NHS
National Institute for Health and Clinical Excellence

## Understanding NICE guidance

**Information for people who use NHS services**

# Removing plaque from narrowed arteries in the legs using a catheter with a small rotating blade

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

This leaflet is about when and how a catheter with a small rotating blade can be used in the NHS to treat people with narrowed arteries in the legs. 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 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 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 the back page.

**Information about NICE interventional procedure guidance 380**
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## What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. In particular, there is not enough evidence about the risk of the procedure causing particles to circulate in the bloodstream, with potential risks of seizure and stroke. If a doctor wants to use the procedure, 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. 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.

NICE has encouraged further research into this procedure and may review it if more evidence becomes available.

## Removing plaque from narrowed arteries in the legs using a small rotating blade

*This procedure may not be the only possible treatment for narrowed arteries in the legs. 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 'Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices'.

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

The main arteries in the legs can become narrowed and stiffened by fatty deposits (plaques). The medical name for this is peripheral arterial disease (PAD). The most common symptom is pain or aching in the leg particularly during walking or exercising, which is felt because the muscles are not getting enough blood. As the condition worsens, people may experience pain when resting. In severe cases foot ulcers or gangrene may develop, in which case amputation may be needed.

In this procedure, a special catheter with a rotating blade is used inside the narrowed arteries to remove the build-up of plaque restricting the blood flow. The procedure is done using a local anaesthetic. A needle is inserted through a small cut in the skin into the femoral artery in the groin. A fine guidewire is pushed through the needle to access the artery. A special tube called a catheter, which contains a sharp rotating blade, is inserted over the guidewire into the artery and positioned at the narrowing. The blade cuts the plaque away, which is collected in the tip of the device and removed. There are different catheters available for this procedure and your specialist can give you more information about the different ways in which they work.

## 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 7 studies on this procedure.

## What does this mean for me?

If your doctor has offered you this procedure, 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?

## How well does the procedure work?

A study of 601 patients reported that the procedure was successful in removing 95% of plaques. After 12 months, 80% of patients had not needed a repeat procedure.

A study of 275 patients who had the procedure showed that amputation had been avoided in 92% of patients when they were assessed after 18 months. A different study of 60 patients reported that 4 patients ultimately needed an amputation at an average of 5 months after the procedure.

In 2 studies that reported on symptom improvement, a study of 34 patients (36 procedures) showed that symptoms had improved in 27 out of 36 procedures after 1 month, and in 12 out of 22 procedures after 12 months. A study of 16 patients (17 limbs) showed that 12 limbs were symptom free after 1 month and 7 remained symptom free after 6 months.

The study of 275 patients showed that after 18 months, 53% of the treated arteries remained open.

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 widen the narrowed arteries and keep them open, prevent amputation, improve leg pain, quality of life and ulcer healing.

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

## Risks and possible problems

In 3 studies involving 1346 procedures, 7 blood clots were reported.

In the study of 601 patients (1258 procedures), the artery wall was perforated in 10 procedures. No artery wall perforations were reported in studies of 60 and 131 procedures.

In the study of 34 patients, 2 required further surgery as a result of complications: 1 to treat a blood clot and 1 to treat a weakened, bulging blood vessel.

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 in theory complications include the formation of remote blood clots, limb loss, bleeding and device-related complications.

## More information about peripheral arterial disease

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 peripheral arterial disease, 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 leaflet is about 'Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices'. This leaflet and the full guidance aimed at healthcare professionals are available at* **www.nice.org.uk/guidance/IPG380**

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2445). 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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