Treating a narrowed windpipe by inserting an inflatable balloon using an endoscope

This document is about when and how inserting an inflatable balloon using an endoscope can be used in the NHS to treat people with a narrowed windpipe not caused by cancer. 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 (or in the case of children, their parents or carers) to decide whether to agree (consent) to it or not. It does not describe a narrowed windpipe or the procedure in detail – a member of your healthcare team should also 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 treat a narrowed windpipe by inserting an inflatable balloon using an endoscope, 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 (or their parent or carer) agrees (or doesn’t agree) to the procedure. The patient (or their parent or carer) 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.

NICE has encouraged further research into treating a narrowed windpipe by inserting an inflatable balloon using an endoscope. NICE may review the procedure if more evidence becomes available.

NICE is asking doctors to send information about children who have the procedure and what happens to them afterwards to the Ashway Intervention Registry (accessible from any computer connected to the N3 [NHS] network) and, about adults, to the ENT UK national audit database so that the safety of the procedure and/or how well it works can be checked over time.

Other comments from NICE

NICE noted that the published evidence was related to a variety of different techniques, some of which are no longer used. There was very little evidence on balloon devices in use at the time this guidance was produced.
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The medical name for this procedure is ‘Endoscopic balloon dilatation for subglottic or tracheal stenosis’.

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

Subglottic or tracheal stenosis is a narrowing of the windpipe between the throat and the lungs, and can cause wheezing, hoarseness and shortness of breath. It most commonly occurs after a person has needed to use a ventilator (breathing machine) and has had a tube down their windpipe for some time. There are a number of other possible causes, including being born with a narrowed windpipe.

Treatments for subglottic or tracheal stenosis include steroids to reduce swelling. Surgery or endoscopic procedures (procedures using a small telescope) may be needed for severe narrowing.

The procedure is usually carried out with the patient under a general anaesthetic. A small balloon is introduced into the narrowed windpipe through an endoscope, which is inserted down the throat. The balloon is then gently inflated to widen the narrowed windpipe, deflated and removed. The procedure can be repeated if necessary.

The procedure can also be used with other treatments. These include drug treatment with steroids, surgery or endoscopic procedures such as laser treatment to remove some tissue from the windpipe, or inserting an expandable mesh tube (called a stent) to widen the windpipe.
What does this mean for me?
If your doctor has offered you, or your child, treatment for a narrowed windpipe by inserting an inflatable balloon using an endoscope, 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 (or your child’s) procedure can be used to help collect more information about treating a narrowed windpipe by inserting an inflatable balloon using an endoscope. 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

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?**

In a study of 10 babies with subglottic stenosis, 7 had improved symptoms after the first or second balloon inflation.

In another study of 10 children with subglottic or tracheal stenosis, 7 either improved or were free of symptoms after an average of 10 months.

A study including 11 patients with tracheal stenosis caused by prolonged use of a ventilator reported that all patients were initially free of symptoms after the procedure. Within 30 days of the procedure, 4 out of 11 patients needed a stent inserting into the narrowed windpipe.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are to avoid the need for more invasive surgery, improve breathing and ability to exercise, reduce wheezing and difficulty speaking, and improve the shape of the airway.

**Risks and possible problems**

In the two studies of 10 babies and 10 children there were no problems reported.

In a study of 37 patients, 1 patient developed a leak from the airway after their fourth balloon inflation. The leak was thought to be related to the procedure and was repaired, but the patient died of breathing difficulties.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.
One study reported that a patient with tracheal stenosis recovered after surgery to repair their windpipe after their second balloon inflation.

A study of 97 patients reported that in 64 out of 124 (52%) procedures there were cuts to the windpipe and airways. All patients recovered from these cuts on their own.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that complications included problems with breathing, damage to the vocal cords, bleeding, and tears in the windpipe and airways. They also said that in theory other problems are the windpipe or airways bursting, damage to the throat, air in the chest cavity causing the lung to collapse, weakness of the windpipe and airways, and problems breathing because of inhaled balloon fragments.
More information about a narrowed windpipe

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information 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. 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 ‘endoscopic balloon dilatation for subglottic or tracheal stenosis’. This document and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG425

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website 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.