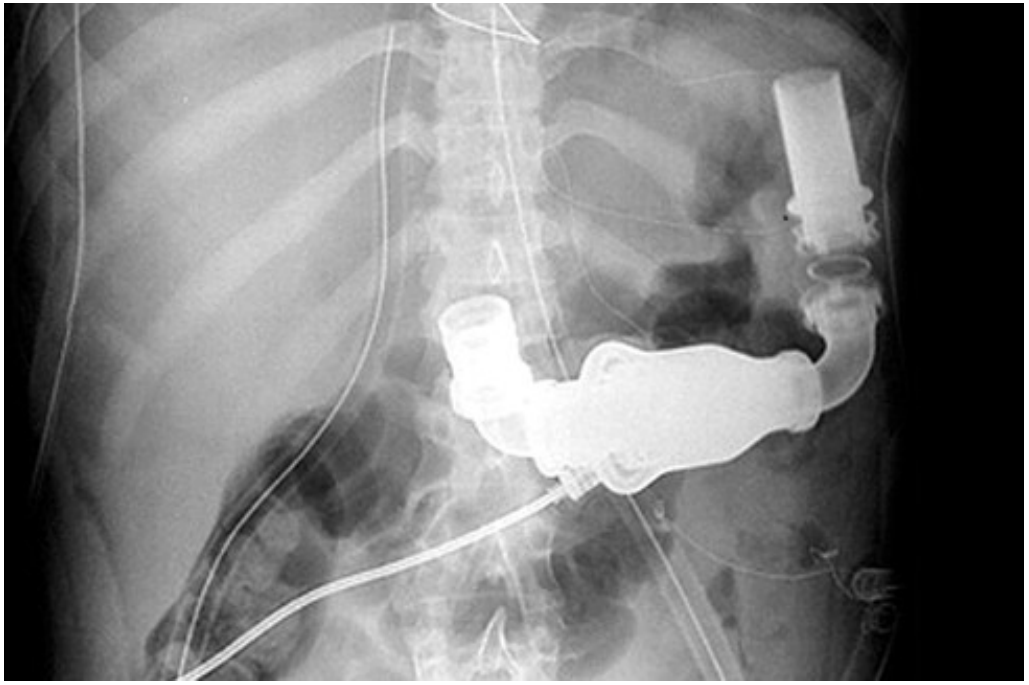
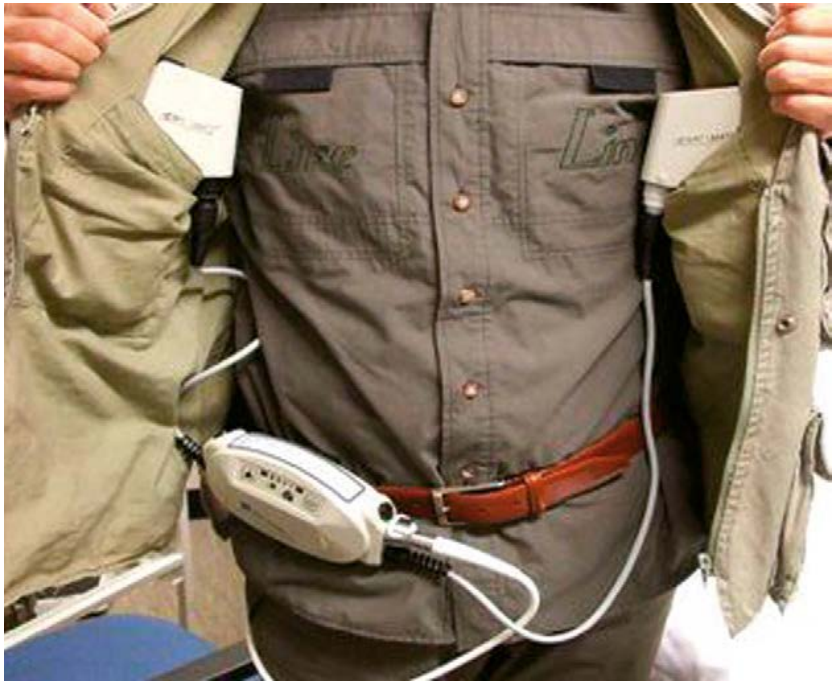
KCE REPORT 264Cs

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SYNTHESIS

LEFT VENTRICULAR ASSIST DEVICES IN THE TREATMENT OF END-STAGE HEART FAILURE





KCE REPORT 264Cs
HEALTH TECHNOLOGY ASSESSMENT

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SYNTHESIS

LEFT VENTRICULAR ASSIST DEVICES IN THE TREATMENT OF END-STAGE HEART FAILURE

MATTIAS NEYT, ROOS LEROY, CARL DEVOS, HANS VAN BRABANDT

FOREWORD

Who in the age category of the undersigned does not remember the first heart transplant by Chris Barnard, in Groote Schuur Hospital in Cape Town? It was December 1967. The procedure was world news, and the mediagenic Barnard promptly became a celebrity. There are also few procedures that appeal so to the imagination as a heart transplant. Today, almost fifty years later, the procedure has acquired a firm place in the cardiac surgery repertoire. The indications to be sure cannot be extended without limit, but there is a chronic shortage of donor hearts to contend with.

