Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder

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www.nice.org.uk/guidance/ipg742

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 <u>Yellow Card Scheme</u>.

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 IPG21.

1 Recommendations

- 1.1 Evidence on the safety of extracorporeal shockwave therapy for calcific tendinopathy in the shoulder shows no major safety concerns in the short term. Evidence on efficacy is inadequate. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research should include randomised controlled trials comparing the procedure with current best practice. It should report details of patient selection, including site and density of calcification, duration of symptoms, and other treatments used at the same time. It should also report details of the technique, including dose and number of treatments, and long-term safety outcomes.

The condition, current treatments and 2 procedure

The condition

2.1 Calcific tendinopathy (also known as calcific tendonitis) is a disorder of the shoulder characterised by the formation of deposits of calcium crystals in 1 or more of the rotator cuff tendons. It can cause symptoms such as pain in the upper arm and shoulder, reduced range of movement, stiffness and weakness. The exact cause is unknown.

Current treatments

2.2 Most cases of calcific tendinopathy resolve in time without treatment. In the early stages, symptom management includes painkillers and antiinflammatory medication. If symptoms persist, physiotherapy may be needed. Other treatment options include steroid injection, percutaneous lavage or barbotage (using a needle to suck up or break up the calcium deposits), or surgery.

The procedure

- 2.3 Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass controlled, short-duration acoustic shockwaves through the skin to the affected area. This produces transient pressure disturbances, which break up calcium deposits. There are 2 different types of ESWT. In focused ESWT the energy generated converges at a selected depth in the body tissues where the maximal pressure is reached. In radial ESWT the maximal pressure is at the skin surface and then diverges as it penetrates deeper.
- 2.4 Local anaesthesia is sometimes used for pain relief during the procedure and ultrasound guidance can be used to assist with positioning the device.
- 2.5 Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature

search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 5 randomised controlled trials (1 of which is also included in the systematic review), 2 non-randomised comparative studies, 1 cohort study and 2 case reports. It is presented in the <u>summary of key evidence</u> <u>section in the interventional procedures overview</u>. Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: patient-reported outcome measures, including pain, function, and quality of life; need for continuing analgesia; and need for further treatment, including surgery.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain during and after the procedure, localised redness, bleeding, bruising and tendon rupture.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was told that calcific tendinopathy in the shoulder can be a very painful and debilitating condition.
- 3.6 The committee was told that the procedure should be used together with physiotherapy.
- 3.7 The committee noted:
 - There is more than one technique used for the procedure.
 - Evidence on efficacy comes from a heterogeneous group of patients, which made it difficult to determine if there was a group who might benefit from the treatment.
 - There were 2 published case reports of humeral head osteonecrosis in people who have had this procedure. This is a serious complication, but it is unclear if it was directly related to the procedure.

• The mechanism of action of extracorporeal shockwave therapy for calcific tendinopathy in the shoulder is unclear.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

Accreditation

