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www.nice.org.uk

What has NICE said?

Implanting a left ventricular assist device in people with <u>chronic heart failure</u>, who need a heart transplant but for whom a transplant is not possible, is safe enough and works well enough for use in the NHS.

NICE is asking health professionals to send information about everyone who has the procedure and what happens to them afterwards to the UK Central Cardiac Audit
Database, so that the safety of the procedure and how well it works can be checked over time.

People for whom a heart transplant is an option should see NICE's guidance on <u>short-term</u> <u>circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery.</u>

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure and discuss the possible benefits and risks with you. You should also be told how to find more information about the procedure. All of this should happen before you decide whether you want this procedure or not. Your health professional should ask you if details of your procedure can be collected.

Other comments from NICE

NICE said that only people who are likely to get continued benefit in terms of improved survival and quality of life should be offered this procedure. It also said that, although complications are common with the procedure, the potential benefits outweigh the potential for harm in the right people.

Your healthcare team

A healthcare team experienced in implanting left ventricular assist devices should decide who should be offered this procedure. This team should include a cardiologist with a specialist interest in heart failure, a cardiothoracic surgeon and a cardiac anaesthetist. The procedure should only be done by surgeons, anaesthetists and intensive care specialists with special training and regular practice in it. Care after the procedure should be provided by a healthcare team with the expertise to deal with people's medical and psychological needs, as well as maintenance of their device.

The condition

Heart failure means your heart doesn't pump enough blood to meet all the needs of your body. Usually this is because the heart muscle has become damaged. The term 'chronic heart failure' is used to describe heart failure as a long-term condition. The main symptoms of heart failure are breathlessness (either with exercise or at rest), feeling very tired and ankle swelling.

If you have chronic heart failure, your heart will need some help to do its job. Treatments include: drug treatment; treatment to bring the pumping action of the heart chambers back in time with each other (usually with a pacemaker or sometimes with a defibrillator);

surgery, for example, to repair a faulty valve; or a heart transplant.

NICE has looked at using a <u>left ventricular assist device</u> as another treatment option for people with advanced chronic heart failure for whom a heart transplant is not suitable.

NHS Choices (<u>www.nhs.uk</u>) and NICE's information for the public about <u>chronic heart</u> failure.

The procedure

Implanting a left ventricular assist device (LVAD) involves putting a mechanical pump into the chest near the heart to help, or take over, the pumping of blood throughout the body. It is often used for people who are waiting for a heart transplant. But, in this procedure, an LVAD is being used as a permanent treatment for people for whom a heart transplant is not possible. This is called 'destination therapy'. The open heart surgery to implant an LVAD into the heart takes several hours. It is done under general anaesthetic and the surgeon cuts through the chest wall. An LVAD has 2 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 device is then attached by a power cable to a control system and battery worn on the outside of the body. Once it starts working, the LVAD pumps oxygenated blood from the heart into the arteries.

Some people may also need a second LVAD implanted at the same time to support the right side of the heart.

Benefits and risks

When NICE looked at the evidence, it decided that it showed implantation of a left ventricular assist device (LVAD) to be safe enough and work well enough for some people with chronic heart failure for whom a heart transplant isn't possible. The 7 studies that NICE looked at involved a total of 2795 patients.

Generally, they showed the following benefits:

• improved survival: 68% to 74% of patients alive after 1 year, 23% to 67% alive after 2 years, compared against 8% of patients on medical treatment after 1–2 years

- ability to walk almost twice as far in 6 minutes
- improved quality of life 1 year after the procedure
- better emotional outcomes at 1 year compared against medical treatment.

The studies showed that the risks of an LVAD (at 2 years) included:

- death due to failure of the device in up to 2% of patients
- death due to loss of power to external parts of the device in 2% of patients
- ischaemic stroke in 7% to 8% of patients and haemorrhagic stroke in 8% to 11% of patients
- right heart failure managed by drugs in 20% to 27% of patients and managed by a right ventricular assist device in 4% to 5% of patients
- respiratory failure in 38% to 41% of patients
- renal failure in 16% to 24% of patients
- abnormal heart beat in 56% to 59% of patients
- LVAD-related infection in 35% to 36% of patients
- pump needing replacement in 9% to 34% of patients
- a blood clot in the pump in up to 4% of patients
- bleeding that needed blood transfusion in 76% of patients and that needed more surgery in 23% of patients.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Medical terms explained

Haemorrhagic stroke

A stroke caused when a blood vessel in the brain burst, and there is bleeding into the brain.

Ischaemic stroke

A stroke caused by a blood clot blocking an artery in the brain.

Stroke

When the normal blood flow to part of your brain is cut off, so cells in the affected area are starved of oxygen and become damaged or die.

About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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Accreditation

