

ARTHROSCOPIC SUBACROMIAL DECOMPRESSION (ASD) IN ADULTS WITH IMPAIRED FUNCTION AND PAIN IN THE AFFECTED SHOULDER JOINT

Questions to be addressed

1. What is the evidence of clinical and cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint?

Reason for review

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, in partnership with Walsall, Wolverhampton and Dudley CCGs, requested a rapid evidence review of the clinical and cost effectiveness of arthroscopic subacromial decompression surgery for adults with functional impairment and pain in the affected shoulder. The review was requested because of recent published evidence, as well as a reported increase in the number of procedures being performed.

Options for commissioners:

1. Due to the lack of evidence for the clinical effectiveness for arthroscopic shoulder decompression (ASD) compared to no treatment, develop a commissioning policy that considers ASD followed by physiotherapy for patients with subacromial pain which has not responded to previous non-operative treatment to be a Low Priority.
2. Due to insufficient volume of evidence demonstrating that ASD is no more effective than either no treatment or physiotherapy alone, continue to routinely commission ASD for patients with subacromial pain who have failed to respond to conservative treatment, including joint injection with corticosteroid, until more evidence is available.

Summary

Refer to glossary in appendix 1 for descriptions of shoulder assessment instruments and outcomes.

Background

- 2.4% of all GP visits in England in 2000 were for shoulder pain. Shoulder impingement syndrome (SIS) is marked by subacromial pain, particularly when the arm is raised [1]. It is due to the impingement of rotator cuff tendons in the subacromial space between the head of the humerus and the inferior surface of the acromion. It is one of the most common types of shoulder pain and accounts for up to 70% of all shoulder pain problems [2].
- Arthroscopic subacromial decompression (ASD) is commonly offered to patients with SIS. It aims to relieve the pain by creating more space for the rotator cuff tendon[3].

- The procedure involves antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone.
- ASD is reported to have increased more than seven-fold between 2000 and 2010 in the NHS in England [4].

Clinical effectiveness

Shoulder Impingement Syndrome (SIS)

- Three randomised controlled trials (RCTs) compared ASD to conservative treatment for patients with SIS and no full thickness tear of the rotator cuff at 12 or 24 months [4,6,7]. Patients with partial thickness rotator cuff tears were not excluded from any of the RCTs. One compared ASD plus physiotherapy to physiotherapy alone (n=140) [7], whereas in the FIMPACT [6] and CSAW [4] RCTs (n=210 and n=313 respectively), there were three treatment arms. Both of these studies compared ASD plus physiotherapy to diagnostic arthroscopy plus physiotherapy. However, in the UK based CSAW RCT, surgery was compared to no treatment at all, whereas in the FIMPACT RCT, the non-operative comparator included a home exercise regime as well as 15 physiotherapy visits.
 - ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. Two RCTs reported no clinically significant difference at either 12-month follow-up [4] or 24 months [6]. This was consistent for all of the outcomes measured: Oxford Shoulder Score (OSS), Constant score, pain, depression and anxiety, health-related quality of life, simple shoulder test and 15D as well as patient satisfaction with the allocated treatment.
 - ASD plus physiotherapy versus no treatment: Although some relatively small differences were seen in favour of ASD plus physiotherapy, there were no clinically important differences for any outcomes measured at 12 months between ASD plus up to four sessions of physiotherapy compared to no treatment at all [4].
 - ASD plus physiotherapy versus physiotherapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7].
- Within each treatment group, all three trials showed clinically significant improvement at 12 or 24 months, when compared to baseline for the OSS, modified Constant score^a and pain [4,6,7].
- Lack of blinding of patients and assessors may have biased the results in favour of surgery. Despite this, the potential confounding did not result in better outcomes for people receiving ASD compared to those receiving conservative treatment for SIS, even though they have previously failed to respond adequately to conservative management.

^a The authors refer to the modified Constant Score but it is not clear how it differs from the Constant Score (also called the Constant-Murley Score). Both the CSAW study publication [4] and the CSAW study protocol [19] reference the 1987 Constant-Murley Score publication [13].

Supraspinatus tendon tear.

- The supraspinatus is one for the four rotator cuff muscles; degeneration of the tendon is associated with impingement on the acromion and subacromial pain.
- One RCT [10] allocated 180 patients with a non-traumatic supraspinatus tear to treatment with arthroscopic acromioplasty (ASD) and physiotherapy, or rotator cuff repair, ASD and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. There were no between group differences for the overall Constant score at 12 months. A statistically significant difference in favour of ASD, with or without the rotator cuff repair, was reported for both the pain and activities of daily living subscores, although there was no difference between surgery and physiotherapy for range of motion, strength or patient satisfaction.

Safety

- Study related complications were reported in two recent RCTs [4, 6]. There were no serious adverse events.
- Six out of the 274 patients in the intention to treat analysis of the CSAW RCT developed frozen shoulder, two in each of the three treatment groups (ASD, arthroscopy only and no treatment) [4]. There was no difference in the incidence of complications between the three treatment groups in the CSAW RCT ($p > 0.9999$ for all comparisons)
- Of the 210 patients recruited to the FIMPACT RCT, adverse events were reported for eight patients at 24 month follow-up. Six events were due to frozen shoulder: three had been treated with ASD, one with diagnostic arthroscopy only and two with physiotherapy. There was no difference between the three treatment groups for adverse events [6].

Cost effectiveness

- There are no studies generalisable to the NHS which measure the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Equity issues

- There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs.
- For the period April 2017 to March 2018, patients registered with a GP in Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population. In contrast, Sandwell and West Birmingham CCG had the lowest at 67.4 per 100,000 population. Both CCGs are considered outliers due to age sex standardised rates of elective ASD that are more than 3 standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access is not due to chance.

Activity and finance

- For the three full years up to and including March 2018, there were 4,794 adult elective admissions for ASD with or without biceps tenotomy and with or without a rotator cuff repair across all of the Birmingham and Black Country CCGs. 2384

(49.7%) of these admissions included a rotator cuff procedure; 2410 (50.2%) were for ASD without a rotator cuff tendon repair.

- The total cost of admissions for these elective ASD procedures during the three year period April 2015 to March 2018 for all Birmingham and Black Country CCGs was £17,963,651 based on the 2018/19 national tariff. For 2017-2018 only, the Birmingham and Black Country CCGs expenditure for elective ASD procedures was £5,702,943.

