

Extracorporeal shockwave therapy for refractory plantar fasciitis

This document replaces previous guidance on extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow) (interventional procedure guidance 139).

1 Guidance

- 1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory plantar fasciitis raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake ESWT for refractory plantar fasciitis 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 provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG311publicinfo).
 - Audit and review clinical outcomes of all patients having ESWT for refractory plantar fasciitis (see section 3.1).
- 1.3 NICE encourages further research into ESWT for refractory plantar fasciitis. 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 Plantar fasciitis is characterised by chronic degeneration of the plantar fascia, which causes pain on the underside of the heel. It is usually caused by injury or biomechanical abnormalities and may be associated with microtears, inflammation or fibrosis.
- 2.1.2 Conservative treatments include rest, application of ice, analgesic medication, non-steroidal anti-inflammatory drugs, orthotic devices, physiotherapy, eccentric training/stretching and corticosteroid injection.

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.

Interventional procedure guidance 311

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. 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 the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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, available at www.nice.org.uk/IP252aoverview

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 293 patients treated by ESWT or sham ESWT reported that 47% (67/144) and 30% (42/141) of patients, respectively, had 'successful' outcomes at 3-month follow-up (defined as at least 50% reduction in pressure-induced pain and pain during walking, at least a 1-point reduction in pain score on a 5-point visual analogue scale [VAS] [higher scores indicate greater pain] and no requirement for pain medication 10–12 weeks after treatment) ($p = 0.008$).
- 2.3.2 In an RCT of 172 patients treated by ESWT or sham ESWT, the mean reduction in pain score (assessed by a 5-point VAS) from baseline to 3-month follow-up was 3.4 in the ESWT group ($n = 112$) compared with 1.8 in the sham ESWT group ($n = 56$) ($p < 0.001$).
- 2.3.3 An RCT of 149 patients treated by ESWT or conservative management reported that 69% of ESWT patients and no patients treated conservatively had an 'excellent' result (no heel pain) and 14% and 55% of each group, respectively, had a 'good' result (50% or greater reduction in baseline pain) at a mean follow-up of 64 months.
- 2.3.4 The Specialist Advisers stated that the key efficacy outcome was relief of symptoms.

2.4 Safety

- 2.4.1 The RCTs of 272 and 166 patients reported pain during treatment in 5% (7/135) and 1% (1/81) of ESWT patients, and 1% (2/136) and 1% (1/85) of sham patients, respectively. The RCT of 125 patients reported throbbing pain and erythema requiring ice in 10% (6/61) of ESWT patients, compared with pain requiring analgesia or ice for a mean duration of 7 days in 13% (8/64) of patients who had a single corticosteroid injection.

- 2.4.2 The RCT of 272 patients reported that 12% (16/135) of ESWT patients and 4% (5/136) of sham ESWT patients had skin reddening. In the RCTs of 272 and 172 patients, 2% (3/135) of ESWT patients and 1 ESWT patient, respectively, had local swelling.

- 2.4.3 The Specialist Advisers listed adverse events as bruising, pain and local skin damage. They considered theoretical adverse events to include exacerbation of the condition because of rupture of the plantar fascia or 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. Previous guidance on this procedure published in 2005 had found the evidence on efficacy inadequate, and new evidence has not been published to alter that view.
- 2.5.2 Plantar fasciitis 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), available from www.nice.org.uk/IPG311
- 3.2 For related NICE guidance see www.nice.org.uk

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. See www.nice.org.uk/IPG311publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1971 for this guidance or N1972 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which 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.

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