

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

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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 clinical governance, consent and audit. For people who are eligible for heart transplantation, refer to NICE's interventional procedures 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 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians should enter details on all patients who have a left ventricular assist device for destination therapy.

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 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.

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 people 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 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 people 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 [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 1,287 patients treated by continuous-flow (n=1,160) or pulsatile-flow (n=127) LVADs, survival rates were 76% and 68% 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 [overview](#).

- 5.1 Death caused by device failure was reported in less than 1% (6 out of 1,160) of patients treated by continuous-flow left ventricular assist devices (LVADs) and 2% (3 out of 127) of patients treated by pulsatile-flow LVADs in a registry of 1,287 patients at 2-year follow-up. Death arising from loss of power to external components of LVADs was reported in 2% (9 out of 414) of patients in a case series of 414 patients treated by continuous-flow LVADs, at a minimum follow-up of 2 years.
- 5.2 Ischaemic stroke was reported in 8% (11 out of 133) of patients treated by continuous-flow LVADs and 7% (4 out of 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 out of 133) of patients treated by continuous-flow LVADs and 8% (5 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up ($p = 0.33$).
- 5.3 Right heart failure, managed by extended inotrope therapy, was reported in

20% (27 out of 133) of patients treated by continuous-flow LVADs and 27% (16 out of 59) of patients treated by pulsatile-flow LVADs 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 out of 133) of patients treated by continuous-flow LVADs and 5% (3 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up ($p = 0.12$).

- 5.4 Respiratory failure was reported in 38% (50 out of 133) of patients treated by continuous-flow LVADs and 41% (24 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$).
- 5.5 Renal failure was reported in 16% (21 out of 133) of patients treated by continuous-flow LVADs and 24% (14 out of 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 Cardiac arrhythmia was reported in 56% (75 out of 133) of patients treated by continuous-flow LVADs and 59% (35 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p = 0.006$).
- 5.7 LVAD-related infection was reported in 35% (47 out of 133) of patients treated by continuous-flow LVADs and 36% (21 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p = 0.01$).
- 5.8 Pump replacement was needed for 9% (12 out of 133) of patients treated by continuous-flow LVADs and 34% (20 out of 59) of patients treated by pulsatile-flow LVADs at 2-year follow-up in the randomised controlled trial of 200 patients ($p < 0.001$).
- 5.9 Pump thrombosis was reported in 4% (5 out of 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).

- 5.10 Bleeding that needed blood transfusion was reported in 76% (315 out of 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 out of 414) of patients (no further details were provided).
- 5.11 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events. They considered 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 the use of left ventricular assist devices for destination therapy in people ineligible for heart transplantation 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 patients who are eligible for heart transplantation, see [NICE's interventional procedures guidance on short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).