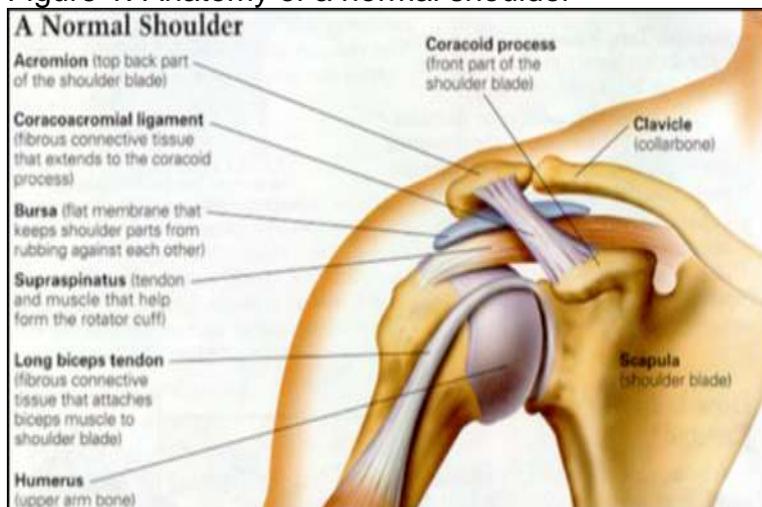
1 Context

1.1 Introduction

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the subacromial space. The illustration of a healthy shoulder joint below (figure 2) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the subacromial space.

Figure 1: Anatomy of a normal shoulder



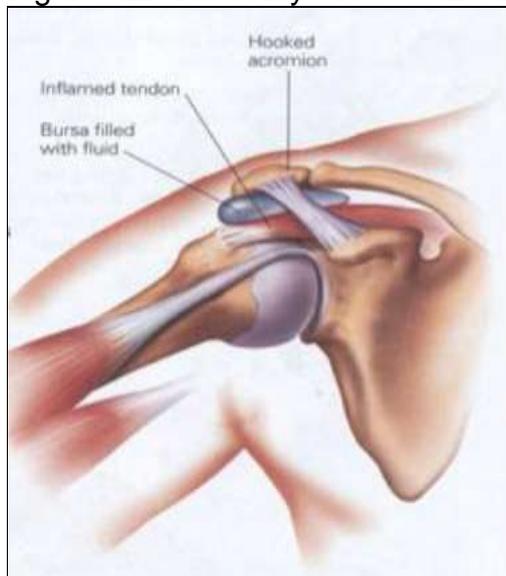
Source: Orthopaedic Surgeons of Long Island Association. Retrieved from http://www.orthomd.com/procedures/impingement_syndrome.html

Shoulder impingement occurs when the tendon rubs or catches on the acromion and the subacromial bursa. Shoulder impingement can start suddenly or come on gradually. As illustrated in figure 2 below, it may occur if

- the tendon is swollen, thickened or torn due to injury, overuse or age-related "wear and tear"
- the subacromial bursa becomes irritated and inflamed (bursitis)

- the acromion is curved or hooked, rather than flat
- there are bony growths (spurs) on the acromion

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



Source: Orthopaedic Surgeons of Long Island Association. Retrieved from http://www.orthomd.com/procedures/impingement_syndrome.html

The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

1.2 Existing national policies and guidance

There are no relevant NICE guidance or guidelines which consider the use of arthroscopic subacromial decompression or arthroscopic acromioplasty for non-traumatic shoulder pain.

2 Epidemiology

Beard et al (2018) reported that painful shoulders accounted for 2.4% of all GP consultations in the UK [4]. This was for a UK cohort identified in 2000. The incidence of new patients consulting their GP for a shoulder condition was 1.47%. Prevalence increased linearly with age whilst incidence peaked at around 50 years of age and then remained static at around 2%. Just under half (47.9%) of the incident cases consulted once only, while 13.6% were still consulting with a shoulder problem during the third year of follow-up. During the 3 year period following initial presentation, 22.4% of patients were referred to secondary care, 30.8% were prescribed non-steroidal anti-inflammatory drugs and 10.6% were given an injection by the GP [5].

Subacromial pain is thought to be responsible for up to 70% of all shoulder pain [6].

3 The interventions

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises. If the pain persists and is unresponsive to conservative treatment including pain medication, exercises and possibly steroid injections, then surgery may be considered.

The term 'arthroscopic' describes any surgical procedure which is performed using surgical instruments inserted through a small 'keyhole' incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a wide range of procedures to different parts of the shoulder anatomy. These may repair damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain excess fluid, or release adhesions.

Arthroscopic subacromial decompression (ASD) which is the focus of this evidence review is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it is may be mildly debrided or left alone [3].

Beard et al (2018) highlighted that in the ten years from 2000 to 2010, the number of patients in England who had ASD increased seven-fold from 2,523 to 21,335 [4].

The focus of this evidence review is on the use of arthroscopic subacromial decompression (ASD) compared to conservative treatment for shoulder pain.

For the purpose of this review, we have standardised key terms, even when an alternative term was used in the original publication.

- Physiotherapy (PT). PT will include written information and guidance on exercises to be conducted at home as well as a number of sessions of physiotherapy or supervised exercise therapy. Some studies used the term exercise therapy (ET).
- Diagnostic arthroscopy (DA). DA refers to the arthroscopic investigation of the joint, rotator cuff tendons and subacromial bursa, but does not involve any further intervention. It has been described in studies as a suitable 'sham' ASD or surgical placebo.
- Arthroscopic Subacromial Decompression (ASD). This will refer to the standard procedures described above, including acromioplasty.

- Shoulder impingement syndrome (SIS). SIS will be used to refer to shoulder pain which in various publications has also been referred to as subacromial impingement syndrome or subacromial pain. It may be accompanied by partial thickness/grade I or II tear of the rotator cuff.

4 Findings

4.1 Evidence of effectiveness

The majority of comparative studies for ASD were for subacromial impingement syndrome. We also included studies where the ASD was performed for shoulder pain due to minor rotator cuff tears.

We selected seven publications from four randomised controlled trials (RCTs) all of which compared arthroscopic subacromial decompression with conservative treatment for shoulder pain, and which met the criteria in the PICO table in section 9. Four of the publications reported results from the same RCT population at four different time intervals.

