NHS
National Institute for
Health and Clinical Excellence

Issue date: May 2006

Living-donor lung transplantation for end-stage lung disease

Understanding NICE guidance – information for people considering the procedure, and for the public

Information about NICE Interventional Procedure Guidance 170

Ordering information

You can download the following documents from www.nice.org.uk/IPG170

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N1031 (full guidance)
- N1032 (information for the public).

**National Institute for
Health and Clinical Excellence**
MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

ISBN 978-1-4731-9135-8

Contents

About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called living-donor lung transplantation. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether living-donor lung transplantation is safe enough and works well enough for it to be used routinely for the treatment of end-stage lung disease.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of living-donor lung transplantation and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Lung transplants are done in people who have lung disease that is not cancer but does not improve when it is treated (or improves very little). They are done in people who are not expected to live more than a year without a transplant. The causes of the lung disease include: cystic fibrosis (an inherited disease that causes the lungs to become blocked with thick mucus); severe pulmonary fibrosis (thickening and stiffening of the lining of the lungs); pulmonary hypertension (high blood pressure in the blood vessels that supply the lungs) and obliterative bronchiolitis (swollen and blocked small airways in the lungs).

Most people who receive lung transplants from living donors have cystic fibrosis. Most of the lung donors are parents, sisters, brothers or children (first-degree relatives) of the recipients. The donors and the recipient need to be compatible in size and have matching ABO blood groups.

Having a lung transplant from living donors instead of from someone who has just died (a cadaveric donor) may be a possibility. Transplants from living donors may be an option for patients who cannot get one from someone who has died. It may also be a possibility for patients who are getting worse so quickly that they are likely to become too ill to have a transplant while they are waiting for a cadaveric donor.

A transplant from a living donor may also be an option for critically ill children because, for them, there is a particular shortage of suitable donors who have died.

A transplant from living donors usually involves three operations, one on each of two donors and one on the recipient. The lower lobe of the right lung is removed from one donor and the lower lobe of the left lung is removed from the other donor. Both lungs are then removed from the recipient and are replaced by the lung implants from the donors in a single operation.

For the operation on the recipient the doctor makes an opening in the chest. While the main procedure is being done the recipient’s circulation is connected to a heart–lung machine (cardiopulmonary bypass). This machine does the work of both the heart and the lungs, pumping the blood around the body and supplying it with oxygen. The doctor removes the diseased lungs and then implants the donated lobes one after the other.

How well the procedure works

What the studies said

One study followed what happened to 123 adults and children after they had lung transplants from living donors. After 1 year 70% (70 out of 100) of the patients were still alive, after 3 years 54% were alive and after 5 years 45% were alive. The most common reason why patients died was infection, which caused about half of the deaths. The second most common reason was obliterative bronchiolitis (see above), which caused 13% of deaths.

Another study compared what happened to 59 patients who had transplants from living donors with what happened to 43 patients who had cadaveric transplants. The study only included patients who had survived for more than 3 months after their transplant. After 1 year, 83% of patients were still alive in both groups. After 3 years, 64% in the living-donor group and 81% in the cadaveric donor group were still alive. After 5 years, 62% of the living-donor group and 75% of the cadaveric donor group were still alive. A proper comparison, however, is difficult because of differences between the two groups of patients. For example, patients who have lung transplants from living donors are often more seriously ill before the transplant compared with patients who have cadaveric transplants. However, when statistical tests were used the differences between the groups were not statistically significant. This means that the differences could have been due to chance rather than to the type of donor.

In studies that measured how well the recipients' lungs worked, they worked better after lung transplants from living donors than before the operation.

What the experts said

Some experts said that they were uncertain about how well patients would do in the long term after transplants from living donors. They were also unsure about whether patients who had transplants from living donors might be more likely to get obliterative bronchiolitis compared with patients who had transplants from cadaveric donors.

Risks and possible problems with the procedure

What the studies said about recipients

There was a limited amount of information about the problems for recipients after lung transplants from living donors.