In 1967 it was also believed that the ultimate dream, an artificial heart, was undoubtedly not far away. After all, the first attempts to have a machine take over heart function already dated from fifteen years earlier. Technology seemed to be capable of anything – weren't we on the point of having people walk on the moon? But it would not be until 1982 that Willem Johan Kolff implanted a Jarvik 7 artificial heart. The patient survived 112 days. And where do we stand in 2016? One thing is certain: the topic still strongly appeals to the imagination.

But in the meantime there is more than just hope and imagination. Today we have various types of devices to support or even replace a failing heart, and a number of them have gone from purely experimental status to clinical practice. Here too, however, the indications remain limited as yet, but that could well change. An accepted indication for the heart assist device considered in this study is to bridge the waiting period until transplantation. The question is whether it could ultimately also become an alternative to transplantation. Given the shortage of donor hearts – and thus the sometimes quite long waiting periods – the boundary between the two is for that matter not always so distinct.

We have here once again a typical recipe for a heated social discussion: a technological tour de force, with a corresponding price tag, for a patient population that is threatened with death in the short term, and where the technology can turn the tide in spectacular fashion and add several unhoped-for years of life… with a quality of life that is not so poor. The KCE has been asked to discuss the health-economic perspective. You will find the plain figures in the report that lies before you, and they are certainly not favourable. But you, the reader, and we too realise that this will not settle the debate.

Christian LÉONARD
Deputy General Manager

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General Manager

SYNTHESIS

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1. ASSIST DEVICES FOR TREATMENT OF HEART FAILURE

1.1. What is heart failure?

In heart failure the heart pumps insufficient blood through the body. Therefore the organs receive less oxygen and nutrients. Someone with heart failure then becomes short of breath and feels fatigued faster. In addition, fluid (oedema) can accumulate in the lungs, legs and abdomen. Other symptoms of heart failure are e.g. a dry cough, tightness of the chest, cold hands and feet and poor sleep.

Usually several symptoms appear at the same time, but their intensity can differ greatly; some patients can still carry out their daily activities very well, while others experience serious problems even at rest.

Sometimes heart failure can also appear acutely. A typical condition is pulmonary oedema. The most severe cases, like cardiogenic shock, often lead to death.

1.2. What is the cause of heart failure?

Heart failure is usually a gradual, insidious process. Some possible causes are: a heart attack (a portion of the cardiac muscle dies off, so that the heart pumps less powerfully), high blood pressure, disorders of the heart valves or heart muscle tissue, viral infections, etc.

1.3. Does heart failure occur often, and in whom?

Heart failure is a very common disorder; it is estimated that more than 10 000 Belgians receive the diagnosis annually.

A relatively small group of people with a congenital heart defect run an increased risk of heart failure, some even at a rather early age. In general, however, heart failure is an age-related disease; in Belgium half of the patients are older than 79 (82 for women, 76 for men) at diagnosis. In people older than 65 it is the most common cause of hospitalisation and death; half of the patients in whom the underlying cause cannot be treated die within 4 years, and even within the year for a severe form. The prognosis is thus worse than for many cancers.

1.4. How is heart failure treated?

Heart failure can be cured if it is caused by a heart valve defect that can be corrected surgically. In most other cases there is no real cure, but the symptoms can be alleviated with appropriate measures. Usually that is quite possible by adjusting the lifestyle (diet and exercise) and taking medication (diuretics, beta blockers, etc.). For patients who do continue to have symptoms, a specific pacemaker can be indicated. Patients with end stage heart failure might be eligible for heart transplantation or the implantation of a mechanical pump.

