Adjustment following implantation of a left ventricular assist device in patients with CHF, and their partners; a prospective, multi-center observational study (ADJUST-LVAD)

Published: 02-12-2010
Last updated: 30-04-2024

Primary:To examine changes in health status (functional status and quality of life) and emotional distress (i.e. anxiety and depression) over time in patients following LVAD implantation, focusing on intra-individual changes, with a view to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON34122

Source
ToetsingOnline

Brief title
ADJUST-LVAD

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: NWO

Intervention

Keyword: emotional distress, end-stage heart failure, health status, left ventricular assist device (LVAD)

Outcome measures

Primary outcome

Primary: Health status; distress (anxiety/depressive symptoms).

Secondary outcome

Secondary: Morbidity (i.e., complications (defined as infection, bleeding,

neurologic dysfunction, and device malfunction) and rehospitalization);

mortality (both cardiac and non-cardiac); heart transplantation.

Study description

Background summary

In The Netherlands, the incidence and prevalence of heart failure are rising as is the case in most other European countries. Overall, there are 200,000 patients with heart failure in The Netherlands and around 25,000 hospitalizations annually with a discharge diagnosis of congestive heart failure (HF). The diagnosis of HF is largely based upon a careful history and physical examination and confirmation by a more objective test aimed at the assessing of the cardiac function.

The development of left ventricular assist devices.
Heart failure severely affects the functional status and quality of life (QoL) of patients. Since there is a great disparity between the number of patients listed for heart transplantation and actual transplants performed, many patients die each year while awaiting heart transplantation. Therefore, improving the long-term outcomes, including morbidity, mortality and QOL of patients with CHF has been de underlying goal of decades of research on mechanical circulatory-support devices. Nowadays, these mechanical

circulatory-support devices are used either as bridge to transplantation or as permanent destination therapy for people who are ineligible as candidates for heart transplantation [6]. The use as destination therapy, however, has not yet been approved in the Netherlands. Historically, patients have been supported by devices engineered with pulsatile design (i.e. Heartmate IP100, VE, XVE, Thoratec PVAD/IVAD). Pulsatile devices, however, have limitations that preclude their practical use for extended mechanical circulatory support. These limitations include a limited durability, large pump size, requirement for extensive surgical dissection for implant and audible pump operation. The development of continuous-flow rotary pump technology represents an innovative design for a new generation of left ventricular assist devices (LVADs). The Heartmate II LVAD has an axial flow design, weighs about 375 grams and measures about 4 cm in diameter. Within the pumps is a rotor that contains a magnet. The rotor assembly is rotated by the electromotive force generated by the motor. The rotor propels the blood from the inflow cannula out to the natural circulation.

The impact of left ventricular assist devices on QoL and functional status.
Because LVADs are increasingly used as bridge to transplant for more extended periods of time (>3 years), with this trend also likely increasing in the future, it is important to understand the impact of device therapy on individuals and the family [6]. There are several trials indicating that the use of continous flow LVADs as bridge to transplantation or destination therapy improves the QoL and functional status of a patient suffering from heart failure. However, little is known about these aspect in patients on long-term mechanical circulatory support. Of the studies focusing on QoL and health status outcomes after LVAD implantation, five were on the first generation pulsatile devices (Heartmate VE/IP) and two on the second generation continuous flow devices (Heartmate II). Patients were followed from two weeks after implantation in one study and up to one year after implantation in another. One of the studies was retrospective and could therefore not draw conclusion about causality. Further limitations of previous studies were the assessment of QoL at a single point in time, excluding patients that were to ill resulting in a possible overestimation of QoL outcomes, the inability to distinguish center effects from individual variability, and neglecting studying the impact of LVAD therapy on anxiety and depression. At all assessment times patients reported significantly better overall QoL, improvement in physical and social functioning, lower levels of stress, and higher coping ability after LVAD implantation. However, while the overall QoL of many patients after LVAD implantations improves, psychological problems often still remain prominent and unexplained. It is not uncommon that psychological symptoms, such as depression, anxiety, and posttraumatic stress disorders, are under diagnosed and may be undertreated in patients with LVADs, which can affect their overall QoL, functional status and survival [15].