Three RCTs focused on patients with SIS which had persisted for at least three months duration and had failed to respond to conservative treatment including physiotherapy [4, 6, 7]. These were the CSAW trial (n=313) [4], the FIMPACT trial (n=210)[6] and Ketola et al (2009)(n=140)[7]. All of the patients in the CSAW trial had also failed to respond to at least one steroid injection, whereas in the other studies only a proportion of patients had also failed to respond to a steroid injection [4].

The participants in the RCT by Kukkonen et al (2014) were being treated for symptomatic non-traumatic tears of the supraspinatus tendon (one of the four rotator cuff tendons) [10]. In this study, 180 patients were randomised to ASD and physiotherapy (ASD+PT), ASD and rotator cuff repair and physiotherapy (ASD+RC+PT) or physiotherapy alone (PT). The outcomes were reported at 3, 6 and 12 months after baseline.

The four trials reported outcomes using a wide range of assessment scores including

- Shoulder function status: Oxford Shoulder Score (OSS), Constant-Murley Score (CM), Simple Shoulder Test (SST), Shoulder Disability Questionnaire (SDQ)
- Pain: PainDETECT score and visual analogues scores(VAS)
- Anxiety and Depression: HADS Depression score, HADS Anxiety score
- Health related quality of life (HRQoL): EQ-5D
- 15D score

These outcome scores are described in more detail in Appendix 1.

The detailed results of the randomised controlled trials are reported in table 1.

4.1.1 Clinical effectiveness

CSAW RCT [4]. In this RCT, 313 adults in the UK between September 2014 and June 2015 were randomised for treatment with ASD plus physiotherapy (ASD+PT), diagnostic arthroscopy plus physiotherapy (DA+PT) as a sham or placebo ASD or no treatment at all. All of the patients had subacromial pain of at least 3 months' duration and had completed non-operative management that included physiotherapy and at least one steroid injection. Patients with a full thickness rotator cuff tendon tear were excluded, although patients with a partial thickness tear were included. The postoperative physiotherapy comprised advice and between one and four routine treatment sessions. The patients who were allocated to no treatment at all were scheduled to be reassessed by the study investigators three months after randomisation. The patients were assessed at baseline and at 6 and 12 months.

The three treatment arms evaluated whether ASD plus physiotherapy is superior to physiotherapy alone, as well as if physiotherapy is superior to no treatment and if ASD plus physiotherapy is better than no treatment at all.

The primary outcome for the study was the Oxford Shoulder Score (OSS), a 12 question, 0-48 point patient reported outcome score [12]. This was assessed at 6 months after randomisation. Secondary outcomes were the OSS at 12 months, and six different outcome measures for pain and quality of life assessed at six and 12 months after randomisation.

The intention to treat (ITT) analysis showed that at 6 (n=274) and 12 months (n=265), all three groups had a higher mean OSS compared to the baseline. The baseline mean OSS for ASD+PT, DA+PT and no treatment were 25.2, 26.7 and 25.5 respectively. At 6 months, these scores had improved to 32.7, 34.2 and 29.4 respectively, with further improvement reported at 12 months (38.2, 38.4 and 34.3).

Six months after randomisation, the OSS for ASD plus PT (mean difference (MD) 2.8 (95%CI 0.5 to 5.2), p=0.0186) and DA plus PT (MD 4.2 (95%CI 1.8 to 6.6), p=0.0014) were statistically better than no treatment at all. At 12 months, the mean difference in the OSS for ASD plus PT and for DA plus PT when compared to no treatment, were 3.9 (p=0.0193) and 3.6 (p=0.0193) respectively. Although both ASD and the DA plus physiotherapy were statistically better than no treatment at all at both 6 and 12 months, the mean differences reported are lower than the minimal clinically important difference (MCID) of 6 points [12], therefore supporting the authors' conclusion that the '*differences were not clinically important*'.

There was no difference in OSS between ASD plus PT and DA plus PT at 6 months (ASD+PT vs DA+PT: MD -1.3 (95%CI -3.9 to 1.3), p=0.3141) or at 12 months (ASD+PT vs DA+PT: MD 0.3 (95%CI -2.9 to 3.5), p=0.8571).

The Constant-Murley Score^b. (CS) is a composite functional assessment tool measuring four subscales: Pain (15 points); Activities of daily living (ADL) (20 points); Range of Motion (ROM) (40 points) and Strength (25 points) [13]. The ITT analysis reported that at 6 (n=249) and 12 months (n=227), all three groups had a higher mean CS compared to the baseline. The baseline mean CS for ASD+ET, DA+ET and no treatment were 39.4, 43.1 and 38.3 respectively. At 6 months, these scores had improved to 56.5, 57.6 and 45.4 respectively, with further improvement reported at 12 months (66.2, 64.9 and 56.7).

At 6 months, the mean difference in the modified CS for ASD plus PT and for DA plus PT when compared to no treatment was 9.3 (95%CI 4.1 to 14.6, p=0.0012) and 9.1 (3.1 to 15.2, p=0.0045) respectively. At 12 months, the mean difference in the modified CS for ASD plus PT and for DA plus PT when compared to no treatment was 8.3 (p=0.0067) and 4.9 (p=0.0173) respectively. Although ASD plus PT and the DA plus PT were statistically better than no treatment at 6 and 12 months, the mean differences are lower than the minimal clinically important difference of 11 points [12].

There was no difference in the modified CS between ASD plus PT and DA plus PT at either 6 months (MD 0.3 (95%CI -4.1 to 4.7), p=0.8972) or 12 months (MD 2.7 (95%CI -2.7 to 8.2), p=0.3087).

Pain. At 6 (n=243) and 12 months (n=208), all three groups had a lower mean PainDETECT score [14] compared to baseline. The baseline mean pain score for ASD plus PT, DA plus PT and no treatment were 11.7, 11.0 and 11.9 respectively. At six months, these scores had improved to 8.4, 7.9 and 10.1 respectively, with further improvement reported at 12 months (8.5, 7.3 and 9.8).

At 6 months, the mean difference in the PainDETECT score for ASD plus PT and for DA plus PT when compared to no treatment, was -1.7 (95%CI -3.5 to 0.0), p=0.0559) and -1.9 (-3.7 to 0.0), p=0.0502) respectively. At 12 months, the mean difference in the pain scores for ASD plus PT and DA plus PT when compared to no treatment were -1.5, (p=0.1721) and -1.8 (p=0.1536) respectively). The differences were not statistically or clinically significant.

