NICE guidance

Extracorporeal shockwave therapy for refractory plantar fasciitis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg311

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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 the public is recommended.
- 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 (ESWT) 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 ESWT 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.

2.3 Efficacy

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.

2.3.1 A randomised controlled trial (RCT) of 293 patients treated by ESWT or sham

ESWT reported that 47% (67 out of 144) and 30% (42 out of 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 to 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 out of 135) and 1% (1 out of 81) of ESWT patients, and 1% (2 out of 136) and 1% (1 out of 85) of sham patients, respectively. The RCT of 125 patients reported throbbing pain and erythema requiring ice in 10% (6 out of 61) of ESWT patients, compared with pain requiring analgesia or ice for a mean duration of 7 days in 13% (8 out of 64) of patients who had a single corticosteroid injection.

2.4.2 The RCT of 272 patients reported that 12% (16 out of 135) of ESWT patients and 4% (5 out of 136) of sham ESWT patients had skin reddening. In the RCTs of 272 and 172 patients, 2% (3 out of 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).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient

consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.