

Improving blood flow to the brain by widening a narrowed artery inside the head using an expandable tube

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

This document is about when and how expandable tubes (called stents) can be used in the NHS to treat people with a narrowed artery inside the head. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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.

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 narrowed arteries inside the head 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.

In an emergency, healthcare professionals may give treatment immediately, without obtaining your informed consent, when it is in your best interests.

What has NICE said?

The evidence that NICE looked at showed that the results of the procedure are not much better than with drug treatment after 1 to 2 years, and that people who have the procedure are at increased risk of stroke and death just before, during or soon after the operation. For these reasons, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial). The research should look at which people could benefit most from this procedure, and should provide results based on at least 2 years of follow-up.

Other comments from NICE

NICE noted that studies have used different devices for the procedure and different drugs to improve blood flow to the brain. This makes comparing the procedure with drug treatment more complicated. NICE also noted that devices used in the procedure and drug treatments continue to be developed.

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

Widening a narrowed artery inside the head using an expandable tube

The medical name for this procedure is 'Endovascular stent insertion for intracranial atherosclerotic disease'.

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

Arteries inside the head supply blood and oxygen to the brain. A stroke or transient ischaemic attack (sometimes called a 'mini-stroke' or TIA) happens when one of these arteries becomes narrowed or blocked.

Arteries can become narrowed by fatty deposits of substances such as cholesterol in the artery walls, which reduces blood flow. The deposits harden and can sometimes burst, causing a blood clot to form, which can block the artery. The medical name for this is atherosclerotic disease. It is usually only diagnosed when a person has already had a stroke.

Usually, drugs are used to prevent blood clots from forming in the arteries and to reduce levels of cholesterol. Drug and lifestyle changes (for example, quitting smoking, having a healthy diet) are usually recommended to lower blood pressure and control diabetes if necessary.

The aim of this procedure is to widen narrowed arteries inside the head to improve blood flow to the brain. This procedure is done with the patient under a general or local anaesthetic. A small inflatable balloon attached to the end of a thin tube (catheter) is inserted into an artery in the arm or leg. It is then guided to the affected artery in the head using an X-ray imaging technique that detects a form of injectable dye called a 'contrast'. Once the balloon is in position, it is inflated to widen the artery and improve blood flow to the brain. This is called balloon angioplasty. A small tube made of metal mesh, called a stent, is then

passed through the catheter and expanded at the site of the narrowing to maintain the improved blood flow. Sometimes the stent contains a drug, which is slowly released to stop the artery narrowing again.

More than one affected artery can be treated in a single procedure, and more than one stent can be inserted.

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study. NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used in this way. 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?

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

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 5 studies on this procedure and a review of 69 studies. Stroke or death that occurred within 30 days of the procedure was considered to be related to the procedure. Reports of stroke or death that occurred after 30 days were used to judge how well the procedure works.

How well does the procedure work?

Three studies (involving 451, 213 and 158 patients) reported strokes occurring more than 30 days after the procedure. In the study of 451 patients, stroke in the area of the brain supplied with blood from the treated artery was reported in 13 out of 224 patients who had the procedure at an average follow-up of 1 year. The same number of strokes was reported in 227 patients who had drug treatment only. Seven patients from each group died within a year of the procedure. In a second study, stroke related to the treated artery was reported in 7 out of 213 patients at follow-up, an average of 27 months after the procedure. In a third study of 158 patients, 22 out of 110 patients had a stroke or transient ischaemic attack between 30 days and 12 months after the procedure.

Three studies (involving 213, 189 and 113 patients) reported that the treated artery had narrowed again. This was found in 19 out of 99 patients at an average of 9 months after the procedure in the study of 213 patients, in 43 out of 174 patients at an average of 4 months after the procedure in the study of 189 patients and in 16 out of 89 patients at an average of 29 months after the procedure in the study of 113 patients.

A review of studies comparing the procedure with balloon angioplasty alone (without the use of stents) found that 12% (123 out of 1070) of

patients who had the procedure compared with 17% of patients (125 out of 731) who had balloon angioplasty alone had a stroke or died within a year.

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 main success factors were fewer strokes and transient ischaemic attacks occurring after the procedure.

Risks and possible problems

Stroke or death occurring within 30 days of the procedure was recorded in a number of studies. In the study of 451 patients, 33 out of 224 patients who had the procedure and 13 out of 227 patients who had only drug treatment had a stroke or died within 30 days. Five patients who had the procedure died because of stroke. One patient who had only drug treatment died from another cause. In the review of studies comparing the procedure with balloon angioplasty alone (without the use of stents), 8% (104 out of 1291) and 9% of patients (91 out of 1027) respectively had a stroke or died within 30 days of the procedure.

The stent became blocked after the procedure in 2 patients in a study of 53 patients. This happened 2 days after the procedure in 1 patient, who had to have surgery to bypass the affected artery because of repeated transient ischaemic attacks. In the other patient the stent became blocked 9 days after the procedure. The patient was not taking blood-thinning drugs to prevent blood clots forming because of bleeding in the gut and died from a stroke.

In the study of 113 patients, an artery was torn in 2 patients when the stent was being inserted. One patient had emergency surgery to stop the bleeding, but the other patient died from a severe form of stroke as a result of the bleeding.

In the study of 189 patients, 1 patient died after an artery burst during the procedure and another patient died because of bleeding in the brain. Three other patients also had bleeding in the brain after the procedure. This stopped without treatment in 2 patients, but 1 patient needed to have another procedure to stop the bleeding. Bleeding in both sides of the brain developed 2 weeks after the procedure in 1 patient in the study of 113 patients. In the study of 213 patients, there were 3 reports of bleeding within the brain but these were not described in detail.

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 damage to part of the brain called the thalamus leading to a stroke, bursting of a major artery causing death, and bleeding from newly unblocked arteries because of irreversible damage are all possible problems that could occur because of the procedure. In theory, other problems could include heart attack, allergic reaction to the contrast dye used for X-ray imaging of the artery, groin haematoma (blood collecting in the groin where the catheter was inserted), embolism (blockage of the treated artery through formation of a blood clot or air bubble), and dissection of the artery (separation of the inner and outer layers of the artery, a common cause of stroke).

More information about narrowed arteries

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.

For details of all NICE guidance on narrowed arteries, 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. HealthTech 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 'Endovascular stent insertion for intracranial atherosclerotic disease'. This leaflet and the full guidance aimed at healthcare professionals are available at

www.nice.org.uk/guidance/HTG288

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 booklet in their own information about this procedure.

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