There was no difference in pain scores between ASD plus PT and DA plus PT at either 6 months (MD 0.1 (95%CI -1.8 to 2.0), p=0.9036) or 12 months (MD 0.4 (95%CI -1.4 to 2.2), p=0.6541).

Depression and anxiety was measured using the HADS (Hospital Anxiety and Depression Scale), a fourteen-item scale; seven of the items relate to anxiety (0-21 points) and seven relate to depression (0-21 points) [15]. The study group reported the depression and anxiety score separately.

Depression. Patients who received either ASD plus PT or DA plus PT had a statistically significantly lower mean depression score at six months compared to the group receiving

^b The authors refer to the Modified-Constant-Murley Score throughout the study, however it is not clear how this differs from the Constant-Murley Score published in 1987 [13]. Both the publication and the study protocol reference the 1987 publication.

no treatment (MD -1.1 (95% CI -1.8 to -0.4), $p=0.0040$ and MD -1.3 (95% CI -2.1 to -0.3), $p=0.0100$ respectively). Although there was a small reduction in HADS depression points for all groups at 12 months when compared to baseline, there was no statistical difference between any of the interventions at 12 months; neither surgical group was better than no treatment at all, and there was no difference in depression score between ASD plus PT and DA plus PT. We noted that the baseline depression scores for ASD plus PT, DA plus PT and no treatment groups were all below 8 points (5.0, 5.0 and 5.7 respectively) and that these are below the cut-off for depression where 8 to 10 points is considered borderline and 11 to 21 points is considered a positive diagnosis of depression.

Anxiety. The outcome for anxiety was similar. At baseline, the mean anxiety scores for all three groups ranged from 6.3 to 6.9, lower than the scores which would indicate anxiety. At 6 and 12 months, there was an improvement in the HADS anxiety scores in all three groups, compared to baseline. There was a statistical improvement in the ASD plus PT group compared to no treatment at 6 months (mean difference -0.8 (95%CI -1.5 to -0.2), $p=0.0168$) but no difference between ASD plus PT and DA plus PT, or between DA plus PT and no treatment. At 12 months' post randomisation, there was no difference between any of the three groups.

Health related quality of life (HRQoL). The EQ-5D is a standardized instrument designed to measure health-related quality of life (HRQoL) [16]. The EQ-5D consists of two parts: a descriptive system comprising five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (for which the EQ-5D-3L has 3 levels of severity for each of the 5 dimensions) together with the EQ-VAS which records self-rated health on a vertical visual analogue scale. The study group reported these two elements of the EQ-5D separately.

From a baseline EQ-VAS score ranging from mean 65.8 to 69.7 points across all three groups, the only significant between group difference in self-reported HRQoL was for ASD plus PT versus no treatment (mean difference 6.4 (95%CI 2.2 to 10.7), $p=0.0043$) at 6 months. This difference was not sustained at 12 months. At 6 months, neither DA plus PT nor no treatment resulted in any significant change to the EQ-VAS score compared to baseline. At 12 months, there was no between group difference; neither surgical group was better than no treatment at all, and there was no difference in EQ-VAS between ASD plus PT and DA plus PT.

At baseline, the mean **EQ-5D-3L Index** for all three groups ranged from 0.50 to 0.55. At 6 months, there was an improved EQ-5D-3L score for both ASD plus PT and DA plus PT compared to no treatment (ASD+PT vs no treatment: 0.12 (0.04 to 0.21), $p=0.0076$; DA+PT vs no treatment : 0.12 (0.02 to 0.21), $p=0.0154$) with no difference between the two surgical intervention groups. At 12 months, there were no between group differences; neither surgical group was better than no treatment at all, and there was no difference in EQ-5D-3L between ASD plus PT and DA plus PT.

FIMPACT RCT. A second, multicentre randomised controlled trial known as FIMPACT was published in July 2018 by Paavola et al (2018) [6]. 210 patients in Finland, aged 35 to 64 years with shoulder impingement syndrome which was unresponsive to conservative treatment, were randomised to three treatment groups between February

2015 and June 2015. These were ASD plus physiotherapy (ASD+PT), diagnostic shoulder arthroscopy plus physiotherapy (DA+PT) or physiotherapy alone. The physiotherapy protocol for the ASD (n=59) and DA (n=63) groups comprised one visit to physiotherapist for instructions on home exercises. Unlike the CSAW trial which offered no treatment at all for the non-operative group, the 71 patients randomised to non-operative received 15 physiotherapy visits as well as instructions for home exercises. Patients were followed up for 24 months.

The primary comparison was for ASD plus PT versus DA plus PT using the primary outcome of shoulder pain at rest and on arm activity measured using a 0-100mm visual analogue score (VAS) where 0 indicated no pain and 100 indicated extreme pain. The MCID was 15 points. No analysis of the comparison between diagnostic arthroscopy and PT was reported.

ASD compared to physiotherapy

Pain. At 24 months, ASD plus one physiotherapy session was statistically better than a course of 15 physiotherapy visits for the two primary outcomes of patient reported perceived pain intensity at rest and during arm activity during the 24 hours preceding the assessment. Both groups reported improvement in pain at rest and during arm activity.

- At baseline, the VAS at rest for ASD plus PT and physiotherapy groups were 41.3 and 41.7 respectively. At 24 months, the VAS at rest for ASD plus PT and physiotherapy groups were 5.3 (95%CI 0.6 to 10.0) and 12.8 (95%CI 8.4 to 17.3). For pain at rest, the mean difference for ASD plus PT versus physiotherapy was -7.5 (-14.0 to -1.0), $p=0.023$.
- At baseline, the VAS during arm activity for ASD plus PT and physiotherapy groups were 71.2 and 72.4. At 24 months, the VAS during arm activity for ASD plus PT and physiotherapy groups were 16.0 (9.6 to 22.5) and 28.1 (22.1 to 34.1). The mean difference for ASD plus PT versus physiotherapy was -12.0 (-20.9 to -3.2), $p=0.008$.
- The change from baseline to 24 months for both VAS pain at rest and pain during arm activity scores exceeded the 15 point minimal clinically important difference (MCID) identified by the study group but the statistical significance of the difference was not calculated.
- For both pain at rest and pain during arm activity, the differences between the two groups did not exceed the MCID (15 points on the 0-100 VAS).

