

Title	Evaluation of the evidence on the HeartMate II and HeartWare® ventricular assist devices for the treatment of chronic end-stage heart failure
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Aim

Currently, three hospitals in Québec carry out cardiac transplantation and use implantable ventricular assist devices (VADs) for adult patients. In 2011, the Ministry of Health and Social Services (MSSS) gave INESSS the mandate to perform an evaluation of implantable VADs. The analysis focuses on the two continuous-flow VADs that are the most relevant to the Quebec context: HeartMate II® (HM II), the device that is the most often used in Québec, and HeartWare® (HW), an emerging technology in Europe.

Conclusions and results

The use of a continuous-flow implantable VAD (HM II or HW) can be considered a clinically-effective therapeutic option, compared to optimal medical treatment, if offered to appropriate patients. For both bridge to transplant and destination therapy patients, results are promising for survival, as well as for impact on function and on quality of life. However, despite recent technical improvements that have decreased risks associated with this device, the principal complications following VAD implantation remain severe bleeding, infections or cardiovascular complications. VAD patients must also adapt their lifestyle and take good care of the equipment by accomplishing a number of technical tasks. There is a lack of information regarding the use of long-term implantable VADs by patients in Québec and their clinical outcomes. Given the aging of the Québec population and the growing prevalence of heart failure, we expect the demand for both donor hearts and implantable VADs to increase.

Methods

A systematic search of the scientific literature published between January 2008 and April 2011 was carried out in bibliographic databases. Data on the number of VADs implanted were obtained from the three transplantation centres in Québec, from publications, and through communication with key contacts in other regions. INESSS also created a

scientific committee of expert clinicians, consisting of a cardiologist and cardiac surgeons representing each transplantation centre in Québec and the Réseau québécois en cardiologie tertiaire (RQCT).

Recommendations

Considering the present evaluation and discussion of the results with our scientific committee of Québec physician-experts, INESSS made recommendations on:

- Context of use
- Structures, processes and organization of care
- Patient selection
- Ethical considerations and the patient's perspective
- Economic considerations and budget implications
- Knowledge development.

Written by

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