

HTA-Report | Summary

Ventricular assist devices for heart failure

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Health political background

Heart failure is a clinical syndrome of major epidemiological and economical importance. In Germany as in other industrialised countries it is the leading cause of mortality, morbidity and disability to work.

The direct costs of heart failure in 2004 in Germany were 2,548 millions Euro. Especially hospitalisation related to progression of the disease is a problem.

Heart failure is the terminal stage of many different diseases leading to impairment of heart function. For patients with end stage heart failure not responding to medical therapies the last possibility is heart transplantation. The number of available donor hearts is declining and does not fit the needs. Thus waiting lists for heart transplantation are long and candidates have to wait a long time period and a part of them die during this time. Ventricular assist devices (VAD) were developed to assist the failing heart in pumping blood. They are used as bridge to transplant (BTT), bridge to recovery (BTR) or as destination therapy (DT) alternative to transplantation. Most of the assist devices are used to assist the left ventricle (LVAD), sometimes to assist either both ventricles (biventricular assist device, BiVAD) or the right ventricle (right ventricular assist device, RVAD).

It is estimated that in Germany yearly between 300 and 500 assist devices are implanted, mostly in the intention as BTT.

It is the aim of this report to give a systematic review of other reviews and primary studies to resume the clinical effectivity and psycho-social aspects of this technology. In the economical part we resume the evidence of ventricular assist devices regarding the cost-effectivity. The results of the included studies are discussed considering the German health care system.

Scientific background

Heart failure (ICD-10: I50) is the result of one or more heart diseases. The heart declines to pump enough blood (and oxygen) around the person's body to meet its metabolic needs during exertion or even during no exertion. The most common causes of heart failure are coronary heart disease (including myocardial infarction) and hypertension.

Heart failure is one of the most common internal diseases. Prevalence and incidence depend on age. The prevalence of heart failure in Germany is about 2 %. This would mean that 16 millions of Germans are having heart failure. Changes in age distribution and longer life of patients with heart diseases are expected to increase the prevalence of heart failure. The statistics of deaths of the year 2005 registered 48.184 deaths for cause of heart failure in Germany. This is about 1 % of the total costs of diseases in the same year.

Heart transplantation is the first alternative to treat end stage heart failure. It is associated with an increase in survival and quality of life. Since 1996 in Germany there are two-fold registrations for heart transplantations than transplantations itself. In the year 2005 there were 396 heart transplantations performed in 24 centres and 793 registrations made. The unfilled need leads to long waiting periods. 20 % of patients die during the

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waiting time. Ventricular assist devices can be used to bridge the time to transplantation. The long term chronic support with LVAD is limited by the incidence of thromboembolism and bleeding. Also infections are a major threat of the patients. The percutaneous site with cannulae connecting the external control unit is often susceptible to infections. In some patients right heart failure occurs. Sometimes mechanical failure of the device requires a pump replacement. The costs of left ventricular assist devices are between 50000 and 90000 Euro depending on the system.

Research Questions

For the clinical aspects these questions were investigated:

- How are the survival rates in patients with LVAD after implantation and after transplantation?
- How many percent of the patients could be successfully transplanted?
- Which complication appeared and how many patients died of them?
- Which part of the patients could be discharged home?
- How many percent of the patients could be successfully weaned?

For the economic aspects the following questions were explored:

- What are the costs of LVAD therapy as BTT, BTR and DT?
- What is the cost-effectiveness ratio of LVAD as BTT BTR and DT?
- What is the actual need of LVAD in Germany? What costs will arise for the German health care system?

For the consideration of the psycho-social aspects the following questions were investigated:

- How is the quality of life in the patients? Which psychological and social problems occur?

Further questions:

- Can heart assist devices replace donor hearts in the long term application?
- What is the influence of assist devices on the number of heart transplants?

Methods

This HTA-report aims to actualise the existing HTA-reports and presenting the conditions in Germany. The most actual report included publications up to October 2003 so the selection was focused on primary studies published later. We included systematic reviews and primary studies of all qualities up to case series with 15 or more LVAD patients and economical evaluations.

We conducted a systematic research of the literature in different databases (EMBASE; MEDLINE, Cochrane Library). The search strategy combined groups of keywords and therefore included the search of clinical, economical and ethical questions. The search was done the 23. January 2006. The references were selected according a priori defined inclusion and exclusion criteria. The quality was assessed with checklists by two reviewers and was presented in a narrative form.

Additionally a search in the internet was conducted, websites of producer were scanned and a community of VAD producer was contacted. We sent out a questionnaire to all German hospitals implanting VAD. We scanned reference lists of the identified HTA-reports. The extracted data are presented in a narrative form. A metaanalyses was not possible because of very heterogeneous data.

In addition we conducted a survey among hospitals which use the technology.

Results and discussion of the scientific questions

We included six HTA-reports. They were about medical and economical aspects of the technology. 30 references were included which were relevant for the assessment of clinical effectiveness, two references were about psycho-social aspects, two were economical considerations.

LVAD patients had significant better survival rates than medically treated patients. Survival rates after transplantations did not yield consistent results. The rates of successful heart transplantation in BTT patients were between 33 % and 87 %. Mostly the rates were at about 70 %. In children the rates were between 0 % and 58 %. Mechanical assistance was associated in all three intentions with frequent and often serious adverse events. Infection, bleeding thromboembolism, neurological events, right heart failure, organ failure and haemolysis were the events which occurred often. The frequency of adverse events diminished within time. Causes of death were mostly infection and sepsis, multi organ failure, neurological events and system failure. Between 14 % and 85 % of the patients could be discharged home. The rates of successful weaning from the device were heterogeneous and were between 1 % and 45 %. Weaning rates in babies, children and youth were comparable to those of adults.

Some studies found a better quality of life in LVAD patients than in medically treated patients. Two studies reported an increase in quality of life with time after implantation. There were numerous psychological and psychiatric problems associated with implantation. There were no controlled studies with heart failure patients without VAD. Many psychiatric problems diminished with time after implantation, in others they increased.

For patients with contraindication for heart transplantation ventricular assist devices are more effective than a medical therapy. Survival rates were better for the period over two years but were not assessed for a longer time. No studies investigated DT in patients that were candidates on the waiting list.

Assist devices as bridge to transplantation can only temporarily release the waiting list. Generally only a successful long term support or successful weaning can decrease the waiting list. There was evidence in UK that implantation of LVAD in children did not have a negative effect on the waiting list.

Conclusions / recommendation

Ventricular support is an invasive therapy for terminal heart failure, which is mainly used in the intention of BTT. LVAD used as BTT allow to survive upon transplantation with an acceptable quality of life. However the technology is associated to high complication rates, specially infection and neurological insults (hemorrhagic and thromboembolic).

The use of assist devices as alternative to the medical treatment of patients for which heart transplantation is contraindicated leads to higher survival and better quality of life.

The technology is very costly. For Germany results of cost-effective analysis are lacking to date. Cost-effectiveness analysis from other countries indicate that the incremental costs pro QALY may be between 60000 and 100000 for BTT and between 200000 and 600000 Euro for DT.

Before the technology can really contribute to a reduction of the need for heart transplantation it will be necessary to reduce the complications rate. Complications reduce not only the effectiveness of the technology they also add an important amount of costs.

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