The Constant-Murley Score (CSS). In this RCT, ASD plus PT was superior to physiotherapy alone for function assessment using the CMS. The baseline CMS for ASD plus PT and physiotherapy groups were 32.2 and 35.2 respectively. At 24 months, the CMS for ASD plus PT and physiotherapy groups were 79.1 (74.7 to 83.4) and 71.2 (67.0 to 75.3) with a mean difference of 7.7 (95%CI 1.6 to 13.9), $p=0.013$.

For ASD plus PT compared to a course of physiotherapy sessions, there was no between group difference at 24 months for the simple shoulder test^c ($p=0.12$), the 15D^d score

^c The simple shoulder test (SST), a measure of impairment of activities of daily living, consists of 12 questions with yes (1) or no (0) response options. The maximum SST score is 12 indicating normal shoulder function, minimum score of 0 points refers to severely diminished shoulder function.

($p=1.00$), the proportion of patients able to return to previous leisure activities ($p=0.31$), the proportion of responders ($p=0.23$) or patients' satisfaction with treatment ($p=0.36$). Although ASD plus minimal physiotherapy showed superiority over 15 sessions of physiotherapy alone for pain and the composite Constant Score, these results should be treated with caution as they are inconsistent with the findings that showed no difference between these two groups for the Simple Shoulder Test, the 15D and the proportion of patients able to resume previous leisure activities, or who were satisfied with their treatment.

ASD compared to diagnostic arthroscopy.

For the primary comparison of the ASD and diagnostic arthroscopy treatment groups, both with minimal supervised physiotherapy, there was marked improvement in both groups at 24 months compared to baseline for the following outcomes:

- pain at rest
- pain on arm activity
- Constant score
- SST.

However no analysis of the difference in scores over time was reported.

Importantly, at 24 months, there was no statistically significant difference between the ASD group and the diagnostic arthroscopy group for any outcomes, indicating that the ASD procedure provides no clinically relevant benefit over diagnostic arthroscopy for patients with shoulder impingement syndrome, refractory to conservative treatment.

Ketola et al (2009) reported the results of a single centre RCT in Finland for 140 patients who had grade II subacromial impingement, which had failed conservative therapy [7]. Patients were recruited between June 2001 and July 2004 and randomised to receive either ASD plus physiotherapy ($n=70$) or physiotherapy alone ($n=70$). The mean number of physiotherapy sessions for each group were 7 and 6 respectively. At 2 years follow-up, 14 patients who were initially allocated to receive treatment with PT elected to receive ASD. The change from baseline for self-reported pain, pain at night, disability and working ability were reported using a 0-10 point VAS. Results were reported two years after randomisation.

There was a significant improvement in self-reported pain which exceeded the MCID^e for both the ASD+PT group and the PT group, compared to baseline.

There was no difference between ASD plus PT and PT alone for self-reported pain (ASD+PT vs PT: -3.9 vs -3.7, $p=0.65$). The p -values were not reported for pain at night, disability and working ability; the absolute changes from baseline appear to be similar in the two groups, indicating little or no significant difference between the two groups for these outcomes (changes from baseline for ASD+PT vs PT groups: disability -4.2 vs -3.8; working ability +2.3 vs +2.0; pain at night -4.2 vs -3.8).

^d The 15D instrument is a health-related quality of life instrument with 15 dimensions. The maximum 15D score is 1 (no problems on any dimension) and the minimum score is 0 (being dead).

^e The minimal clinically important difference (MCID) is used to determine whether a medical intervention improves perceived outcomes in patients. The MCID for pain measured on a 0-10 VAS was 2 points, based on previous research [22]

Ketola et al (2009) also reported similar change from baseline for the Shoulder Disability Questionnaire (SDQ)^f for the ASD plus PT and PT groups (change from baseline for ASD+PT vs PT groups: 53.1 vs 50.0, no p-value reported). In addition, they reported no difference in the proportion of pain free patients at two years (ASD+PT vs PT: 0.65 vs 0.64, $p=0.90$) and similar changes from baseline in the number of painful days reported by both groups (ASD+PT vs PT: -55.0 vs -53.3, no p-value reported).

In 2017, Ketola et al [9] reported the long-term follow-up of 90 of the initial 140 patients recruited (64%) for a mean duration of 12.3 years (range 11.0 to 13.8 years). Outcomes data were available for 44/70 patients who had ASD plus PT and 46/70 patients who were allocated to treatment with PT.

There was no significant difference in the VAS scores between ASD plus PT and PT groups for any of the following outcomes: self-reported pain ($p=0.12$), change in pain from 5 to 10 years $p=0.14$, change in pain from 0 to 10 years ($p=0.18$), pain at night ($p=0.19$), disability ($p=0.41$) and working ability ($p=0.57$).

The between group SDQ scores were similar for ASD plus PT and PT treatment groups ($p=0.61$) and for the 15D scores ($p=0.38$). There was no difference between the ASD plus PT and PT groups when asked about the number of painful days that they had experienced during the previous 3 months due to shoulder pain ($p=0.32$) and the number of days on which NSAIDs were taken during the previous 3 months due to shoulder pain ($p=0.47$).

ASD for supraspinatus tears.

Participants in the RCT by Kukkonen et al (2014) were being treated for symptomatic non-traumatic tears of the supraspinatus tendon, rather than shoulder impingement syndrome [10]. In this study, 180 shoulders in 173 patients aged over 55 years were randomised to either ASD followed by physiotherapy (ASD+PT, $n=59$), ASD and rotator cuff repair followed by physiotherapy (ASD+RC+PT, $n=59$) or physiotherapy alone (PT, $n=58$). A biceps tenotomy was also performed in 51% and 42% of the ASD+PT and ASD+RC+PT groups respectively. Due to a 7.2% dropout, the outcomes for 167 shoulders were reported at one year follow-up. The physiotherapy regime for all three groups comprised written instructions to patients for exercises to be conducted at home, as well as 10 sessions with a physiotherapist for supervised and progressive exercises.

There was no significant difference at one year between the three treatment groups in the overall Constant score ($p=0.34$). However, each of the three treatment groups showed a clinically significant improvement^g in the Constant score from baseline to 12 months (ASD+PT: 59.6 to 77.2; ASD+RC+PT: 58.1 to 77.9; PT alone: 57.1 to 74.1). Although there was no statistical analysis for the significance of the improvement within each group, there was a greater than 10.4 point clinically meaningful improvement in the Constant score one year after starting treatment for all three groups.

