NICE guidance

Biodegradable subacromial spacer insertion for rotator cuff tears

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg775

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 IPG558.

1 Recommendations

When debridement is a suitable option

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.

When debridement is not a suitable option

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 ideally be randomised controlled trials. It should report details of patient selection (including demographics and the tear size), measures of shoulder function, pain relief and quality of life. Follow up should ideally be for at least 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 tendons. 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 place. The balloon spacer is made from a biodegradable polymer and resorbs over 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 the 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 debridement with 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 showed non-inferiority of the procedure compared with partial rotator cuff repair. It concluded that more research is needed to address the uncertainties about the long-term safety and efficacy of the procedure.

3.7 The committee was informed that this procedure should not be used in people with a missing or non-intact coracoacromial ligament.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation