

Treating leg popliteal aneurysms by inserting a mesh tube

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

This leaflet is about when and how a mesh tube (or stent) can be used in the NHS to treat people with popliteal aneurysms. 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.

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 leaflet 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 popliteal aneurysms or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet 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 8.

What has NICE said?

Although there are no major safety concerns about this procedure, there are still uncertainties about how well it works in the long term. If a doctor wants to use a mesh tube to treat popliteal aneurysms, they should make sure that extra steps are taken to explain the uncertainty about how well it works in the long term. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet 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.

A healthcare team including a vascular surgeon and an interventional radiologist with specific training and experience in the technique should decide which patients should have this procedure.

NICE encourages more research to be done on this procedure and may look at the procedure again if more information becomes available.

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

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The medical name for this procedure is 'endovascular repair of popliteal aneurysms'. The procedure is not described in detail here – please talk to your specialist for a full description.

The popliteal artery is the vessel at the back of the knee that carries blood to the lower leg and foot. An aneurysm is a balloon-like swelling caused by a weakness in the wall of the blood vessel. Popliteal artery

aneurysms can lead to the artery becoming blocked or clotted, or may burst, and any of these events will restrict blood flow to the leg. A common treatment for this condition is to attach a healthy blood vessel taken from elsewhere in the body to the popliteal artery so that blood flow bypasses the blocked section of the artery.

In the new procedure, with the patient under local or general anaesthesia, a cut is made through the skin and into an artery in the groin (femoral artery). Using X-ray control to guide a fine wire and thin plastic tube (or catheter) down the artery, a mesh tube is then inserted in order to form a new channel through the middle of the aneurysm. The stent allows blood to flow cleanly through the central channel to the lower leg without touching the blood clot in the surrounding aneurysm and prevents further stretching of the wall of the artery.

What does this mean for me?

If your doctor has offered you stents for popliteal aneurysms, 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 leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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 9 studies on this procedure.

How well does the procedure work?

In 1 study there was no difference in patency rate (or 'openness' of the blood vessel) after stent insertion (84%, or 36 out of 43 patients) compared with open repair (85%, or 99 out of 116 patients) at 1 year. Another study, of 43 patients, showed there was no difference between the 2 procedures at 2 years (83% for stents and 88% for open repair).

In a study of 43 people, 15 aneurysms were treated by stents and had a patency success rate of 83% compared with 88% treated by open surgery.

In another study of 50 patients using stents, 55 out of 57 limbs with aneurysms were saved. In a study of 42 people with 21 patients treated by stent insertion, 3 needed open repair because the stent became blocked, when they were checked at an average of 47 months after the procedure.

In the study of 50 patients, 9 out of 57 aneurysms became blocked. Two were treated by thrombolysis (where drugs are used to break down the blood clots), 5 were treated by open bypass surgery using the femoral artery, and 1 patient had no symptoms and wasn't treated. One patient needed the limb to be amputated.

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 key success factors were treatment of the aneurysm, prevention of thrombosis (blood clots) and of other arteries becoming blocked in the long term, prevention of rupture, and saving the limb.

Risks and possible problems

Blood clots blocking the stent occurred the following day in 2 out of 21 patients who had the procedure in 1 study. Both needed further treatment (1 of them needed open surgery). In the study of 33 aneurysms (29 patients), blood clots formed in 2 aneurysms within 24 hours of the procedure. Both aneurysms were treated successfully. A further 4 patients in this study had blood clots during follow-up.

In the study of 60 patients the stent broke in 3 out of 73 aneurysms, causing blockages in two instances. The stent moved from its original place in 9 out of 73 aneurysms, and in 4 out of 57 procedures in the study of 50 patients. In 2 out of 73 procedures, further treatment was needed because of narrowing of the blood vessel.

In the study of 50 patients, 1 patient had a blocked blood vessel lower down the leg, which required the limb to be amputated.

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 possible problems include the stent becoming blocked leading to a shortage of oxygen in the limb, blood clots blocking the stent, leaking of blood into the aneurysm sac, and bleeding where the catheter is inserted. In theory, other problems could include the stent becoming infected, and further expansion or rupture of the aneurysm.

More information about aneurysms

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 aneurysms, 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. This 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 leaflet is about 'endovascular stent-grafting of popliteal aneurysms'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG259

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2511). 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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