

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation

Implantation of a left ventricular assist device (LVAD) involves implanting a mechanical pump into the chest to support, or take over, the role of the weakened left chamber of the heart by pumping blood throughout the body. It is often used for people who are waiting for a heart transplant. 'Destination therapy' means using an LVAD as a permanent treatment for people who cannot have a heart transplant.

The National Institute for Health and Care Excellence (NICE) is examining the implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 December 2014

Target date for publication of guidance: March 2014

1 Provisional recommendations

- 1.1 Current evidence on the efficacy and safety of the implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation is adequate to support the use of this procedure provided that normal arrangements are in place for

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clinical governance, consent and audit. For patients who are eligible for heart transplantation, refer to NICE's interventional procedure guidance on [short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery](#).

- 1.2 Patient selection should be done by a multidisciplinary team that includes a cardiologist with a specialist interest in heart failure, a cardiothoracic surgeon and a cardiac anaesthetist (see section 1.3).
- 1.3 Implantation of left ventricular assist devices for destination therapy should be done by surgeons, anaesthetists and intensive care specialists with special training and regular practice in performing this procedure and caring for these patients. Subsequent care should be provided by a multidisciplinary team including staff with the expertise to deal with patients' medical and psychological management, and with the maintenance of their left ventricular assist devices.
- 1.4 Clinicians should enter details on all patients who have a left ventricular assist device for destination therapy onto the [UK Central Cardiac Audit Database](#).

2 Indications and current treatments

- 2.1 Heart failure is a complex clinical syndrome of symptoms that occur when the efficiency of the heart as a pump is impaired. It leads to reduced blood flow to the body tissues and increased filling pressure in the heart, which causes congestion and oedema in the lungs (causing breathlessness) or the body (causing swelling of the

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legs). Other symptoms include reduced exercise tolerance, fatigue and malaise.

- 2.2 Medical treatment of heart failure involves drugs such as diuretics and inotropic agents. Invasive therapies include electrophysiological interventions such as pacemakers and implantable cardioverter defibrillators, revascularisation by percutaneous coronary angioplasty and stenting or coronary artery bypass grafting, valve replacement or repair, and temporary use of intra-aortic balloon pumps. In chronic heart failure, conventional treatment strategies may no longer work, resulting in the need for heart transplantation. Ventricular assist devices can be used to provide temporary circulatory support while a patient awaits heart transplantation (bridge-to-transplantation).

3 The procedure

- 3.1 'Destination therapy' is a term that refers to the implantation of a left ventricular assist device (LVAD) with the aim of providing permanent circulatory support to patients with advanced heart failure who are ineligible for heart transplantation. This guidance is based on evidence from studies in which the intended treatment strategy was destination therapy, and not bridge-to-transplantation.
- 3.2 The LVAD is implanted with the patient under general anaesthesia and involves open heart surgery, usually with cardiopulmonary bypass. Initially, the pump component of the LVAD is placed in the pericardium. An inflow pipe is then inserted into the left side of the heart (usually the left ventricle) and an outflow pipe is inserted into the systemic arterial system (usually the aorta). Subsequently, a power cable, attached to the pump, is brought out of the abdominal

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wall to the outside of the body and attached to a control system and battery. Once the pump begins to work and support the heart, the cardiopulmonary bypass machine is removed and the chest incision is closed. The LVAD draws oxygenated blood from the failing left ventricle and pumps it into the systemic arterial system under pressure.

- 3.3 The first LVADs used pulsatile pumps that mimicked the natural pulsing action of the heart. Newer, more commonly used, devices use a rapidly spinning rotor to produce a continuous flow of blood into the systemic arterial system. Some patients may also need simultaneous implantation of a second device to support right ventricular function.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 In a randomised controlled trial of 129 patients treated by pulsatile-flow left ventricular assist device (LVAD) destination therapy (n=68) or optimal medical management (n=61), survival rates were 23% and 8% respectively at 2-year follow-up (p=0.09). At 4-year follow-up, survival rates were 16% in the pulsatile-flow LVAD group and 8% in the optimal medical management group (no p value reported).
- 4.2 In a registry of 1287 patients treated by continuous-flow (n=1160) or pulsatile-flow (n=127) LVADs, survival rates were 76% and 68%

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respectively at 1-year follow-up ($p < 0.0001$). At 2-year follow-up, survival rates were 67% in the continuous-flow group and 45% in the pulsatile-flow group ($p < 0.0001$).