^f The Shoulder Disability Questionnaire (SDQ) evaluates functional status limitation using self-assessment by patients. The scores range from 0 (no functional limitations) to 100 (affirmative answer to all applicable items) [11].

^g The authors estimated that the smallest clinically significant difference in terms of Constant score is 10.4 points in a cohort of operatively treated rotator cuff tear patients [20]

Analysis of the individual components of the Constant score showed that at one year, the combined surgical groups of patients who had ASD with or without repair of the supraspinatus tendon had statistically better outcomes for pain ($p=0.0321$) and for activities of daily living ($p<0.0001$) compared to those who had physiotherapy alone. However, there was no difference between the combined ASD groups and the PT groups for range of movement ($p=0.74$) or strength ($p=0.76$). Although patient satisfaction was lower for the group who had physiotherapy alone, the difference was not significant (ASD+PT: 96%, ASD+RC+PT:95%, PT:87%, $p=0.14$).

For patients with non-traumatic, symptomatic supraspinatus tears, the authors concluded that at one year follow-up, ASD with or without repair of the supraspinatus tendon plus ten sessions of physiotherapy was no better than conservative treatment with ten sessions of physiotherapy alone.

The improvements seen in all groups could have been due to the 10 sessions of physiotherapy that were in the treatment protocol for all three groups or the natural history of the disease, rather than due to surgery. Patients and hospital staff were not blinded to the treatment received which could have introduced bias, reducing the reliability of the results where between group differences were reported (particularly for the self-reported elements of the Constant score: pain and activities of daily living). The study design attempted to limit bias by using an independent study nurse to record the Constant score at all timepoints. This might explain why significant between group differences were reported for pain and activities of daily living but not for ROM and strength, which might be less subjective. The extent to which differences in individual components of the Constant score, a validated composite shoulder instrument, should be interpreted is not clear, particularly when there are no between group differences for the overall Constant score.

4.1.2 Cost effectiveness

We found no studies which evaluated the cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint.

Two of the RCTs selected for inclusion in this review (both based in Finland) reported the cost of resources used to deliver the health interventions in the study.

For the 92 patients diagnosed with SIS with complete data at 2 year follow-up, the mean health care costs per patient for ASD plus PT and PT only were €2961 and €1864 respectively [7]. ASD plus PT was €1,097 more expensive than PT alone.

The authors reported that the ICER was €5,431 in order to achieve the one MCID unit (equivalent to 2 points difference for pain measured using a 0-10 point VAS). However, since the change in the mean 2-point MCID unit for ASD plus PT and for PT alone was 1.238 and 1.439 respectively (a difference of 0.2 between the groups), it is not clear that the incremental MCID for ASD plus PT over PT alone can be achieved in practice

regardless of the incremental cost of each treatment option. Costs were based on Euros in Finland in 2004 and are unlikely to be generalisable to the NHS in England in 2018.

In the study of patients with symptomatic supraspinatus tears, at 12 month follow-up, the direct costs of 10 sessions of physiotherapy were significantly less expensive than treatment with ASD plus PT (regardless of whether or not the supraspinatus tendon was repaired) ($p < 0.0001$) [10]. The mean cost of ASD plus PT was €4765 (€5709 if supraspinatus was also repaired) compared to €2417 for PT alone. The authors did not specify the dates during which the costs were evaluated, but since the last patient was recruited to the study in December 2012 and the outcomes reported were at 12 month follow-up, it is likely that these costs are the costs associated with treatment in Finland in 2013 and they are unlikely to be generalisable to the NHS in England in 2018.

The authors reported the mean direct cost for patients and the mean indirect societal costs. We have not reported them here as neither are relevant to the NHS setting in England.

Table 1: Summary of randomised controlled trials for use of arthroscopic subacromial decompression compared with conservative treatment for people with shoulder pain with or without a rotator cuff tear.

Study	Patients	Intervention	Comparator	Outcomes
<p>Beard et al 2018 [4]</p> <p>CSAW trial</p> <p>Multicentre, randomised, pragmatic parallel group, placebo controlled, three group trial</p> <p>32 hospitals, 51 surgeons in the UK</p>	<p>n=313 adults</p> <p>Mean age 53.4 yrs</p> <p>With subacromial pain for at least 3 months and with intact rotator cuff based on Consultant clinical diagnosis of tendinopathic pain or partial thickness rotator cuff tear (using local pathways of diagnosis including X rays, MRI scans or ultrasounds)[20].</p> <p>Completed non-operative management including physiotherapy that includes a remedial exercise programme and at least one steroid injection</p> <p>Recruited Sept 2014 to June 2015</p> <p>Excluded: full thickness rotator cuff tear</p> <p>Baseline Scores: Mean (SD), n (if reported)</p> <p>Oxford Shoulder Score</p>	<p>ASD plus physiotherapy (4 sessions) (ASD+PT) (n=106)</p> <p>6 pts had surgery to the acromioclavicular joint or the long head of biceps [22]</p> <p>6 months' post randomisation, 24(23%) pts had not yet received treatment</p> <p>12 months' post randomisation, 19(18%) pts had not yet received treatment</p> <p>Median time to treatment: 90 days (IQR 58-123)</p>	<p>a. Investigational arthroscopy plus physiotherapy (4 sessions) (DA+PT) (n=103)</p> <p>6 months' post randomisation, 43 (42%) pts had not received treatment</p> <p>12 months' post randomisation, 35 (34%) pts had not yet received treatment</p> <p>Median time to treatment: 82 days (IQR56-134)</p> <p>b.No treatment (re-assessment appointment at 3 months only) (n=104)</p> <p>6 months' post randomisation, 12 (12%) pts had not been reassessed</p> <p>12 months' post randomisation, 26(25%)pts had not</p>	<p>Primary outcome: Oxford Shoulder Score</p> <p>Mean (SD), n at 6 months ASD+PT: 32.7 (11.6), n=90 DA+PT: 34.2 (9.2), n=94 No treatment: 29.4 (11.9), n=90</p> <p>Mean difference (95%CI), p value at 6 months ASD vs DA+PT: -1.3(-3.9 to 1.3), 0.3141 ASD+PT vs no treatment: 2.8(0.5 to 5.2), 0.0186^h= not clinically important DA+PT vs no treatment: 4.2(1.8 to 6.6), 0.0014= not clinically important</p> <p>Mean (SD), n at 12 months ASD+PT: 38.2 (10.3), n=88 DA+PT: 38.4 (9.3), n=93 No treatment: 34.3(11.8), n=84</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.3(-2.9 to 3.5), 0.8571 ASD+PT vs no treatment: 3.9(0.7 to 7.1), 0.0193 DA+PT vs no treatment: 3.6(0.6 to 6.6), 0.0193</p> <ul style="list-style-type: none"> At 6 and 12 months, all groups had better mean OSS compared to baseline. <p>Modified Constant-Murley Score</p> <p>Mean (SD), n at 6 months ASD+PT: 56.5 (21.8), n=82 DA+PT: 57.6 (17.7), n=84 No treatment: 45.4(21.3), n=83</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.3(-4.1 to 4.7), 0.8972 ASD+PT vs no treatment: 9.3(4.1 to 14.6), 0.0012 DA+PT vs no treatment: 9.1(3.1 to 15.2), 0.0045</p> <p>Mean (SD), n at 12 months ASD+PT: 66.2 (19.9), n=76 DA+PT: 64.9 (17.2), n=81 No treatment: 56.7(22.1), n=70</p>

