NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Extracorporeal shockwave therapy for Achilles tendinopathy

Achilles tendinopathy is a condition of the tendon that connects the calf muscles to the heel bone. There may be tiny tears in the fibres of the tendon. It is usually caused by overuse or injury. Symptoms include pain and weakness or stiffness in the lower calf and back of the heel. In extracorporeal shockwave therapy a machine is used to deliver sound waves to the painful area. It is thought that extracorporeal shockwave therapy may stimulate healing.

The National Institute for Health and Care Excellence (NICE) is examining extracorporeal shockwave therapy for Achilles tendinopathy and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about extracorporeal shockwave therapy for Achilles tendinopathy.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 20 May 2016

Target date for publication of guidance: September 2016

1 Draft recommendations

1.1 The evidence on extracorporeal shockwave therapy (ESWT) for Achilles tendinopathy raises no major safety concerns. Current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity. Therefore, ESWT for Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research.

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

- Inform the clinical governance leads in their NHS 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 *[[URL to be added at publication]]* is recommended.
- Audit and review clinical outcomes of all patients having ESWT for Achilles tendinopathy (see section 7.2).

1.3 NICE encourages further research into ESWT for Achilles tendinopathy. Studies should clearly describe patient selection, treatment protocols, use of local anaesthesia and the type and duration of energy applied (see section 3). Studies should include validated outcome measures and have a minimum of 1 year of follow-up. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Achilles tendinopathy is characterised by chronic degeneration of the Achilles tendon and is usually associated with injury or overuse. Symptoms include pain, swelling, weakness and stiffness over the Achilles tendon and tenderness over the heel. Achilles tendinopathy is classified as insertional or non-insertional. Insertional Achilles tendinopathy occurs at the bone-tendon junction in more active people, and non-insertional (or mid-portion) Achilles tendinopathy occurs more proximally in older, less active and overweight people.

2.2 Conservative treatments include rest, application of ice, non-steroidal anti-inflammatory drugs (NSAIDs), orthotic devices and splints, physiotherapy, Achilles tendon exercises or stretching,

topical nitroglycerin, low-level laser therapy and injections with corticosteroid or autologous blood. Surgery may rarely be considered in patients with refractory symptoms with the aim of repairing partial tears in the Achilles tendon.

3 The procedure

3.1 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 may be used to assist with positioning of the device. The shockwaves can be either focused or unfocused (often referred to as radial shock waves). The focused shockwaves are generated using electrohydraulic, electromagnetic or piezoelectric energy. The unfocused shockwaves are generated pneumatically.

3.2 Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves. ESWT may be applied in a series of treatments or a single session. Local anaesthesia may be administered before treatment because high-energy ESWT (>0.12 mJ/mm2) can be painful; however, there is evidence that the use of local anaesthesia may adversely influence the outcome of ESWT. Low-energy ESWT (EFD ≤0.12 mJ/mm2) can be used repeatedly and does not require local anaesthesia.

3.3 The mechanism by which this therapy might have an affect on tendinopathy is not known.

4 Efficacy

This section describes efficacy 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 interventional procedure overview ***[add URL]***.

Extracorporeal shockwave therapy (ESWT) for non-insertional (mid-portion) Achilles tendinopathy

4.1 In a systematic review and meta-analysis on ESWT (n=633), evidence for mid-portion Achilles tendinopathy (tendinopathy 2-6cm from the insertion into the calcaneus) was reported from 2 randomised controlled trials (RCTs) of 75 and 68 patients respectively (Rompe 2007, Rompe 2009). The RCT of 75 patients (Rompe 2007) compared ESWT (n=25) with eccentric loading exercise (n=25) and found no statistically significant effects on pain and functional outcomes at 4-month follow-up (Visual analogue scale [VAS] score standard mean difference [SMD] 0.17, 95% confidence interval [CI] -0.38 to 0.73; Victorian institute of sport assessment questionnaire–Achilles [VISA-A] score SMD 0.29, 95% CI -0.27 to 0.85; Likert scale risk ratio 1.20, 95% CI 0.64 to 2.25). The study also compared ESWT (n=25) with a 'wait and see' group (no-treatment control, n=25) and found statistically significant effects that favoured ESWT at 4-month follow-up (VAS score SMD -0.93, 95% CI -1.52 to -0.34; VISA-A score SMD -1.03, 95% CI -1.62 to -0.44; Likert scale risk ratio 0.63, 95% CI 0.40 to 1.00). The RCT of 68 patients (Rompe 2009) comparing combined ESWT and eccentric loading exercise in mid-portion Achilles tendinopathy (n=34) with eccentric loading exercise alone (n=34) found greater improvement in pain and function at 4-month follow-up (VAS score SMD -0.53, 95% CI -1.01 to -0.05; VISA-A score SMD -0.76, 95% CI -1.25 to -0.27; Likert scale risk ratio 0.40, 95% CI 0.18 to 0.91).

4.2 The systematic review also reported evidence from a case-control study of 68 patients (Furia 2008) comparing ESWT (n=34) with conservative treatment including rest, footwear modification, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening (n=34) and found that ESWT was statistically significantly better in improving pain and functional outcomes at 3–month follow-up (VAS score SMD -3.75, 95% CI -4.56 to -2.95; Roles and Maudsley score SMD 0.20, 95% CI 0.09 to 0.46) and after follow up of at least 12 months (VAS score SMD -3.42, 95% CI -4.18 to -2.66; Roles and Maudsley score risk ratio 0.20, 95% CI 0.09 to 0.46).