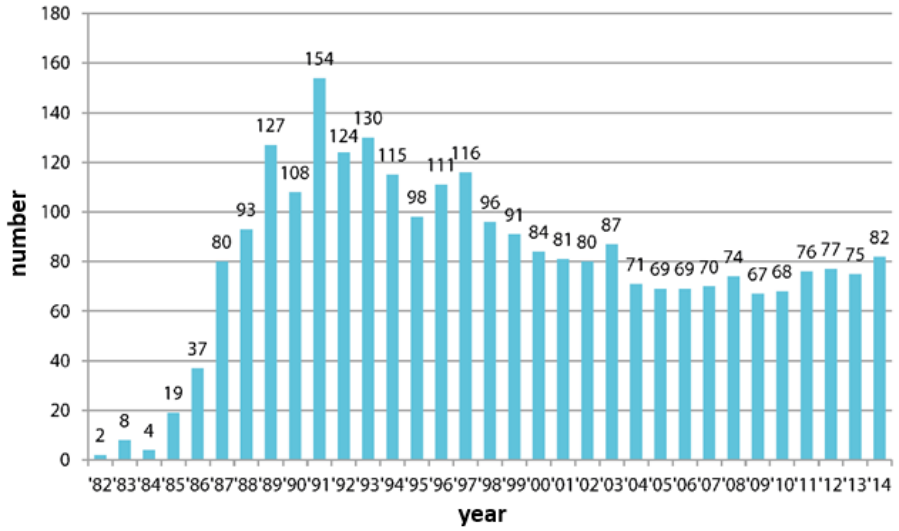
1.5. Heart transplantation: better survival and quality of life, but too few donor hearts

Heart transplantation significantly increases survival and quality of life; 10 years after the procedure, over half of the patients are still alive. In the last 20 years, however, there has been no further increase in the number of heart transplants due to a shortage of donor hearts (see Figure 1). Therefore candidates for transplantation must be carefully selected. They are chosen depending on amongst others the urgency of the procedure, the degree to which a donor heart would impact their life expectancy, and the risk of complications.

Age is not a criterion in itself, but due to the generally poorer health status of older patients a heart transplant is often less effective, because, among other things, they sometimes suffer from several other disorders as well. Therefore transplants are usually performed in patients younger than 65. Not everyone on the transplantation list ultimately receives a donor heart.

Today there are seven recognised centres in Belgium where heart transplants are performed: Antwerp, Brussels (2), Leuven, Ghent, Aalst and Liège. Together, they performed approximately 80 heart transplants annually in recent years (see Figure 1).

Figure 1 – Heart transplants in Belgium



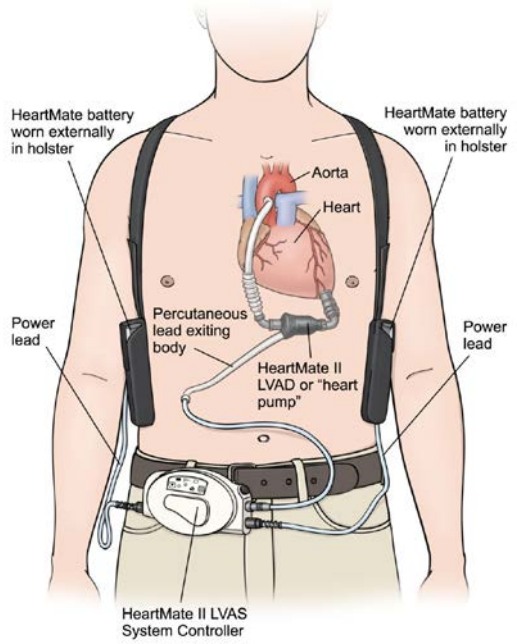
Source: Eurotransplant (https://www.eurotransplant.org/)

1.6. The LVAD or left ventricular assist device: a mechanical alternative

Due to the shortage of donor hearts, the development of artificial mechanical implants has been encouraged. They offer an alternative to a donor heart: they can support or even completely take over the poorly working heart function. One of these implants, and the topic of this study, is the LVAD (Left Ventricular Assist Device) or heart assist device.

In a heart assist device, a small pump placed in the chest cavity or upper abdominal cavity of the body interconnects the left ventricle and the aorta and takes over the heart function. The system works on electricity; the pump is connected to a cable (called the driveline) that passes outside the body through the abdominal wall. This driveline is connected to a controller that gives a sound and light signal when necessary. The controller is in turn connected to batteries that can be worn on the body (see Figure 2). The batteries must be charged every 8 hours and replaced every two years.

Figure 2 – Illustration of a heart assist device (Heartmate II)



Source: https://wikem.org/wiki/Left_Ventricular_Assist_Device_%28LVAD%29

The patient must always carry all of this. For his safety, he and his family members must be very familiar with how they must react to any alarm signals, how the batteries must be handled and charged, and how infections of the place where the driveline leaves the body can be prevented. To prevent accumulation of blood clots around the pump, which can cause a stroke or lead to blockage of the pump (pump thrombosis), the patient must also take anticoagulants ('blood thinners').

