NICE guidance

Biodegradable subacromial spacer insertion for rotator cuff tears

Interventional procedures guidance
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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. However, 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.

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.

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.

1 Recommendations

1.1 Current evidence on the efficacy and safety of biodegradable subacromial

spacer insertion for rotator cuff tears is limited in quantity and quality. 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 may include collaborative data collection and clinical trials. Patient selection should be clearly documented. Outcomes of interest include measures of shoulder function, pain relief and quality of life. All complications should be reported. Follow-up should ideally be for a minimum of 2 years.

2 Indications and current treatments

2.1 Patients with rotator cuff tears may have shoulder pain and weakness accompanied by functional limitation 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 confirmed by ultrasound or MRI.

2.2 Conservative treatment may include physical therapy, pharmacological treatments (including pain relief and topical or oral non-steroidal anti-inflammatory drugs) 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.

3 The procedure

3.1 Biodegradable subacromial spacer insertion aims to improve pain symptoms and restore shoulder function in patients who have irreparable rotator cuff tears. The intention is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It aims to be a less invasive and potentially safer alternative to tendon transfer or shoulder arthroplasty, with shorter procedure and rehabilitation times.

3.2 Biodegradable subacromial spacer insertion is done with the patient under general or regional anaesthesia. The subacromial space is visualised using either

arthroscopy or minimal access open surgery. A surgical clearance of the damaged area is carried out. Measurements are made to determine the required size of the biodegradable spacer. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once 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.

4 Efficacy

This section describes efficacy 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 interventional procedure overview.

4.1 A prospective case series of 20 patients with massive irreparable rotator cuff tear reported a significant increase in total Constant score (0 to 100, from worst to best outcomes) of 31.54 points 3 years after the procedure ($p<0.0001$). No improvement in the total Constant score was reported in 10% (2/20) of patients; MRI of these 2 patients 3 years after implantation showed suspected synovitis without cystic formation (reported in section 5.2).

4.2 The prospective case series of 20 patients also reported the following significant findings 3 years after the procedure (all $p<0.0001$): an increase in activity of daily living score (0 to 20, from worst to best) of 9.24 points; an increase in range of motion score (0 to 40, from worst to best) of 8.1 points; an increase in power score (0 to 25, from worst to best) of 7.19 points; an increase in subjective pain score (0 to 15, from worst to best) of 6.44 points; and an increase in night pain score of 1.05 points (scale not given).

4.3 The specialist advisers listed key efficacy outcomes as decrease in pain (particularly at night), increase in range of movement and improvement in shoulder function.

4.4 Three commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes 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 interventional procedure overview.

5.1 Severe pain immediately after the procedure was reported in 6% (2/32) of patients in a case series of 32 patients with massive irreparable rotator cuff tear. The pain improved 6 weeks after the procedure. Anterior shoulder pain was reported in 6% (2/32) of patients in the same case series of 32 patients. The cause of the pain may have been device displacement (reported in section 5.4).

5.2 Suspected synovitis without cyst formation was reported in 2 patients 3 years after implantation (seen on MRI) in a prospective case series of 20 patients with massive irreparable rotator cuff tear (no further details given). Local inflammation or suspected aseptic synovitis was reported in 6% (3/50) of patients in a prospective case series of 50 patients with massive rotator cuff tear (no further details reported).

5.3 Deterioration in shoulder function was reported in 1 patient in the prospective case series of 50 patients with massive rotator cuff tear; the device was removed (no further details reported).

5.4 Displacement of the device was reported in 1 patient in the prospective case series of 50 patients (no further details reported). Suspected displacement of the device was reported in 6% (2/32) of patients in the case series of 32 patients.

5.5 A technical issue with the device during the procedure was reported in 1 patient in the case series of 32 patients. The device had to be changed for another device.

5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers reported bursting of the balloon as an anecdotal adverse event. They considered that the following were theoretical adverse events: nerve injury, balloon rejection and

inflammatory response, infection, increased pain, and secondary bony changes (erosion).

6 Committee comments

6.1 The committee noted that current evidence is from small numbers of patients and is restricted to patients with massive, full thickness rotator cuff tears.

6.2 The committee noted from the published literature and the comments received from patients who had had biodegradable subacromial spacer insertion for rotator cuff tears that it appears to cause pain lasting a few weeks after the procedure.

7 Further information

7.1 For related NICE guidance, see the NICE website.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). 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.

Accreditation