud y Políticas Sociales
JUNTA DE ANDALUCÍA
Avda. de la Innovación, s/n. Edificio ARENA 1, s/n. Planta baja.
41020 Sevilla
España – Spain

ISBN: 978-84-15600-34-3
NIPO: 680-13-097-9

Eficacia y seguridad de los dispositivos de asistencia ventricular

Efficacy and safety of ventricular assist devices. *Executive summary*

INFORMES DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS
AETSA

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN
DE TECNOLOGÍAS Y PRESTACIONES DEL SISTEMA NACIONAL DE SALUD

JUNTA DE ANDALUCÍA
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

Executive summary

Heart failure is a damage of cardiac structure or function that makes the heart unable to supply oxygen at a rate consistent with the tissues requirements despite normal filling pressures.

In the latest stages of the disease, usual treatment options (drugs, resynchronization devices and implantable cardioverter defibrillator) become unsuccessful, it is heart transplantation and ventricular assist device that allow to extend survival and improve patient's life quality.

At the moment, the most usual ventricular assist devices are continuous flow left ventricular assist devices. They have been implemented in more than 75 % of patients with end-stage heart failure according to data collected in the fourth INTERMACS 2012 report, performed in the United States of America.

For this reason, the Health Technology Assessment Agency of Andalusia (AETSA) propose to evaluate third-generation continuous flow left ventricular assist devices in order to develop -after studying the areas of uncertainty- a potential tool to be incorporated into clinical practice.

Objectives

The main objectives of this report are:

- To evaluate the efficacy -in terms of mortality, hemodynamic function, quality of life- and safety of ventricular assist devices in patients with terminal heart failure. In particular the HeartMate II, HeartWare, DuraHeart and CentriMag devices.
- Synthesize the available evidence on the ventricular assist devices mentioned above.

Material and methods

For the systematic review of the literature, a structured search was conducted in the following reference databases up to February 2013: Medline, EMBASE, Web of Knowledge (WOK) and Cochrane Library.

A search was also conducted in the Center for Reviews and Dissemination (CRD), the National Institute for Health and Clinical Excellence (NICE) and the registry of ongoing clinical trials in the U.S. ClinicalTrials (http://clinicaltrial.gov/).

For the critical appraisal of the studies, the classification system of the evidence Critical Appraisal Skills Programme adapted to Spanish (CASPe) was used.

Results

The results were organized according to the comparative efficacy of the ventricular assist devices for the artificial heart, the cellular therapy and the heart transplant.

No studies were found evaluating the efficacy and comparative safety with the proposed comparators.

For ventricular assist devices and the artificial heart comparison, 229 citations have been located in the search databases, of which 15 were duplicates. 2 articles were selected for full text review. One was an emerging technology synthesis report with good methodological quality and the other study was a prospective study with only 7 patients. In addition, the protocols for three ongoing studies were located in the U.S. clinical trials registry.

For ventricular assist devices and the cellular therapy comparison, 63 citations have been located in the search databases, of which 4 were duplicates. No article was selected for full text review. In addition, the protocols for three ongoing studies were located in the U.S. clinical trials registry.

For ventricular assist devices and the cardiac transplantation comparison, 519 citations have been located in the search databases, of which 48 were duplicates. No article was selected for full text review. In addition, the protocols for three ongoing studies were located in the U.S. clinical trials registry.

Conclusions:

- No studies evaluating the comparative efficacy and safety of ventricular assist devices HeartMate II, HeartWare, DuraHeart and CentriMag -third generation continuous flow- with the artificial heart, cellular therapy and heart transplantation in patients with terminal heart failure were found.
- Studies comparing the ventricular assist devices Thoratec and Novacor (second generation) with the artificial heart CardioWest in patients with terminal heart failure were found. The CardioWest device showed a higher survival rate.
- Studies take into account cellular therapy with stem cells as a treatment for terminal heart failure in development were found. A document was found noting the necessity of solving the uncertainties related to gene expression and the magnitude of the survival of stem cells, identification of patients eligible for treatment and adverse effects, legal and ethical considerations.

- Found research protocols for stem cells therapy are orientated towards complementing the treatment with ventricular assist devices. Both treatments can be considered complementary. The goal of combining both treatments was to improve the efficacy of ventricular assist devices.
- "Gold standard" treatment for patients with terminal heart failure transplant is heart transplantation if the patient was a appropriate candidate. Given the shortage of organs, further research for durable and cost-effective devices is required.
- The comparison of ventricular assist devices one from another for selected patients from a cost-effective perspective could arise as a research line with relevance for the clinical practice.