NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder

Calcific tendinopathy in the shoulder happens when calcium deposits build up in the tendons, causing pain and stiffness, although some people do not have any symptoms. In this procedure, a device is placed on the skin (extracorporeal) that delivers short pulses of sound (shockwaves) into the shoulder. The aim is to reduce pain and improve shoulder function.

This is a review of NICE's interventional procedures guidance on extracorporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Issue date: April 2022

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 May 2022

Target date for publication of guidance: October 2022

1 Draft 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 be 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.

2 The condition, current treatments and 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 anti-inflammatory 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 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 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 summary of key evidence section in the interventional procedures overview. 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.

Committee comments

3.4 The committee was told that calcific tendinopathy in the shoulder can be a very painful and debilitating condition.

3.5 The committee was told that the procedure should be used together with physiotherapy.

3.6 The committee noted:

- There is more than 1 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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Chair, interventional procedures advisory committee
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