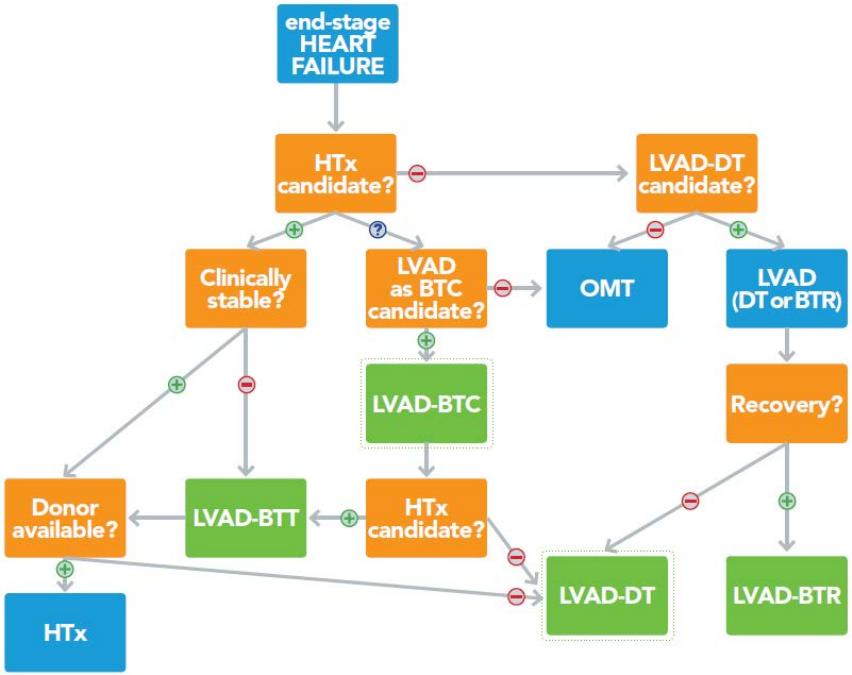
Not to be confounded: LVAD and total artificial heart.

A total **artificial heart** is a device that is implanted in the chest and that replaces the entire heart. It is directly connected with the great vessels (aorta, pulmonary artery, …).

A **left ventricular assist device (LVAD)** does not replace the heart. It is intended to assist the left ventricle and is placed in parallel with the heart. It is connected to the left ventricle and the aorta with a tube (cf. figure).

1.7. Use of heart assist devices: for which patients?

Figure 3 – Treatment intentions with LVADs



HTx: harttransplantatie. OMT: optimal medical treatment.

For a patient with terminal heart failure, the question arises whether he is eligible for a donor heart (heart transplantation, HTx) and if not, whether he is then eligible for treatment with a heart assist device (LVAD). If he is not suitable for either of these options, he receives further **optimal medical treatment (OMT)** (see Figure 3).

If he is a good candidate for HTx, and if it is expected that he can survive the waiting period on the transplant list under medical treatment, he receives **a HTx** when a donor heart is available.

If the assessment is that the HTx candidate cannot survive the waiting period, or if his heart failure suddenly becomes life-threatening while he is waiting for a donor heart, an LVAD can be implanted as bridging therapy. This is then referred to as a **Bridge to Transplant (BTT) LVAD**. Heart assist devices were initially developed primarily for this group, and in Belgium the vast majority of them are still used for this type of patients.

A patient can also present with acute terminal heart failure from the beginning, with no time to assess his suitability for HTx. For example, there may be uncertainty as to whether he suffers from other illnesses that make a HTx impossible, but due to the life-threatening nature of the situation there may be no time to investigate this further. Then the question arises whether he is eligible for an LVAD as a **Bridge to Candidacy (BTC),** so that time becomes available to investigate whether he is a good HTx candidate.

If after this he appears to be suitable for HTx, his LVAD then receives the BTT label. If he appears not to be suitable for HTx, the LVAD that he has already received as BTC then receives the label **Destination Therapy (DT)**.

In some patients with terminal heart failure, it will already be clear from the beginning that they are not a good candidate for a HTx, but it may be decided to treat them with an LVAD as destination therapy (DT). In rare cases the hearts of these patients recover over time and the LVAD can be removed. In retrospect it is then said that he received an LVAD as a Bridge to Recovery (BTR).

In the scientific literature this small group of BTR patients, along with the BTC patients, is called the **Bridge to Decision (BTD**) group. Because almost all BTD patients are in fact BTC patients, it has been agreed with the Belgian experts not to use the BTD concept in this report.

