National Institute for Health and Clinical Excellence

Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Issued: August 2009

NICE interventional procedure guidance 312

www.nice.org.uk/ipg312

NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for three years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

NHS Evidence accredited provider
NHS Evidence - provided by NICE
www.evidence.nhs.uk

Contents

1 Guidance

1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory Achilles tendinopathy raises no major safety concerns: there have been reports of occasional tendon rupture in treated patients, but this may also occur when the procedure has not been used. However, current evidence on efficacy of the procedure is inconsistent. Therefore, ESWT for refractory Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake ESWT for refractory Achilles tendinopathy should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy, and about its safety in relation to a possible risk of tendon rupture, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having ESWT for refractory Achilles tendinopathy (see section 3.1).

1.3 NICE encourages further research into ESWT for refractory Achilles tendinopathy. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied (see section 2.5). The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Achilles tendinopathy is characterised by chronic degeneration of the Achilles tendon, and is usually caused by injury or overuse. Symptoms include pain, swelling, weakness and stiffness over the Achilles tendon and tenderness over the heel (insertional tendinopathy).

2.1.2 Conservative treatments include rest, application of ice, non-steroidal anti-inflammatory drugs, orthotic devices, physiotherapy (including eccentric loading exercises) and corticosteroid injection. Surgery may be considered in some patients with refractory symptoms.

2.2 Outline of the procedure

2.2.1 Extracorporeal shockwave therapy is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance can be used to assist with positioning of the device.

2.2.2 Extracorporeal shockwave therapy may be applied in one or several sessions. Local anaesthesia may be used because high-energy ESWT can be painful. Different energies can be used and there is evidence that local anaesthesia may influence the outcome of ESWT.

2.2.3 The mechanism by which this therapy might have an effect on tendinopathy is unknown.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 75 patients compared ESWT, eccentric loading and a wait-and-see policy for the treatment of non-insertional Achilles tendinopathy. Patient-assessed recovery from baseline (on a 6-point Likert scale ranging from 1 [completely recovered] to 6 [much worse]) was reported as 1 or 2 points (completely recovered or much improved) in 52% (13/25), 60% (15/25) and 24% (6/25) of each group, respectively, at 4-month follow-up. An RCT of 50 patients treated by ESWT or eccentric loading for insertional Achilles tendinopathy reported that 64% (16/25) of patients treated by ESWT reported a score of 1 or 2 (using the 6-point Likert scale) compared with 28% (7/25) of patients treated by eccentric loading at 4-month follow-up ($p < 0.02$).

2.3.2 An RCT of 48 patients treated by ESWT or sham ESWT for Achilles tendinopathy reported that there was a reduction in pain in both groups (assessed using a visual analogue scale [VAS]; points scale not defined) and no significant difference between groups (no data provided).

2.3.3 The Specialist Advisers listed key efficacy outcomes as relief of symptoms, improved function, resolution of pain and decreased morning stiffness.

2.4 Safety

2.4.1 In the RCT of 75 patients, transient skin reddening occurred in all ESWT patients. In 2 case–control studies including 35 and 34 patients treated with ESWT, transient skin reddening occurred in 2 patients and 1 patient, respectively; in each of these studies 2 patients had pain during the procedure (unclear whether patients were in treatment or control arms of these studies). In 1 of the studies, 1 patient had transient numbness for 24 hours after ESWT.

2.4.2 Two patients in the RCT of 49 patients had Achilles tendon rupture 2 weeks after an ESWT treatment session; no patients in the sham study arm had tendon rupture.

2.4.3 Calf ache was reported in 'the majority' of patients in both treatment groups in the RCT of 49 patients (absolute numbers not reported).

2.4.4 The Specialist Advisers listed adverse events as bruising and weakening of the tendon leading to tendon rupture, occurring particularly in older patients, and transient reddening of the treated area. The Specialist Advisers considered theoretical adverse events to include exacerbation of the condition and local soft tissue damage.

2.5 Other comments

2.5.1 The Committee found interpretation of the data difficult because of the diversity of treatment protocols and comparators used, varying reported end points, and inconsistencies in terms of the use of local anaesthesia and energy type. The results of studies conflicted and there was evidence of a substantial placebo response.

2.5.2 Achilles tendinopathy is a common condition and many patients who have it are refractory to other treatments. If the procedure is efficacious in selected patients, it has the potential for a high impact. This makes provision of robust data particularly important.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Other NICE recommendations on extracorporeal shockwave therapy

Guidance has also been issued on Extracorporeal shockwave therapy for refractory plantar fasciitis and Extracorporeal shockwave therapy for refractory tennis elbow. It replaces the previous guidance on Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow) (IPG139, November 2005).

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

6 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk
nice@nice.org.uk
0845 033 7780