

Extracorporeal shockwave therapy for refractory tennis elbow

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg313

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.

This guidance replaces IPG139.

1 Guidance

- 1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory tennis elbow 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 tennis elbow 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 tennis elbow (see section 3.1).
- 1.3 NICE encourages further research into ESWT for refractory tennis elbow. 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 Tennis elbow (also known as lateral epicondylitis) is characterised by chronic degeneration at the origin of the extensor carpi radialis brevis muscle on the lateral epicondyle of the humerus. It is usually caused by injury or overuse. Symptoms include pain, weakness and stiffness of the outer elbow.
- 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 In a randomised controlled trial (RCT) comparing 272 patients treated by ESWT or

sham ESWT, success was reported in 26% (32 out of 124) and 25% (31 out of 122) of patients, respectively, at 3-month follow-up (success defined as a Roles and Maudsley score of 1 or 2 out of 4 and no requirement for additional treatment). An RCT of 93 patients treated by ESWT or steroid injection reported treatment success (at least 50% improvement in Visual Analogue Scale [VAS] score) in 60% (29 out of 48) and 84% (21 out of 25) of patients, respectively, at 3-month follow-up ($p < 0.05$).

- 2.3.2 An RCT of 75 patients treated by ESWT or sham ESWT reported that at 3 months, 35% (14 out of 40) and 37% (13 out of 35) of patients, respectively, had at least a 50% improvement in VAS score for pain during the day ($p < 0.01$ in both treatment groups); and 30% (12 out of 40) and 43% (15 out of 35) of patients, respectively, had at least a 50% improvement in VAS score for pain at night (p value stated as 'non-significant' and $p < 0.05$, respectively).
- 2.3.3 The Specialist Advisers listed key efficacy outcomes as relief of symptoms and functional improvement.

2.4 Safety

- 2.4.1 Two RCTs of 272 and 114 patients reported pain in 11% (15 out of 134) and 50% (28 out of 56) of ESWT patients, and 4% (6 out of 136) and 22% (13 out of 58) of sham ESWT patients, respectively.
- 2.4.2 In the RCT of 272 patients, transient skin reddening occurred in 31% (42 out of 134) of ESWT patients and 8% (11 out of 136) of sham ESWT patients, and transient swelling occurred in 7% (9 out of 134) and 6% (8 out of 136) of patients, respectively.
- 2.4.3 The RCT of 114 patients treated by ESWT or sham ESWT reported a local reaction (not otherwise described) in 11% (6 out of 56) and 9% (5 out of 58) of patients, respectively. In this study 18% (10 out of 56) of patients in the ESWT group experienced nausea compared with none in the sham ESWT group.
- 2.4.4 In the RCT of 75 patients, 2 patients in the ESWT group had worsened symptoms after 2 treatment sessions and withdrew from the study.

- 2.4.5 The Specialist Advisers listed adverse events as bruising, transient skin reddening and local skin damage. Theoretical adverse events include rupture of the common extensor tendon.

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 Tennis elbow 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](#).