

Understanding NICE guidance

Information for people who use NHS services

Treating refractory Achilles tendinopathy using shockwave therapy

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 shockwave therapy can be used in the NHS to treat people with refractory Achilles tendinopathy (also known as Achilles tendonitis). 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 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 Achilles tendinopathy 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 the back page.

What has NICE said?

There is evidence to say that this procedure is safe, although occasionally, treated patients have had tendon rupture (but this can also occur if patients don't have the procedure). However, there are still uncertainties about how well it works. If a doctor wants to use shockwave therapy for refractory Achilles tendinopathy, they should make sure that extra steps are taken to explain the uncertainty about how well it works and the possible risk of a tendon rupture, as well as the 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 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 using shockwave therapy for refractory Achilles tendinopathy, and patients' progress should be assessed for up to a minimum of 1 year after the procedure. NICE may review the procedure if more evidence becomes available.

Other comments from NICE

The Committee found interpreting the data difficult because the studies were very different from each other, the results were inconsistent and the placebo treatments had a large beneficial effect.

If the procedure works in selected patients, it could have a big impact because Achilles tendinopathy is common and in many patients other treatments don't work. This means that having reliable evidence is particularly important.

Treating refractory Achilles tendinopathy using shockwave therapy

This procedure may not be the only possible treatment for Achilles tendinopathy. 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 'extracorporeal shockwave therapy for refractory Achilles tendinopathy'. 'Extracorporeal' means outside the body and 'refractory' means that the condition does not respond to conventional treatments. The 'shock waves' are inaudible, high-energy sound waves. The procedure is not described in detail here – please talk to your specialist for a full description.

Achilles tendinopathy is pain and inflammation of the tendon at the back of the heel. It is usually caused by injury or overuse. Symptoms include pain, swelling, weakness and stiffness, and tenderness over the heel. Conventional treatments include rest, applying ice, anti-inflammatory medication, support devices, physiotherapy, physical exercises and corticosteroid injection, or possibly surgery.

In this procedure shock waves are passed through the skin to the affected area using a special device, and ultrasound guidance may be used. Shockwave therapy can be given in one or more sessions. It may be carried out under local anaesthesia if high-energy shock waves are used because it can be painful. However, local anaesthesia may influence the outcome.

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 although it is safe (although occasionally tendon rupture may occur), there are uncertainties about how well it works. 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, including the risk of tendon rupture. 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. 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. 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 7 studies on this procedure.

How well does the procedure work?

A study of 75 patients looked at 3 treatments for Achilles tendinopathy (25 in each group). The patients scored their results 4 months later on a scale from 1 (completely recovered) to 6 (much worse). The number of patients scoring 1 or 2 on this scale were 13 for shockwave therapy, 15 for stretching exercises and 6 for 'wait-and-see'. Another study looked at recovery from a different type of Achilles tendinopathy using the same scoring system. After 4 months, 16 out of 25 patients who had the procedure, and 7 out of 25 patients who were given stretching exercises, had a score of 1 or 2. In a study of 48 patients who either had the procedure or placebo treatment, the reduction in pain was similar.

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

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

advisers said that the main success factors are symptom and pain relief, improved function in the foot, reduction in pain and a reduction in morning stiffness.

Risks and possible problems

In the study of 75 patients, all who had the procedure had short-lasting skin reddening. In 2 other studies, involving a total of 69 patients who had the procedure, 3 patients had short-lasting skin reddening. One patient had numbness that lasted for 24 hours. In a study of 49 patients calf ache was reported in 'the majority' of patients in both treatment groups (procedure or placebo). Two patients had a ruptured tendon 2 weeks after the procedure. But this didn't happen in any of the patients who had the placebo treatment.

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 problems include rupturing of the tendon and short-lasting reddening of the skin around the treated area. In theory, problems could include the condition getting worse and damage to nearby soft tissue.

More information about Achilles tendinopathy

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 Achilles tendinopathy, 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 'extracorporeal shockwave therapy for refractory Achilles tendinopathy'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG312

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1974). 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.