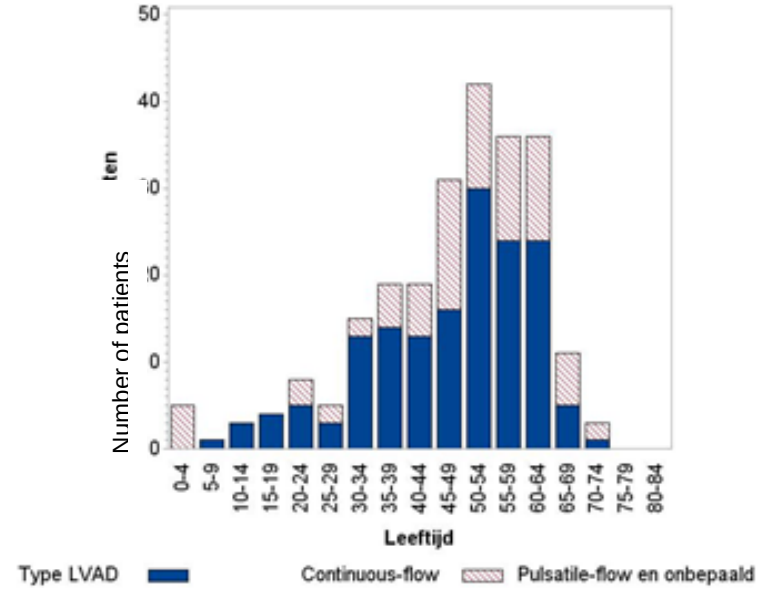
1.8. Steadily increasing demand in Belgium

From the available data on 83 heart assist devices implanted in 2014 and 2015, it appears that 70 (or 84%) were used for BTT, 8 (10%) for BTC, and 5 (6%) for DT.[a]

Of the 238 Belgians who received a heart assist device in 8 years' time (2006-2013), ¾ were men and ¼ women. Their average age was 48.

The older heart assist devices imitated the beating action of the heart (pulsatile-flow LVAD). Since 2010 almost all patients have received the more recent devices. These have a small rapidly spinning rotor that provides a continuous blood flow (continuous-flow LVAD). The most-used brands today are the HeartMate II and the HeartWare Ventricular Assist Device (HVAD).

Figure 4 – Age distribution (n=238)



Source: IMA (2006-2013)

[a] Belgian Association for Cardio-Thoracic Surgery (BACTS)

The RIZIV [*National Institute for Health and Disability Insurance]* initially reimbursed a limited number of heart assist devices annually for ***BTT patients*** only. This number gradually increased, by request of clinicians, from 20 (in 1999) to 50 (in 2014). There is a stipulation that the heart assist device be implanted by one of the seven recognised transplant centres and that the patients be on the Eurotransplant waiting list. Since 1 July 2014 ***BTC patients***, thus people for whom it is still uncertain whether they will ever be eligible for heart transplantation, can also be eligible for one of the 50 heart assist devices reimbursed annually.

To date there is no reimbursement in Belgium for ***DT patients.***

Clinicians are now inquiring for reimbursement of more than 50 heart assist devices per year so as to be able to treat more BTC patients and even also DT patients with a heart assist device. Therefore the RIZIV asked the KCE to investigate the clinical efficacy and cost effectiveness of LVADs for BTC and DT in the framework of a Health Technology Assessment (HTA, see box). The presently existing reimbursement of BTT patients is not part of the present study.

What is a Health Technology Assessment (HTA)?

An HTA is a multidisciplinary scientific research process in which the safety and efficacy, but also the economic, social and ethical acceptability, of a technology or product are examined. These various aspects are not necessarily discussed (in the same depth) in every HTA.

The aim of an HTA is to inform policymakers in making decisions on development of a safe, efficient and patient-focussed healthcare policy. The cost effectiveness of the technology is also examined: what added value is offered, at what price. This can be useful in striving toward the most efficient possible use of the available resources.

1.9. Method

In the search for evidence on the safety, efficacy and cost effectiveness of LVADs, a systematic review of the literature was conducted. Reimbursement data from the health insurance funds were analysed and a context-specific economic evaluation was conducted.

2. THE CLINICAL EFFICACY OF HEART ASSIST DEVICES

2.1. Extension of life expectancy and improvement in the quality of life

Extension of life expectancy and improvement in quality of life are the aims in implanting an LVAD.

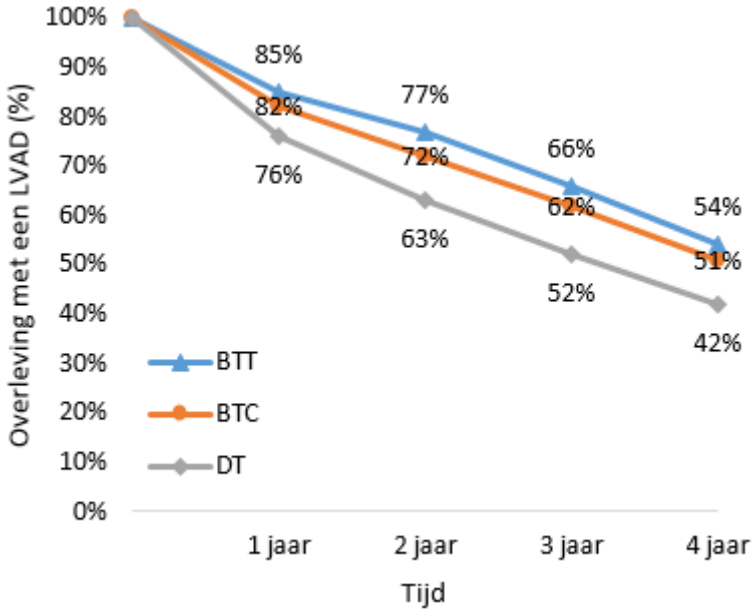
However, there are no reliable studies that directly examine whether patients with the most recent types of LVADs (continuous flow) live longer than patients who receive the best possible treatment with medication. We did find a reliable study that compares the older types of heart assist device (pulsatile) with drug treatment, and a study of good quality that compares the two types of heart assist devices with each other. In this way an indirect comparison could be made, associated with extra uncertainty, between the more recent LVADs and the best possible medical treatment.

