

# Short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg177](http://www.nice.org.uk/guidance/ipg177)

## 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. However, 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.

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.

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 Guidance

- 1.1 Limited evidence on the safety and efficacy of short-term circulatory support with left ventricular assist devices (LVADs) as a bridge to cardiac transplantation or recovery appears adequate to support the use of this procedure provided that the normal arrangements are in place for audit and clinical governance.
- 1.2 Clinicians should ensure that patients fully understand the high complication rates associated with this procedure and that the procedure is a temporary measure. In addition, use of the Institute's [information for the public](#) is recommended.
- 1.3 Publication of further research will be useful, particularly on the use of this procedure in patients with cardiogenic shock following acute myocardial infarction.

## 2 The procedure

### 2.1 Indications

- 2.1.1 The management of patients with end-stage heart failure or acute heart failure from naturally reversible causes is challenging; it may involve combination medical therapy (including inotropic support), intra-aortic balloon pumping and heart transplantation.
- 2.1.2 Short-term circulatory support with an LVAD may be indicated for patients with end-stage heart failure (of any aetiology) who are awaiting a donor heart for transplantation, and for patients with a severe acute heart failure syndrome from which myocardial recovery is anticipated (such as acute myocarditis). An LVAD is sometimes used if weaning from cardiopulmonary bypass after cardiac surgery fails.

### 2.2 Outline of the procedure

- 2.2.1 A number of LVADs that increase cardiac output by providing mechanical support to the failing left ventricle are available. The choice of device depends on the patient's body size, the length of time support is required, the degree of

support needed and the type of blood flow desired.

2.2.2 Implantation of an LVAD is done under general anaesthesia through a chest incision; surgery usually takes several hours. The inflow pipe of the LVAD is inserted into the left side of the heart, usually the left ventricle, and the outflow pipe is inserted into the systemic arterial system, usually the aorta. The LVAD pumps oxygenated blood from the failing left ventricle into the systemic arterial system under pressure.

## 2.3 Efficacy

2.3.1 In the active arm of a non-randomised controlled study, 78% (32/41) of patients survived for a mean of 215 days with LVAD support. In another comparative study, 81% (13/16) of patients survived to transplant (duration of support not stated). One case series showed that at 30 days of bridging to transplantation with an LVAD, survival was 83%, falling to 19% after 24 months' support.

2.3.2 In a non-randomised controlled trial, post-transplant survival of patients bridged on LVAD support was 66% (21/32) at 41 months, compared with 67% (98/146) of patients at 36 months who had a transplant without circulatory support, although patients in the latter group were significantly older. One case series of 243 patients in whom LVADs were used to bridge to transplantation reported actuarial post-transplant survival of 91% at 1 year, 70% at 5 years and 40% at 10 years. Results from case series included in a systematic review showed that between 60% (12/20) and 83% (5/6) of patients survived to transplantation or were still alive awaiting transplantation on LVAD support.

2.3.3 Of the total cases of bridge to recovery reported, 58% (7/12) of patients survived to final follow-up; successful explantation of the device or weaning from support was achieved in all these patients. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers commented that LVADs may improve quality of life and survival rates in patients with an otherwise fatal condition while waiting for transplantation.

## 2.4 Safety

- 2.4.1 Definition of infection varied among the studies identified. In a case series documented in a systematic review, rates of infection during LVAD support ranging from 0% (0/10) to 100% (5/5) were reported. A non-randomised controlled trial noted infection in 8% (1/13) of patients during LVAD bridging, and one case series reported an infection rate of 18% (43/243).
- 2.4.2 Definitions of cerebral events varied between studies, which made interpretation difficult. Cerebral infarction causing stroke was found to have occurred in 21% (55/264) of patients in one series. In a second case series, cerebrovascular accident occurred in 5% (13/243) of patients, and stroke occurred in 5% (13/243) of patients during support time (mean 78 days). In a third series, a neurological event (not defined) occurred in 8% (1/13) of patients.
- 2.4.3 In a systematic review, significant haemorrhage was reported in between 10% (1/10) and 30% (6/20) of patients. Re-operation because of bleeding was required in 31% (4/13) of patients in one series.
- 2.4.4 Other complications reported during LVAD support were renal failure, respiratory failure and haemolysis. For more details, refer to the 'Sources of evidence' section.
- 2.4.5 The Specialist Advisers noted that adverse events relating to the procedure include bleeding, infection, device malfunction, haemolysis, peripheral ischaemia and perforation of a ventricle or the aorta. In addition, they noted that theoretical complications include device-related thrombosis and device-related strokes.

## 2.5 Other comments

- 2.5.1 This guidance refers to patients for whom other treatments such as intra-aortic balloon pumping would be ineffective, who are considered eligible for heart transplantation, or who have acute severe heart failure that is likely to be reversible (such as acute myocarditis). It was noted that other patients might potentially benefit from this procedure, such as patients who cannot be weaned off cardiopulmonary bypass after cardiac surgery and patients with cardiogenic shock after acute myocardial infarction.

- 2.5.2 It was noted that a number of different devices are available for this procedure and that the technology is evolving rapidly. Some devices include a right-ventricular assist device (biventricular assist devices). The Institute may review this guidance upon publication of further evidence.
- 2.5.3 It was also noted that implantation of an LVAD could unmask previously subclinical right ventricular dysfunction.
- 2.5.4 These recommendations exclude circulatory support with left ventricular devices as destination therapy.

### 3 Further information

- 3.1 NICE has issued a clinical guideline '[Chronic heart failure: management of chronic heart failure in adults in primary and secondary care](#)'.
- 3.2 The NHS R&D Health Technology Assessment Programme is producing a report on 'Evaluation of the ventricular assist device programme in the UK (EVAD)', due to be published in October 2006.

Andrew Dillon  
Chief Executive  
June 2006

### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedure overview of left ventricular assist devices as a bridge to transplantation or to recovery'](#), December 2005.

### Information for patients

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

## 4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It has been incorporated into the [NICE pathway on chronic heart failure](#), along with other related guidance and products.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

### Changes since publication

19 January 2012: minor maintenance.

### Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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## Endorsing organisation

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