The impact of left ventricular assist devices on survival and mortality.
LVAD therapy is associated with great benefits in patients with heart failure

in comparison to medical therapy. This is reflected in a 1-year survival rate of 52% for patients with a pulsatile-flow device versus 25% receiving medical-treatment (p=0.002) and a 2-year survival rate of 23% versus 8%, respectively (p=0.09). A more recent study showed 1- and 2 year survival estimates of 68% (95%CI, 60-75) and 58% (95%CI, 49-67), respectively, with the continuous-flow devices and 55% (95%CI, 42-69) and 24% (95%CI, 1-46) with the pulsatile-flow device [16]. Within two weeks after LVAD implantation patients reported to be bothered by their physical dependence on others, insomnia, fatigue, shortness of breath, weakness and a lack of control over their life. Most deaths occurred within the first three months and were attributable to stroke, infection or multiorgan failure. During this period neurological complications are also frequently recorded, including strokes, transient ischemic attacks and delirium. As a result concerns have been raised about functional and neurobehavioral changes during LVAD support which can manifests themselves by cognitive deficits in attention and impairment in recent and delayed memory [24].

Importantly, after three months improvements could be detected in New York Heart Association (NYHA) functional class, patient activity scores and mobility. Significantly fewer complications and deaths were observed during late follow-up (6-12 months), with the continuous flow LVADs demonstrated at least equal efficacy with regard to hemodynamic support, ability to improve renal and hepatic function and overall patient survival over longer durations compared to pulsatile devices.

Emotional distress in patients implanted with a left ventricular assist device. Despite many LVAD patients reporting feelings of sadness, lack of control, anxiousness and fear after implantation, few studies have focused specifically on symptoms of anxiety, depression and the role of personality in relation to LVAD concerns, complications and outcomes. Patients with a more pessimistic attitude, unsure and worried about the LVAD implantation had more post-operative difficulties and more pain [4]. These findings are consistent with the results from other studies on heart failure patients which showed that personality traits such as negative affectivity and social inhibition (i.e., Type-D personality; the tendency to experience increased negative emotions and emotional non-expression) have a negative influence on patient health status, perceived disability, and even mortality. This further supports the need to assess the role of LVAD patients* psychological profile in determining emotional distress, QoL, and functional status. Knowledge of the role of psychological factors and their importance relative to clinical factors and disease severity may help optimize treatment in these patients.

The impact of LVAD implantation on the partner/caregiver of the patient. In addition to anxiety, depression and personality traits, other factors, such as social support, loneliness and marital quality may have notable effects on health outcomes in LVAD patients, and may have a more profound impact than clinical characteristics, including disease severity. Because the caregiver of

the LVAD patient is usually the patients* partner, the LVAD implantation can have a tremendous effect on the patient-partner dyad and general family relationships. The caregiver is expected to be available to the patient 24 hours a day and must undergo extensive training and education by an LVAD coordinator. For most partners the emotional stress increases when they are given the responsibility of taking care of the patient at home.

A paucity of studies have examined the QoL and psychological burden of partners and caregivers. One of these studies used semi structured interviews, the other reported that 65% had a high overall stress rate, with 82% experiencing moderate to extreme worry, 61% anxiety and 39% depression. Such distress was found to have a profound impact, preventing more than 20% of the partners and caregivers from returning to their normal daily life activities or previous employment. Most caregivers have mixed feelings consisting of guilt and, hope and start to realize the severity of the disease and the burden to the family life. They feel they have no time for themselves, no social life and have to change their lifestyles. With time caregivers learn to cope with the responsibility, they are able to adapt to *the new life* and become more optimistic. Hence, including partners in a study simultaneously with LVAD patients seems an essential novelty in this research area. Data from the partners need to be compared to that of LVAD patients to develop a more comprehensive picture of how LVAD implantation affects the family, and to understand how stress and coping patterns of LVAD patients and their partners affect each other.