^h Minimal clinically important difference (MCID) for the OSS is 6 points [12]

	<p>ASD+PT: 25.2 (8.5) n=106 DA+PT: 26.7 (8.8), n=103 No treatment: 25.5 (8.3), n=104</p> <p>Constant Score ASD+PT: 39.4 (13.9) n=102 DA+PT: 43.1 (15.5), n=101 No treatment: 38.3(14.2), n=100</p> <p>PainDETECT ASD+PT: 11.7 (6.6) n=105 DA+PT: 11.0 (5.9) No treatment: 11.9(6.6), n=100</p> <p>HADS Depression ASD+PT: 5.0 (3.8) n=105 DA+PT: 5.0 (3.7) n=102) No treatment: 5.7(4.2),</p> <p>HADS Anxiety ASD+PT: 6.3 (4.3) DA+PT: 6.3 (4.2) No treatment: 6.9(4.5)</p> <p>EQ VAS ASD+PT: 65.8 (19.4) DA+PT: 69.7 (19.2) No treatment: 64.4(23.2)</p> <p>EQ-5D-3L ASD+PT: 0.52 (0.30), n=105 DA+PT: 0.55 (0.29), n=102 No treatment: 0.50 (0.33)</p>		<p>been reassessed</p> <p>Median time to treatment: 217 days (111-262)</p>	<p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 2.7(-2.7 to 8.2), 0.3087 ASD+PT vs no treatment: 8.3(2.5 to 14.1), 0.0067 DA+PT vs no treatment: 4.9(0.9 to 8.9), 0.0173</p> <p>PainDETECT Score Mean (SD), n at 6 months ASD+PT: 8.4(7.1), n=81 DA+PT: 7.9 (5.7), n=82 No treatment: 10.1(6.3), n=80</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.1(-1.8 to 2.0), 0.9036 ASD+PT vs no treatment: -1.7(-3.5 to 0.0), 0.0559 DA+PT vs no treatment: -1.9(-3.7 to 0.0), 0.0502</p> <p>Mean (SD), n at 12 months ASD+PT: 8.5 (7.1), n=67 DA+PT: 7.3(5.7), n=72 No treatment: 9.8(7.6), n=69</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.4(-1.4 to 2.2), 0.6541 ASD+PT vs no treatment: -1.5(-3.7 to 0.7), 0.1721 DA+PT vs no treatment: -1.8(-4.3 to 0.7), 0.1536</p> <p>HADS Depression Score Mean (SD), n at 6 months ASD+PT: 3.6(4.0), n=88 DA+PT: 3.6(3.9), n=91 No treatment: 5.5(4.4), n=89</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.2(-0.8 to 1.2), 0.6738 ASD+PT vs no treatment: -1.1(-1.8 to -0.4), 0.0040 DA+PT vs no treatment: -1.3(-2.2 to -0.3), 0.0100</p> <p>Mean (SD), n at 12 months ASD+PT: 3.2 (3.5), n=84 DA+PT: 3.5(3.7), n=88 No treatment: 4.4(4.0), n=78</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.1(-0.7 to 0.5), 0.6906 ASD+PT vs no treatment: -0.7(-1.5 to 0.2), 0.1208 DA+PT vs no treatment: -0.5(-1.3 to 0.2), 0.1452</p>
--	--	--	--	---

				<p>HADS Anxiety Score Mean (SD), n at 6 months ASD+PT: 5.1(4.0), n=87 DA+PT: 5.6(4.6), n=92 No treatment: 6.7(4.7), n=88</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: -0.1(-1.0 to 0.8), 0.7368 ASD+PT vs no treatment: -0.8(-1.5 to -0.2), 0.0168 DA+PT vs no treatment: -0.6(-1.4 to 0.1), 0.1096</p> <p>Mean (SD), n at 12 months ASD+PT: 5.2(4.1), n=83 DA+PT: 5.7(4.5), n=87 No treatment: 5.9(4.2), n=81</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.1(-0.9 to 0.6), 0.7474 ASD+PT vs no treatment: -0.1(-1.0 to 0.8), 0.8220 DA+PT vs no treatment: 0.0(-1.0 to 1.1), 0.9215</p> <p>EQ VAS Mean (SD), n at 6 months ASD+PT: 74.2(20.3), n=89 DA+PT: 72.8(20.2), n=93 No treatment: 67.8(22.1), n=89</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 3.1(-3.5 to 9.7), 0.3393 ASD+PT vs no treatment: 6.4(2.2 to 10.7), 0.0043 DA+PT vs no treatment: 3.4(-1.4 to 8.2), 0.1601</p> <p>Mean (SD), n at 12 months ASD+PT: 73.7(21.0), n=85 DA+PT: 75.9(20.0), n=91 No treatment: 73.4(22.4), n=82</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: -0.4(-4.4 to 3.7), 0.8530 ASD+PT vs no treatment: 0.0(-4.3 to 4.2), 0.9947 DA+PT vs no treatment: 0.3(-5.1 to 5.7), 0.9050</p> <p>EQ-5D-3L Index Mean (SD), n at 6 months ASD+PT: 0.65(0.29), n=89</p>
--	--	--	--	---

