NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Biodegradable subacromial spacer insertion for rotator cuff tears

The rotator cuff is a group of muscles and tendons that surround the shoulder joint and help to keep it stable. The rotator cuff can be injured and tear suddenly, or a tear can develop gradually. A rotator cuff tear is painful and makes the shoulder weak.

In this procedure, a balloon-shaped device (spacer) is inserted between the underside of the acromion (the prominent top part of the shoulder blade connected to the collar bone) and the top of the upper arm bone. The aim is to reduce pain and improve shoulder function. The spacer is left in place and dissolves after about 1 year (biodegradable).

NICE is looking at biodegradable subacromial spacer insertion for rotator cuff tears. This is a review of NICE's interventional procedures guidance on biodegradable subacromial spacer insertion for rotator cuff tears.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

Issue date: May 2023

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

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: 26th July 2023

Target date for publication of guidance: November 2023

1 Draft recommendations

1.1 When debridement is a suitable option, biodegradable subacromial spacer insertion for rotator cuff tears should not be used. Find out why NICE recommends not to use some procedures on the NICE interventional procedures guidance page.

1.2 When debridement is not a suitable option, biodegradable subacromial spacer insertion for rotator cuff tears should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.3 Further research should report details of patient selection, measures of shoulder function, pain relief and quality of life. Follow up should ideally be for a minimum of 2 years.

1.4 Patient selection should be done by a multidisciplinary team experienced in managing the condition, including clinicians with specific training in the procedure.

1.5 The procedure should only be done by surgeons with specific training in inserting the device.

Why the committee made these recommendations

Good quality evidence from the UK shows that symptoms including shoulder dysfunction and pain may be worse after this procedure compared with after debridement (removing damaged tissue from around the shoulder joint). So, the procedure should not be used when debridement is a suitable option.

It is not clear from the evidence if the procedure is beneficial for people with rotator cuff tears when debridement is not suitable. The evidence does not suggest any major safety concerns but evidence on long-term safety and benefit is limited. So, when debridement is not a suitable option, this procedure should be used only in research.

2 The condition, current treatments and procedure

The condition

2.1 People who have rotator cuff tears may have shoulder pain and weakness, with reduced shoulder function, leading to a reduced quality of life. Rotator cuff tears can be caused by an injury or can develop gradually. They can be minor or severe depending on the degree of damage to the tendon. Minor tears to the rotator cuff are very common and may not cause any symptoms at all. Diagnosis is usually by ultrasound or MRI.

Current treatments

2.2 Conservative treatment may include physical therapy, pharmacological treatments (including pain relief and topical or oral non-steroidal anti-inflammatory medicines) and corticosteroid injections. If the tear is severe or has not responded to other treatments, surgical interventions such as debridement, rotator cuff repair, subacromial smoothing, tendon transfer or shoulder arthroplasty may be needed.

The procedure

2.3 Inserting a biodegradable subacromial spacer aims to improve pain and restore shoulder function in people who have irreparable rotator cuff tears. The aim is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It is a less invasive and potentially safer alternative to reverse shoulder arthroplasty or tendon transfer, and has shorter procedure and rehabilitation times.

2.4 The procedure is done under general or regional anaesthesia. The subacromial space is visualised using either arthroscopy or mini-open surgery. The damaged area is surgically cleared.

Measurements are taken to determine the size of biodegradable spacer needed. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once a sufficient volume is reached, the balloon is sealed and left in situ. The balloon spacer is made from a biodegradable polymer and resorbs over a period of about 1 year.

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 2 randomised controlled trials (RCTs), 2 systematic reviews, 1 case-control study, 1 retrospective comparative study and 3 case series. 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: improvement in shoulder function, reduction in pain and patient-reported outcomes.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection and reduction in range of shoulder motion.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that there was strong evidence from a UK-based, group-sequential, double-blind multicentre RCT. It found that biodegradable subacromial spacer insertion was inferior to debridement alone and did not improve the primary outcome of

Oxford Shoulder Score at 12 months. The study was stopped early because of futility. The result of this study was the main factor in the committee's decision to recommend that the procedure should not be used when debridement is a suitable option. The committee also understood that there is some uncertainty among experts about the benefit of debridement compared with non-surgical care.

3.6 The committee noted that another RCT had conflicting findings and showed non-inferiority of the procedure compared with partial rotator cuff repair. Patient selection may have contributed to these conflicting results, so more research is needed in other populations, and the committee made recommendation 1.4 on the importance of patient selection.

3.7 The committee was informed that biodegradable subacromial spacer insertion for rotator cuff tears may have a role in people with a rotator cuff tear who also have inflammatory arthritis. This may be because mobilisation and reintroduction of biological medicines can happen sooner after surgery than with other procedures.

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Chair, interventional procedures advisory committee
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