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Information for the public

National Institute for Health and Clinical Excellence

Treating persistent air leaks in the lungs by inserting valves into the airways

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how inserting valves into the airways can be used in the NHS to treat people with persistent air leaks in the lungs. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This document 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 air leaks in the lungs or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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 page 7.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to insert valves into the airways for persistent air leaks in the lungs, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

Inserting valves into the airways for persistent air leaks in the lungs is usually considered when other treatment options have not worked or are not possible. A team of healthcare professionals who are experienced in the management of chest conditions should decide which patients should have this procedure. The team should include a doctor who specialises in treating chest conditions and a surgeon who specialises in operations on the chest.

NICE has encouraged further research into the insertion of valves into the airways and may review the procedure if more evidence becomes available.

Treating persistent air leaks in the lungs by inserting valves into the airways

This procedure may not be the only possible treatment for air leaks. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'insertion of endobronchial valves for persistent air leaks'.

Endobronchial is a medical term that means 'inside the lung's air passages'.

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

Air can leak from the lungs after chest surgery or because of a chest injury or lung disease. If air leaks from the lung into the area between the lung and the ribcage, the lung can collapse and this can cause difficulty breathing. Air leaks are usually treated with a temporary chest drain (a tube inserted through the skin and rib cage) that removes the air from between the lung and the ribcage. The air leak will then often seal and close. Sometimes the air leak does not seal and further treatment is needed, such as surgery or pleurodesis (a procedure to close the space between the tissues covering the lung).

Inserting valves into the airways for persistent air leaks aims to reduce or stop air leaks so the rest of the lung can function normally. It also aims to help the lung tissue around the leaks to heal naturally and therefore stop leaking. The patient is given a general anaesthetic or sedation. A thin hollow flexible tube with a camera on the end (bronchoscope) is inserted via the patient's nose or mouth into the lungs. The air leak is identified and then small one-way valves are passed through the bronchoscope and placed into the airway. Several valves can be inserted. The valves may be removed when the leak on the lung surface has sealed.

What does this mean for me?

If your doctor has offered to insert valves into your airways for persistent air leaks in your lungs, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this document, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

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

Summary of possible benefits and risks

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 8 studies on this procedure.

How well does the procedure work?

A study of 40 patients who had the procedure reported that it completely stopped the air leak in 19 patients, and partially stopped it in 18 patients. There was no change in 2 patients.

In a study of 7 patients, 5 people were able to have chest drains removed about 16 days after the procedure (sometimes drains are left in place after the valve has been inserted to allow time for the tissue to heal). In 1 patient, the air leak returned after the valve was removed 15 days later.

A study of 4 patients found that the insertion of valves helped reduce lung collapse in 3 of the patients.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that main success factors were how long the air leak lasts, if air leaks are reduced or stopped, if patients can leave hospital sooner, if patients spend less time in intensive care or a high-dependency unit, a reduction in the need for ventilation (medical help with breathing), and if there is an improvement in quality of life.

Risks and possible problems

In 1 patient, the valve had moved out of place after 2 months and it was removed 5 months after the procedure. A study of 40 patients reported that the valves were incorrectly positioned in some patients and had to be moved. This study also reported that a valve was coughed up.

Other problems included chest infection, and in 1 patient a section of their lung partly collapsed.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems include the air leak returning or air beginning to leak between the lung and the rib cage again, coughing up blood, the lungs not working well, infection or pneumonia (inflammation of the tissue in the lungs), and tissue forming around the valves (in an attempt to heal the site where the valve is). They also said that in theory, the procedure could cause death.

More information about air leaks in the lungs

NHS Choices (www.nhs.uk) may be a good place to find out more.

For details of all NICE guidance on air leaks and conditions that cause these, visit our website at www.nice.org.uk

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. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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 document is about 'Insertion of endobronchial valves for persistent air leaks'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG448

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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