The body's natural defence (immune) system may perceive the transplanted lungs as 'foreign' and attempt to destroy them (acute rejection). To suppress this response recipients are given drugs (immunosuppressants). However, in many patients acute rejection episodes still occur. In the studies that included both adults and children, each patient had an average of just under 1 to 1.5 episodes of acute rejection.

In a study of 30 patients the problems after lung transplants from living donors included build-up of fluid in the lungs (pulmonary oedema) in 20% of patients (6 out of 30), serious bleeding that needed an operation in 7% (2 out of 30) and cardiac tamponade (compression of the heart caused by the build-up of fluid in the space between the heart muscle and the outer covering sac of the heart) in 7% (2 out of 30). Tracheostomy is an operation to make an opening into the windpipe, through the neck, to relieve obstruction to breathing. A tube is inserted into the windpipe through the opening. Half of the patients needed tracheostomy and 23% (7 out of 30) of them needed to have a tube reinserted into their windpipe.

What the studies said about donors

There were no reports of donors dying after their operations. In one study 20% of donors (50 out of 253) had at least one problem as a result of their operation. The most common problem was the need to have a tube inserted through an opening in the chest wall to drain fluid away (thoracostomy tube), which occurred in 30% of donors (15 out of 50). The most serious problem was a blood clot in the artery supplying the lungs, which happened in 1% of donors. Another operation was needed because of various problems in 3% of donors. In a study that followed what happened to 253 donors, the lungs of donors who could be contacted after 1 and 2 years did not work as well as they did before the operation.

What the experts said

The experts considered that the main problems for recipients were rejection of the transplant and over-expansion of the transplant. This over-expansion leads to serious damage to the lung, which eventually stops working.

The experts said that the potential problems for donors were prolonged air leaks through holes in the lung tissue into the spaces outside the airways, bleeding, pleural sepsis (bacterial infection of the membrane covering of the lungs and the inside of the chest wall) and a blood clot in the vessels supplying the lungs.

The experts also said that the lungs of donors were likely to work less well after their operation than before it.

What has NICE decided?

NICE has considered the evidence on living-donor lung transplantation. It has recommended that when doctors use this procedure for people with end-stage lung disease, they should be sure that:

- the procedure is only used in the patients who are most likely to benefit from the procedure and who would otherwise die
- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has said that there is not much information about what happens to donors after the operation but there is a real risk that they could have health problems. Because of this doctors who want to carry out living-donor lung transplantation should make sure that the donor:

- understands what is involved and agrees (consents) to the operation
- has thorough physical and psychological checks before having the operation
- has counselling about the possible health problems of being a donor and the possible health outcomes for the recipient, and
- is given clear written information (including this booklet).

NICE recommends that living-donor lung transplantation should only be done in specialist centres where there is an appropriate team of specialist doctors. Operations to remove lung from donors should be done by specialist chest surgeons.

There should also be special arrangements for monitoring what happens when a person has living-donor lung transplantation or is a donor. NICE is asking doctors to send information about every recipient and every donor and what happens to them afterwards to a central store of information, the UK National Audit of Intrathoracic Transplantation, so that the safety of the procedure and how well it works can be checked over time.

What the decision means for you

Your doctor may have offered you living-donor lung transplantation or discussed the possibility that you could be a donor. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS for selected patients who would otherwise die. Nonetheless, you should understand the benefits and risks of living-donor lung transplantation before you agree to the procedure, or agree to be a donor. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has also decided that more information is needed about living-donor lung transplantation. So NICE has recommended that some details should be collected about every recipient who has this procedure and about every donor in England and Wales. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have living-donor lung transplantation or to be a donor, you will be asked to agree to your details being entered into an electronic database for this purpose. A clinician looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be allowed to have the procedure or to be a donor.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on living-donor lung transplantation for end-stage lung disease that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on lung diseases on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

National Institute for
Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

N1032 1P May 06

ISBN 978-1-4731-9135-8