NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Superior capsular augmentation for massive rotator cuff tears

The rotator cuff is a group of muscles and tendons that surround the shoulder joint and help to keep it stable. A tear in a rotator cuff tendon can cause pain, limit arm movement and may lead to arthritis. This procedure involves using a graft to fix the top of the shoulder socket to the top of the upper arm bone when the muscles and tendons are no longer repairable. The aims are to stabilise the shoulder joint, reduce pain and improve shoulder function.

The National Institute for Health and Care Excellence (NICE) is looking at superior capsular augmentation for massive rotator cuff tears. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the <u>Interventional Procedures Programme process</u> guide.

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Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

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

Closing date for comments: 19 April 2018

Target date for publication of guidance: July 2018

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of superior capsular augmentation for massive rotator cuff tears is limited in quantity and inadequate in quality. Therefore, this procedure should only be used in the context of research.
- Research should address patient selection, type of graft and technique used, long-term outcomes including shoulder function, and patient-reported outcome measures.

2 The condition, current treatments and procedure

The condition

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 by ultrasound or MRI.

Current treatments

2.2 Conservative treatment may include physiotherapy, 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, bridging rotator cuff reconstruction, subacromial smoothing, tendon transfer, or shoulder arthroplasty may be needed.

The procedure

2.3 Superior capsular augmentation aims to improve pain symptoms and shoulder function in patients with massive and otherwise irreparable rotator cuff tears. The intention is to reduce superior gleno-humeral translation and restore superior stability with minimal re-tear rates. The optimal repair uses the patient's own rotator cuff muscles and tendons, but if the tear is too large augmentation with other tissue may be needed. 2.4 Superior capsular augmentation is done arthroscopically or by open surgery with the patient either in the lateral decubitus position, or the 'beach-chair' position, and under general anaesthesia. It involves using a fascia lata autograft, an allograft or a regenerative tissue matrix. The arm of the patient is kept in neutral abduction and in neutral rotation. The supraspinatus and infraspinatus are repaired as much as possible and a biceps tenotomy or tendonesis are done on any biceps tear or instability. The superior glenoid and greater tuberosity are debrided to prepare for reconstruction. Using suture anchors, the graft is attached medially to the glenoid superior tubercle and laterally to the greater tuberosity. Side-to-side sutures between the graft and the infraspinatus tendon, as well as between the graft and the residual anterior supraspinatus/subscapularis may also be added to improve force coupling. Post-operative rehabilitation is essential and can be long and difficult.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 4 sources, which was discussed by the committee. The evidence included 2 case series and 1 case report, and is presented in table 2 of the <u>interventional procedures</u> <u>overview</u>. The committee also considered safety data from 1 conference abstract. Other relevant literature is in the appendix of the overview.

Page 4 of 6

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in pain, improvement in shoulder function and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: graft failure, infection, suture and anchor detachment.

Committee comments

- 3.4 Various types of grafts have been used for this procedure.
- 3.5 The committee was advised that patients having this procedure should have intensive physiotherapy done by a physiotherapist specialised in shoulder rehabilitation, before and after the procedure.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee March, 2018

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