Greatly improved survival

We were able to deduce that the ***most recent type of heart assist device*** greatly improves survival. After one year, 68% of the patients are still alive, and after two years, 58%, while with optimal drug treatment that is only 28% after one year and 13% after two years. Patients with end-stage heart failure live on average approximately 9 to 10 months with medication. If these patients receive a heart assist device (as DT), their life expectancy rises by 4 years (4.82 vs. 0.82 life years), or by 3 years adjusted for the quality of life (3.46 vs. 0.44 QALYs; for more explanation see chapter 4)[b].

The survival percentages cited above are the results on the basis of two Randomized Controlled Trials (RCTs) in which only DT patients were selected. However, there are also differences in survival among the LVAD patients themselves depending on the LVAD category to which they belong (see Figure 5). That is logical, because their health characteristics also differ. Thus survival is highest in the BTT patients, the group that due to their relatively good state of health are eligible for heart transplantation. For BTC and DT the results are worse, because often older patients with multiple disorders are involved.

Figure 5 – Survival of LVAD patients (by type of patient)



BTC: bridge to candidacy; BTT: bridge to transplant; DT: destination therapy
Source: INTERMACS registry, 2015 Q2

[b] These are non-discounted values.

A better quality of life as well

Patients who receive an LVAD also see a significant increase in their quality of life after the procedure, despite the possible complications (see section 2.2). This has been evaluated with various questionnaires on the general quality of life and also specifically for a population with heart failure. Quality of life can be indicated on a scale of 0 to 1, where a score of 0 means 'deceased', and 1 corresponds to 'perfect health'. According to one study the quality of life of patients with heart failure who are being treated with medication is 0.53. In patients with an LVAD the quality of life reaches a score of 0.72 after the first month. However, this result should be interpreted with caution, since in the underlying study information is lacking for over half of the patients, and the chances are that this is the case especially with patients who are less well off.

2.2. Complications: risk of bleeding in particular

The clear benefit of life extension and better quality of life is however decreased by a large number of potential complications.

Bleeding occurs most often, especially within the week after the procedure. As of the 31th day after the operation, stomach and intestinal bleeding in particular occur in 12 to 23% of the patients.

Eight to eleven percent of the patients develop a ***cerebral infarction or cerebral haemorrhage*** in the first two years after the procedure.

Local ***infections*** are reported in 20 to 49%, infections of the driveline in 12 to 22%, and blood poisoning (sepsis) in 20 to 36%.

Residual ***right heart failure*** is reported in 5 to 25% of LVAD recipients.

Sometimes the ***device*** fails and must be replaced; otherwise the patient dies. The most dreaded complication is pump thrombosis (see section 1.6).

Ultimately it is the complications that most often cause the death of the patient, especially stroke (17.4%), residual right heart failure (11.3%) and bleeding (9.3%).

3. THE COST OF ASSIST DEVICES VERSUS STANDARD TREATMENT

The most important expense item in implantation of an LVAD is the cost of the ***device*** itself. Each heart assist device costs health insurance €67 106 at the moment.

On the basis of 148 procedures (2006-2013) with a recent LVAD in mainly BTT patients in Belgium, the cost of the ***procedure*** for the community is estimated at an average of approximately €46 000, without including in this the costs prior to the operation. In 2013, the most recent year for which we had all the cost data available, this cost was approximately €10 000 lower due to a shorter hospitalisation period (29 hospitalisation days on average in 2013 instead of an average of 42 hospitalisation days over all the years).

On the basis of Belgian figures it appears that after successful LVAD implantation the patient spends almost 5% of his time on average ***in hospital***. One month in the hospital amounts to an average cost of approximately €26 000.

Out-of-hospital costs include medication, physiotherapy, outpatient examinations, etc. These costs are much lower and come to approximately €1300 per month.