- 4.3 In a randomised controlled trial of 200 patients treated by continuous-flow ($n=134$) or pulsatile-flow LVADs ($n=66$), 6-minute walking test distances improved from 182 m to 318 m ($p < 0.001$) and 172 m to 306 m ($p < 0.001$) respectively at 1-year-follow-up (p value between groups= 0.22).
- 4.4 In the randomised controlled trial of 200 patients treated by continuous-flow or pulsatile-flow LVADs, mean Minnesota Living with Heart Failure questionnaire scores (scores range from 0 to 105, with lower scores indicating better quality of life) improved from 75.4 to 34.1 ($p < 0.001$) and 76.1 to 44.4 ($p < 0.001$) respectively at 1-year follow-up (p value between groups= 0.03). In the same study, mean overall Kansas City Cardiomyopathy questionnaire scores (scores range from 0 to 100, with higher scores indicating better quality of life) improved from 27.4 to 65.9 ($p < 0.001$) in the continuous-flow group and from 46.5 to 59.1 ($p < 0.001$) in the pulsatile-flow group at 1-year follow-up (p value between groups= 0.06).
- 4.5 In the randomised controlled trial of 129 patients treated by pulsatile-flow LVAD destination therapy or optimal medical management, mean SF-36 emotional domain scores (scores range from 0 to 100, with higher scores indicating better emotional outcomes) changed from 33 to 64 and from 25 to 17 respectively at 1-year follow-up (p value between groups <0.05).

- 4.6 Specialist advisers listed key efficacy outcomes as: event-free survival; cardiac output; exercise capacity; quality of life; and the 'potential for heart recovery'.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Death caused by device failure was reported in less than 1% (6/1160) of patients treated by continuous-flow left ventricular assist devices (LVADs) and 2% (3/127) of patients treated by pulsatile-flow LVADs in a registry of 1287 patients at 2-year follow-up.
- 5.2 Death arising from loss of power to external components of LVADs was reported in 2% (9/414) of patients in a case series of 414 patients treated by continuous-flow LVADs, at a minimum follow-up of 2 years.
- 5.3 Ischaemic stroke was reported in 8% (11/133) of patients treated by continuous-flow LVADs and 7% (4/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in a randomised controlled trial of 200 patients ($p=0.38$). In the same study, haemorrhagic stroke was reported in 11% (15/133) of patients treated by continuous-flow LVADs and 8% (5/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up ($p=0.33$).
- 5.4 Right heart failure, managed by extended inotrope therapy, was reported in 20% (27/133) of patients treated by continuous-flow LVADs and 27% (16/59) of patients treated by pulsatile-flow LVADs

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at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$). In the same study, right heart failure, treated by right ventricular assist devices, was reported in 4% (5/133) of patients treated by continuous-flow LVADs and 5% (3/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up ($p = 0.12$).

- 5.5 Respiratory failure was reported in 38% (50/133) of patients treated by continuous-flow LVADs and 41% (24/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$).
- 5.6 Renal failure was reported in 16% (21/133) of patients treated by continuous-flow LVADs and 24% (14/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$).
- 5.7 Cardiac arrhythmia was reported in 56% (75/133) of patients treated by continuous-flow LVADs and 59% (35/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p = 0.006$).
- 5.8 LVAD-related infection was reported in 35% (47/133) of patients treated by continuous-flow LVADs and 36% (21/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p = 0.01$).
- 5.9 Pump replacement was needed for 9% (12/133) of patients treated by continuous-flow LVADs and 34% (20/59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$).

- 5.10 Pump thrombosis was reported in 4% (5/133) of patients treated by continuous-flow LVADs and 0% of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients (no p value reported).
- 5.11 Bleeding that needed blood transfusion was reported in 76% (315/414) of patients in the case series of 414 patients treated by continuous-flow LVADs. In the same study, bleeding that needed surgical re-exploration was reported in 23% (95/414) of patients (no further details were provided).
- 5.12 Specialist advisers did not highlight any adverse events additional to those reported in the literature. Specialist advisers stated that aortic regurgitation was a theoretical adverse event.

6 Committee comments

- 6.1 The Committee noted that heart failure is very common. It considered that use of this procedure needs very careful selection of patients who are likely to derive sustained benefit in terms of survival and quality of life.
- 6.2 The Committee recognised that this procedure is associated with a high incidence of complications, but it judged that the potential benefit for appropriately selected patients outweighed its potential for harm.
- 6.3 The Committee noted that technology for this procedure has evolved significantly in recent years and continues to do so.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#). For patients who are eligible for heart transplantation, see NICE's interventional procedure guidance on [short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery](#).

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November, 2014