Study objective

Primary:
To examine changes in health status (functional status and quality of life) and emotional distress (i.e. anxiety and depression) over time in patients following LVAD implantation, focusing on intra-individual changes, with a view to delineating a profile of high-risk patients with respect to the outcomes.

Secondary:
1. To compare the level of health status and emotional distress in LVAD patients and their partners and the determinants of health status and distress in both parties.
2. To examine the potentially moderating role of marital quality, loneliness and Type D personality on patient distress and health status.
3. To investigate the determinants (i.e. demographic, clinical and psychological) of morbidity and mortality in LVAD patients at 2-year follow-up.

Study design

The currents study is a prospective, observational, multi-center study, with a 2-year follow-up period. Psychological assessments will take place at 4 points in time: T0= baseline (i.e. 2-3 weeks after LVAD implantation during hospitalization), T1=3 months, T2=6 months, and T3=12 months.

The cardiologist will approach participants for study participation, and will inform them orally and in writing about the study. If the patient agrees to participate, the partner will also be approached, and they will both be asked to sign an informed consent form. In the consent form participants have the possibility to tick a box indicating that they want to be informed about the outcomes of the study upon study completion. Subsequently, participants are handed the first (baseline) booklet of questionnaires.

The first assessment time was chosen based on the following considerations; in approximately 50% of cases there will not be the possibility to obtain a proper pre-implantation assessment, due to the patient*s acute critical condition demanding immediate implantation of an LVAD. Moreover, it is an extremely emotional and stressful time for both the patient and the partner, and it might be considered not only unethical to add to this burden but also questionable whether such assessment would reflect their emotional state or rather pre-implantation distress. In turn, assessment at this time point would lead to missings (with respect to non-elective patients) but also potentially study participation refusal due to patients and partners already being emotionally strained. Shifting the baseline to 2-3 weeks after LVAD implantation will ensure that patients are medically stable, that the baseline assessment is homogeneous across the sample and also hopefully lead to less missing data, including higher response rate. Based on the article of Grady et al. patients were quite satisfied with their lives 1 to 2 weeks after LVAD implantation based on total QoL Index scores. Furthermore, mean symptom distress 2 weeks after surgery was low in most patients.
The follow-up assessments were based on time points when patients are scheduled for a visit to the outpatient clinic for a check-up, such as to minimize the burden to the patients. During these follow-ups blood tests, an echocardiography and exercise capacity-test will be performed in a standard manner. Blood samples (WBC count, platelet, Hb, HcT, creatinine, ureum, sodium, potassium liver enzymes, CRP and NT--proBNP) will be taken every 3-6 months as part of the standard care. In addition to the 12 month follow-up with psychological questionnaires, patients will be followed up long term (i.e. 2 years) for heart transplantation, mortality and morbidity.

Study burden and risks

There is no risk associated with the study. Hence, compensation is not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients: implantation with an axial-flow Heartmate II (Thoratec) left ventricular assist device, aged >=18 years, sufficiently proficient in the Dutch language to be able to complete the study questionnaires, and providing written informed consent.
Partners: study participation of the LVAD patient, aged >=18 years, sufficiently proficient in the Dutch language to be able to complete the study questionnaires, and providing written informed consent.

Exclusion criteria

Patients: implantation with an LVAD other than the axial-flow Heartmate II (Thoratec), <18 years of age, history of psychiatric illness other than cognitive-affective disorder, insufficient

knowledge of the Dutch language.
Partners: no study participation of LVAD patient, <18 years of age, history of psychiatric illness other than cognitive-affective disorder, life expectancy less than 1 year, insufficient knowledge of the Dutch language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2011
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32675.078.10