According to our health economics model the average total cost for a patient with LVAD comes to approximately ***€260 000***, including the price of the device, for an estimated average life expectancy of 4.8 years.

The costs for the standard treatment with medications include next to the drug costs also the costs for medical follow-up and hospitalizations. The total cost is however much lower due to the limited life expectancy of these patients (9 to 10 months): approximately ***€18 000***. These costs may have been underestimated, e.g. by the absence of Belgian data on this specific patient group. The possible impact of this on the results was calculated by means of a sensitivity analysis (see following chapter).

4. COST-EFFECTIVENESS OF LVADS AS *DESTINATION THERAPY* AND *BRIDGE TO CANDIDACY*

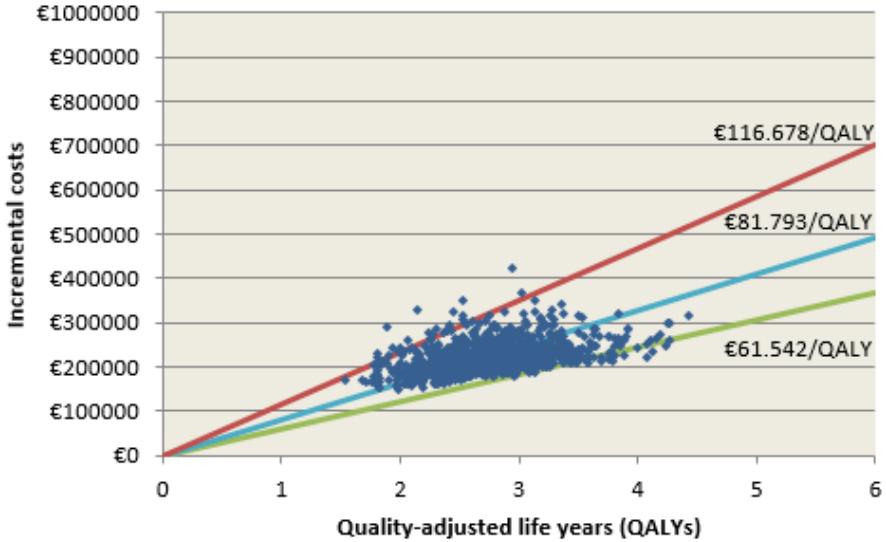
How is cost effectiveness calculated?
A cost effectiveness analysis expresses the benefits of a treatment in 'life years gained' or in 'life years gained adjusted for quality of life' (QALY – Quality-Adjusted Life-Year) for patients. When a treatment costs less and provides more benefits for patients than the current standard practice, the decision is obvious. But often a treatment improves health, but also costs more than the standard treatment. In that case the key question arises: what are the additional costs of an additional (healthy) life year?

4.1. Heart assist devices as *Destination therapy (DT)*: €82 000 per quality-adjusted life year gained

A health economic model has been developed for the Belgian situation, drawn up according to the KCE guidelines for economic evaluations (see KCE report 183[c]).

Compared to a standard treatment, implanting an LVAD costs approximately €222 000[d] more on average, for an average health gain of 2.76 QALYs (quality-adjusted life years gained, so taking account of the quality of life). Because in such a health economic model uncertainty exists in various parameters, a large number of different simulations are done that reflect this uncertainty, from which an average value can then be deduced. After 1000 simulations we finally came to an average extra expenditure of **€82 000 per QALY gained** (*incremental cost-effectiveness ratio, or ICER*) (Figure 6) for heart assist devices used as DT.

Figure 6 – Cost effectiveness plane (reference case analysis)



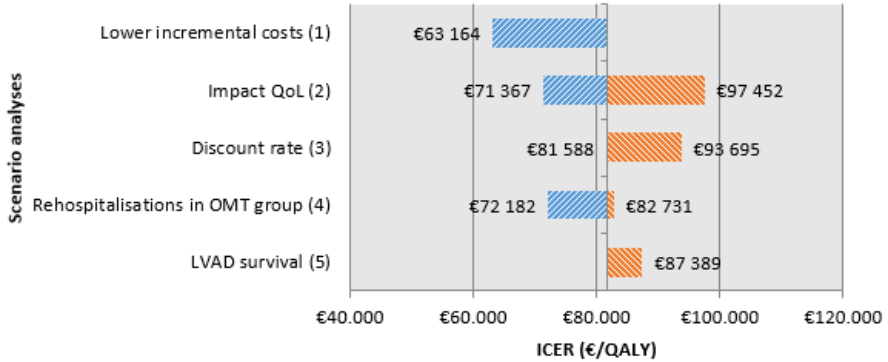
The blue line is the average. The green and red line represent the 2.5- en 97.5-percentiles.

