

Understanding NICE guidance

Information for people who use NHS services

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

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how an **LVAD** (which stands for left ventricular assist device) can be used to provide short-term circulatory support for someone who is waiting for a heart transplant or who is recovering from a cardiac condition in the NHS in England, Wales and Scotland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe short-term circulatory support with an LVAD or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the last page.

What has NICE said?

This procedure can be offered to people who need short-term circulatory support until they receive a heart transplant or their heart recovers provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

Doctors should make sure that patients understand the high complication rate and that this procedure is temporary.

Other comments from NICE

- This procedure is only for patients in whom other treatments do not work, who are suitable for a heart transplant, or who have severe short-term heart failure that is likely to recover.

This procedure may not be the only possible option for short-term circulatory support. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Short-term circulatory support with an LVAD

The procedure is not described in detail here – please talk to your specialist for a full description.

Heart failure may be managed by a combination of medical therapy, intra-aortic balloon pumping and heart transplantation.

A temporary solution for patients who are waiting for a heart transplant is to insert an LVAD into the chest near the heart. The LVAD is a mechanical device that helps the heart to pump blood around the body. LVADs can be used to support the heart while it is recovering from a severe short-term heart failure syndrome (such as myocarditis). LVADs are sometimes also used while waiting for the heart to recover after cardiac surgery. This short-term mechanical support is sometimes described as bridging.

Several different LVADS are available and your surgeon will choose the one that is most suitable for you. The surgery to implant the device into the heart takes several hours and is done under general anaesthetic. The surgeon will cut through the chest wall. The LVAD has two pipes. One (the inflow) is inserted into the left side of the heart and the other (the outflow) is inserted into an artery, usually the aorta (the main artery from the heart to the body). The LVAD pumps oxygenated blood from the heart into the arteries.

Summary of possible risks and benefits

Some of the benefits and risks seen in the studies considered by NICE are **briefly** described below. NICE looked at six studies on this procedure.

How well does the procedure work?

Studies have shown that LVADs can enable patients to survive until they can have a heart transplant.

One study showed that 32 out of 41 patients (78%) survived for an average of 215 days with LVAD support. Another study showed that 13 out of 16 patients (81%) survived until they had a heart transplant, although the study did not say how long this was for. Another study reported that 83% of patients survived for at least 30 days with an LVAD; 19% of patients survived for 24 months.

Use of an LVAD did not affect whether patients survived a heart transplant afterwards. In one study, a similar percentage of patients survived a heart transplant whether or not they had had an LVAD beforehand. In a study of 243 patients in whom LVADs were used to provide support while awaiting transplantation, 91% of patients survived for a year, 70% survived for 5 years and 40% survived for 10 years.

A systematic review showed that 60–83% of patients survived on LVAD support while awaiting a transplant.

Expert advisers commented that use of an LVAD may improve quality of life and chance of survival for patients waiting for a transplant.

Risks and possible problems

The two greatest risks associated with this procedure were haemorrhage (excessive bleeding) and cerebral events, which refer to effects on the brain and the blood flow of the brain; stroke is a common example of a cerebral event.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks this procedure is suitable for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Stroke caused by a cerebral infarct (interruption of blood flow to the brain because of a blood clot) occurred in 55 out of 264 patients (21%) in one study. In a case series, stroke occurred in 13 out of 243 patients (5%) and stroke-like problems occurred in 13 out of 243 patients (5%) while they had an LVAD in place providing circulatory support (which was for an average of 78 days). In another study, a neurological event occurred in 1 of 13 patients.

Significant haemorrhage occurred in between 10% and 30% of patients. In one series, 4 out of 13 patients needed repeat surgery because of haemorrhage.

Other complications that can occur during support with an LVAD include kidney failure, respiratory failure, haemolysis (destruction of red blood cells, leading to anaemia) and infection.

The expert advisers commented that failure of the device, peripheral ischaemia and damage to the heart or aorta were also possible.

More information about heart failure

The organisation below can provide more information and support for people who are waiting for a heart transplant or who are recovering from heart failure. Please note that NICE is not responsible for the quality or accuracy of any information or advice provided by this organisation.

- British Heart Foundation, Heart Information Line 08450 70 80 70, www.bhf.org.uk

NHS Direct online (www.nhsdirect.nhs.uk) may also be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG177

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1059).