ESWT for insertional Achilles tendinopathy

4.3 In the systematic review and meta-analysis on ESWT (n=633), evidence for insertional Achilles tendinopathy (tendinopathy up to 2 cm from the insertion into the calcaneus) was reported from 1 RCT of 50 patients (Rompe 2008) comparing ESWT (n=25) to eccentric loading exercise (n=25). It found statistically significant improvement for outcomes of pain and function at 4-month follow-up (VAS score SMD -0.86, 95% CI -1.44 to -0.27; VISA-A score SMD -1.54, 95% CI -2.18 to -0.91; Likert scale risk ratio 0.50, 95% CI 0.28 to 0.89).The systematic review also reported evidence from 1 case-control study of 68 patients (Furia 2006) comparing ESWT (n=34) with conservative treatment including rest, footwear modification, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening (n=34) and found that ESWT was statistically significantly better in improving pain and functional outcomes at 3-month follow-up (VAS score SMD -2.42, 95% CI -3.05 to -1.78; Roles and Maudsley score SMD 0.28, 95% CI 0.13 to 0.62) and after follow up of at least 12 months (VAS score SMD -

2.39, 95% CI -3.02 to -1.76; Roles and Maudsley score risk ratio 0.28, 95% CI 0.13 to 0.62). The effect of ESWT was diminished when a local anaesthetic was administered before treatment in this study.

ESWT for non-insertional (mid-portion) or insertional Achilles tendinopathy

4.4 In a systematic review and meta-analysis of 246 patients, evidence from meta-analysis of data from 2 RCTs (Rompe 2007, patients with mid-portion tendinopathy; Rompe 2008, patients with insertional tendinopathy) found no significant effects on pain and functional outcomes at 16-week follow-up (VISA-A score SMD -0.55, 95% CI -2.21 to 1.11).

4.5 In the systematic review and meta-analysis on ESWT (n=633), evidence for mid-portion or insertional Achilles tendinopathy was reported from 2 RCTs of 49 and 48 patients respectively (Costa 2005, Ramussen 2008) comparing ESWT with no treatment (placebo). The RCT of 49 patients (Costa 2005) found no significant difference between ESWT (n=22) and sham treatment (n=27) at 3-month follow-up (VAS score SMD -0.44, 95% CI -1.01 to 0.13; Functional index of lower limb activity [FILA] SMD -1.05, 95% CI -1.65 to -0.45; EQ-5D SMD -0.21, 95% CI -0.77 to 0.36). The RCT of 48 patients (Rasmussen 2008) used the same intervention as Costa 2005 but with a higher energy level and an extra treatment session. It found that patients in the ESWT group had significantly better American orthopaedic foot and ankle society (AOFAS) scores than the sham group at 3-month follow-up (SMD -0.52, 95% CI -1.09 to 0.06). The 3 prospective studies (Firdman 2008, Saxena 2011, Vulpiani 2009) included in this systematic

review reported improvements in pain and functional outcomes at an average follow up of 20 to 24 months.

4.6 The specialist advisers listed key efficacy outcomes as pain reduction, pain relief and improved function.

4.7 Twelve commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes 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 interventional procedure overview ***[add URL]***.

5.1 Transient skin reddening occurred in all patients treated by extracorporeal shockwave therapy (ESWT) in 1 RCT (Rompe 2007) and in 3 patients each in the 2 case–control studies (Furia 2006 and 2008) included in a systematic review of 11 studies. Some patients reported the presence of cutaneous bruises after the applications of ESWT in the case series of 102 patients with Achilles tendinopathy (number not reported).

5.2 Pain during ESWT in 2 patients and transient numbness for 24 hours after ESWT in 1 patient was reported in a case-control study (Furia 2006) included in the systematic review of 11 studies.

5.3 Calf ache was reported in some patients who had eccentric loading exercise in 1 RCT (Rompe 2007, numbers not reported), and in an equal number (‘the majority’) of patients in both groups in another RCT (Costa 2005, numbers not reported) included in the systematic review of 11 studies.

5.4 Achilles tendon rupture 2 weeks after the first ESWT treatment session, associated with falls, was reported in 2 patients in 1 RCT (Costa 2005) included in the systematic review of 11 studies.

5.5 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: temporary pain and erythema. They considered that the following were theoretical adverse events: persistent or worsening symptoms and damage to the soft tissues.

6 Committee comments

6.1 The committee was informed by specialist advisers that low energy devices are now more commonly used and may be associated with less procedural pain.

6.2 The committee noted that patient commentary was mixed in terms of the benefits of the procedure and noted that some patients found the treatment painful.

6.3 The committee noted that there were occasional reports of tendon rupture in treated patients, although this can also happen when the procedure has not been used.

6.4 The Committee found it difficult to interpret the evidence because of the diversity of treatment protocols and comparators used, varying reported end points, and inconsistencies in use of local anaesthesia and energy type.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

7.3 This guidance is a review of NICE's interventional procedure guidance on extracorporeal shockwave therapy for refractory Achilles tendinopathy.

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May 2016