

# **Understanding NICE guidance**

Information for people who use NHS services

# Treating chronic plantar fasciitis 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 plantar fasciitis. 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 plantar fasciitis 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?

Although there is evidence to say that this procedure is safe, there are still uncertainties about how well it works. If a doctor wants to use shockwave therapy for chronic plantar fasciitis, they should make sure that extra steps are taken to explain the uncertainty about how well the procedure works, as well as the 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 using shockwave therapy for plantar fasciitis, 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 plantar fasciitis is common and in many patients other treatments don't work. This means that having reliable evidence is particularly important.

# Treating plantar fasciitis using shockwave therapy

The medical name for this procedure is 'extracorporeal shockwave therapy for refractory plantar fasciitis'. '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.

Plantar fasciitis occurs when the ligament at the bottom of the foot between the heel and the toes deteriorates and causes foot pain. It often follows injury. Conventional treatments include rest, applying ice, pain-relieving and anti-inflammatory medication, support devices, physiotherapy, physical exercises and corticosteroid injection.

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.

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 9 studies on this procedure.

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

#### 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 the procedure is safe there are uncertainties about how well it works. This does not mean that it 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.

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 about this procedure. 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?

## How well does the procedure work?

In a study of 293 patients, in which 144 had the procedure and 141 had a placebo (dummy) procedure, 67 and 42 patients, respectively, had less pain after 3 months and didn't need pain medication.

In a study of 172 patients, the average reduction in pain score at 3 months was greater in patients who had the procedure (112 patients) than in those who had the placebo treatment (56 patients).

In a study of 149 patients, 69% of patients who had the procedure reported an 'excellent' result (no heel pain), whereas all patients who had conventional treatment reported some pain, after an average of 64 months.

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 factor is relief of symptoms.

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 2 studies, involving a total of 216 patients who had the procedure and 221 who had a placebo treatment, 8 patients who had the procedure had pain during treatment, compared with 3 patients in the placebo group. In another study, 6 out of 61 patients who had the procedure had throbbing pain and skin reddening, and 8 out of 64 patients who had a different treatment (a corticosteroid injection) had pain that needed medication or ice for about a week.

In another study, 16 out of 135 patients who had the procedure had skin reddening, compared with 5 out of 136 patients who had the placebo treatment. In 2 studies involving a total of 250 patients who had the procedure, 4 had swelling around the treatment site.

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 bruising, pain and skin damage around the site of treatment. In theory, problems could include the condition getting worse because of rupture of the ligament at the bottom of the foot, or damage to the soft tissue.

#### More information about plantar fasciitis

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 plantar fasciitis, 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 plantar fasciitis'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG311

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1972). 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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