Because this ICER was so high, we also examined whether this would drop substantially by developing various scenarios in which, among other things, the following assumptions were made: a more pronounced improvement in the quality of life, other survival data, a reduction in the cost of the device or the monthly costs, or an increase of costs in the group treated with medication. In all the aforementioned scenarios however the ICER still remained rather high, because the costs of the device, the procedure, readmissions and monthly costs combined were still relatively high. A substantial drop in the extra costs by €50 000 would lead to an average ICER of approximately €63 000 per QALY (Figure 7). Even if the cost of the LVAD device were not included, the average ICER would still come to €56 000 per QALY.

[c] https://kce.fgov.be/nl/publication/report/belgische-richtlijnen-voor-economische-evaluaties-en-budget-impact-analyses-tweed

[d] The costs and effects are discounted at 3% and 1.5% according to the national guidelines.

Figure 7 – Tornado figure: impact of different scenarios on the ICER



5. DISCUSSION

There is no doubt that heart assist devices prolong live and improve the quality of life of patients with end-stage heart failure. From the point of view of the individual physician and patient, it is therefore a procedure that should be considered and is even to be recommended, if the costs are not taken into account.

From the point of view of society, however, these conclusions are less obvious; LVADs are a heavy financial burden for a healthcare system today. The high ICER indicates that the extra costs are very high in relation to the extra benefits compared to the standard treatment. An expansion of reimbursement of LVADs therefore is not an efficient use of the limited resources. Systematic reimbursement of interventions with such an unfavorable cost-effectiveness in the long term threatens to undermine the sustainability of our healthcare system.

And what about LVADs for BTC patients?

Another reason to request an expansion of the annual reimbursement of 50 heart assist devices is that more BTC patients can also be eligible for reimbursement.

Unfortunately there is no reliable evidence that heart assist devices as a BTC are cost effective. But, we can predict this by deduction: an increase in the number of LVADs (BTT, BTC or DT) will not cause the number of donor hearts and so transplants to increase. When you allow the number of LVADs as BTC to increase, the risk exists that the only consequence of this will be that more people will (fruitlessly) wait for a donor heart and there will in fact be more (chronic) DT patients.

As already stated, heart assist devices for DT patients have an unfavourable cost effectiveness.

From a health economic point of view, there are no arguments for an extension of the reimbursement to more than 50 LVADs per year.

RECOMMENDATIONS

To the Minister for Public Health and the competent bodies at RIZIV – INAMI

- **A heart assist device as destination therapy results in a significant improvement in life expectancy and an improvement in the quality of life in comparison with optimal medical treatment. Despite these clear benefits, the average cost effectiveness ratio is relatively high (€82 000 per QALY on average). From a health economic point of view, there are no arguments for an extension of the reimbursement to more than 50 LVADs per year. A social and ethical debate has to be conducted on the basis of these elements.**

COLOPHON

Title:	Left ventricular assist devices in the treatment of end-stage heart failure – Synthesis
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Acknowledgements:	Nicolas Fairon (KCE), Irm Vinck (KCE)
Other reported interests:	Membership of a stakeholder group on which the results of this report could have an impact.: Marc Goethals (BTS) Owner of subscribed capital, options, shares or other financial instruments: / Holder of intellectual property (patent, product developer, copyrights, trademarks, etc.): / Fees or other compensation for writing a publication or participating in its development: / A grant, fees or funds for a member of staff or another form of compensation for the execution of research: Luc Jacquet (BENEMACS trial), Bart Meyns (BENEMACS trial) Consultancy or employment for a company, an association or an organisation that may gain or lose financially due to the results of this report: / Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Martine Antoine, Jo Defraigne, Luc Jacquet, Bart Meyns Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Patrick Galloo (Voorzitter Commissie Tegemoetkoming Implantaten en Invasieve Medische Hulpmiddelen - CTIIMH) Participation in scientific or experimental research as an initiator, principal investigator or researcher: Luc Jacquet (BENEMACS trial), Bart Meyns (BENEMACS trial) Other possible interests that could lead to a potential or actual conflict of interest: /

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- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
- **Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.**
- **Finally, this report has been approved by common assent by the Executive Board (see http://kce.fgov.be/content/the-board).**
- **Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.**

Publication date:	11 april 2016
Domain:	Health Technology Assessment (HTA)
MeSH:	Heart-Assist Devices; Heart Failure; Technology assessment, Biomedical; Cost-Benefit Analysis
NLM Classification:	WG 169.5
Language:	English
Format:	Adobe® PDF™ (A4)
Legal depot:	D/2016/10.273/28
ISSN:	2466-6459

How to refer to this document?

Neyt M, Leroy R, Devos C, Van Brabandt H. Left ventricular assist devices in the treatment of end-stage heart failure. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2016. KCE Reports 264. D/2016/10.273/28.

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