Left Ventricular Assist Device (LVAD) as Destination Therapy

Spanish full text

Introduction: heart failure (HF) is a worldwide epidemic that has a significant impact on healthcare costs in developed countries. Despite the progress made over the last 20 years in the medical treatment of HF, a high percentage of patients whose illness reaches an advanced or terminal stage still remains. When medical therapy is no longer effective, heart transplantation is considered the treatment of choice. However, due to the limited availability of organs and the waiting time until a compatible organ is available, Left Ventricular Assist Devices (LVAD) are an acceptable therapeutic alternative. In the case of patients with a permanent contraindication for heart transplant due to their age or comorbidities, LVAD used as a destination therapy are one of the main options.

Aims: to analyse the safety, effectiveness, considerations for use, and the economic, organisational, social, ethical, or legal aspects arising in relation to the use of LVAD as a destination therapy.

Methods: specific search strategies were designed in order to locate studies that have evaluated the safety and/or effectiveness of LVAD as a destination therapy, their economic and organisational impact, patient acceptability and satisfaction, and the ethical, social, and legal aspects associated with its use. These strategies were carried out in November 2017 using the principal medical literature databases. The main features and results of the studies that were included were summarised in evidence tables. A qualitative synthesis of the evidence was carried out using the GRADE system, for which 14 result variables were selected, all of which except one were classified by the clinicians as critical. In order to evaluate the bias risk of the studies, specific tools were used depending on the type of study. The quality of evidence was evaluated using the GRADE system in the case of the quantitative studies, and the GRADE-CERQual version was used for the qualitative studies. Both the extraction of data from the studies and the synthesis and evaluation of the evidence were carried out independently and blind by two investigators.

Results: throughout the bibliographic search, a health technology assessment (HTA) report from Health Quality Ontario HTA agency (Canada) was found. This was updated and extended, obtaining 8 original studies, 6 that evaluated safety and/or effectiveness (1 ENDURANCE randomised clinical trial, and 5 observational studies), 2 cost-effectiveness studies, 3 qualitative studies on patient/carer acceptability, and 7 studies that analysed the ethical impact. The quality of the evidence was classified as moderate to very low, according to the GRADE system.

In randomised clinical trials with LVAD as a destination therapy (REMATCH and ROADMAP) it has been found that patients treated with continuous or pulsatile-flow LVAD achieved a higher 1, 2, and 4-year survival rate a better quality of life, and a better functional status in comparison with the optimal medical treatment. The continuous-flow LVAD presented a lower frequency of right heart failure, respiratory dysfunction, device-related infection, and sepsis than the pulsatile-flow LVAD. However, the continuous-flow LVAD presented a thrombosis rate of 4%, compared to no cases with the pulsatile-flow LVAD. The continuous-flow LAVD increased the 1 and 2-year survival rate, and improved functional status in comparison to the pulsatile-flow LAVD, although finally the quality of life of patients treated with either of the two versions was similar. The ENDURANCE trial found that patients treated with HeartWare™ LAVD system had a higher frequency of stroke in comparison with the HeartMate® II, although the survival rate for both groups was similar. The

studies that assessed patient and/or carer acceptability indicated in some cases, the important burden of treatment with LAVD as a destination therapy, while others highlighted the opportunity the device has offered them to improve their quality of life.

As regards aspects associated with the implementation of LAVD as a destination therapy, it is important to note the incremental cost-effectiveness ratio, which is higher than 100,000 euros/QALY (107,000 to 187,000 euros), in addition to its organisational impact i.e. presence of a multidisciplinary team with adequate and continuous training, education for patients and/or caregivers, adaptation of patient's homes, and coordination of the different healthcare settings.

Finally, the aspects associated with the use of LAVD as a destination therapy are focused on offering the patient and/or carer the different therapeutic options that are available through a specially designed informed consent form for end-of-life clinical situations.

Conclusions: based on the evidence that has been published on LAVD as a destination therapy, the HeartWare™ (centrifugal pump) and HeartMate II® (axial pump) continuous-flow devices appear to be the best therapeutic option for patients with advanced heart failure and contraindications for heart transplant. However, there is uncertainty with regard to in-hospital death rates, as well as the influence of reimplantation or the learning curve on the frequency of adverse events. The organisational and economic impact, as well as patient and/or caregiver acceptability may condition the use of these devices. Therefore, it is considered appropriate to create a registry in order to identify the patient group that would obtain the best results, and to value the organisational and economic impact derived from using LAVD as a destination therapy.