				<p>DA+PT: 0.67(0.26), n=93 No treatment: 0.52(0.36), n=89</p> <p>Mean difference(95%CI), p value at 6 months ASD+PT vs DA+PT: 0.00(-0.09 to 0.08), 0.9308 ASD+PT vs no treatment: 0.12(0.04 to 0.21), 0.0076 DA+PT vs no treatment: 0.12(0.02 to 0.21), 0.0154</p> <p>Mean (SD), n at 12 months ASD+PT: 0.74(0.28), n=86 DA+PT: 0.73(0.27), n=92 No treatment: 0.66(0.33), n=80</p> <p>Mean difference(95%CI), p value at 12 months ASD+PT vs DA+PT: 0.04(-0.03 to 0.10), 0.2750 ASD+PT vs no treatment: 0.08(0.00 to 0.16), 0.0517 DA+PT vs no treatment: 0.05(-0.04 to 0.13), 0.2644</p> <p>Complications (study related) ASD+PT: 2 DA+PT: 2 no treatment: 2</p> <p>Complications (unrelated) ASD+PT: 1 DA+PT: 2</p>
<p>Paavola et al 2018 [6]</p> <p>FIMPACT</p> <p>Multicentre, three group, randomised, double blind sham controlled trial</p> <p>3 orthopaedic clinics in Finland</p>	<p>n=210 at first randomisation n=193 after 2nd randomisation (n=17 excluded)</p> <p>Adults aged 35 to 65 years</p> <p>Symptoms of shoulder impingement syndrome (concomitant grade I or II) for more than 3 months, unresponsive to conventional conservative treatment, partial thickness RCT were</p>	<p>ASD within 12 wks after randomisation+ one visit to physiotherapist /home exercises (ASD+PT) (n=59)</p>	<p>a. Diagnostic Arthroscopy within 12 wks after randomisation + one visit to physiotherapist /home exercises (DA+PT) (n=63)</p> <p>b. PT within 2 weeks - 15 physiotherapy sessions +home exercises (n=71)</p>	<p>At 2 years f/up ASD+PT: n=59 DA+PT: n=59 PT: n=68</p> <p>For ASD+PT vs Diagnostic Arthroscopy (DA+PT) Pain at rest (VAS 0-100) Mean (95%CI) ASD+PT: 5.3(0.8 to 9.7) DA+PT: 9.9(5.4 to 14.3) ASD+PT vs DA: -4.6(-11.3 to 2.1), p=0.18</p> <p>Pain on arm activity (VAS 0-100) Mean (95%CI) ASD+PT: 15.8(9.4 to 22.2) DA+PT: 24.8(18.4 to 31.2) ASD+PT vs DA: -9.0(-18.1 to 0.2), p=0.054</p> <p>Constant-Murley Score Mean (95%CI) ASD+PT: 77.9(73.7 to 82.3) DA+PT: 73.7(69.5 to 78.0)</p>

	<p>included in the study</p> <p>Recruited 1 Feb 2015 to 25 June 2015</p> <p>Full or partial thickness tears (grade III/IV) were excluded</p> <p>Baseline, 3,6,12,24 months after randomisation. Data and analysis reported at 24 months only.</p>			<p>ASD+PT vs DA: 4.3(-20. to 10.5), p=0.18</p> <p>Simple shoulder test Mean (95%CI) ASD+PT: 10.3(9.7 to 10.9) DA+PT: 9.9(9.3 to 10.5) ASD+PT vs DA: 0.5(-0.4 to 1.3), p=0.29</p> <p>15D score Mean (95%CI) ASD+PT: 0.92(0.91 to 0.93) DA+PT: 0.92(0.91 to 0.93) ASD+PT vs DA: 0.0(-0.02 to 0.02), p=1.00</p> <p>Proportion of pts able to return to previous leisure activities Mean (95%CI) ASD+PT: 0.82(0.72 to 0.92) DA+PT: 0.77(0.66 to 0.88) ASD+PT vs DA: 0.06(-0.10 to 0.22), p=0.45</p> <p>Proportion of responders Mean (95%CI) ASD+PT: 0.95(0.89 to 1.0) DA+PT: 0.91(0.84 to 0.99) ASD+PT vs DA: 0.04(-0.06 to 0.14), p=0.42</p> <p>Pts' satisfaction with treatment Mean (95%CI) ASD+PT: 88.1(82.9 to 93.3) DA+PT: 87.1(81.9 to 92.3) ASD+PT vs DA: 0.9(-6.6 to 8.3), p=0.82</p> <p>For ASD+PT vs PT VAS at rest Mean (95%CI) ASD+PT: 5.3(0.6 to 10.0) ET: 12.8(8.4 to 17.3) ASD+PT vs PT: -7.5(-14.0 to -1.0), p=0.023</p> <p>VAS, on arm activity Mean (95%CI) ASD+PT: 16.0(9.6 to 22.5) ET: 28.1(22.1 to 34.1) ASD+PT vs PT: -12.0(-20.9 to -3.2), p=0.008</p> <p>Constant-Murley Score Mean (95%CI) ASD+PT: 79.1(74.7 to 83.4) ET: 71.2(67.0 to 75.3) ASD+PT vs PT: 7.7(1.6 to 13.9), p=0.013</p> <p>Simple shoulder test Mean (95%CI) ASD+PT: 10.3(9.7 to 10.9) ET: 9.7(9.1 to 10.2) ASD+PT vs PT: 0.7(-0.2 to 1.5), p=0.12</p>
--	---	--	--	---

				<p>15D score Mean (95%CI) ASD+PT: 0.91(0.90 to 0.93) ET: 0.91(0.90 to 0.92) ASD+PT vs PT: 0.00(-0.02 to 0.02), p=1.00</p> <p>Proportion of pts able to return to previous leisure activities Mean (95%CI) ASD+PT: 0.82(0.72 to 0.92) ET: 0.76(0.65 to 0.86) ASD+PT vs PT: 0.07(-0.07 to 0.21), p=0.31</p> <p>Proportion of responders Mean (95%CI) ASD+PT: 0.95(0.90 to 1.01) ET: 0.90(0.81 to 0.98) ASD+PT vs PT: 0.06(-0.04 to 0.16), p=0.23</p> <p>Pts' satisfaction with treatment Mean (95%CI) ASD+PT: 88.2(82.8 to 93.5) ET: 84.9(79.9 to 89.8) ASD+PT vs PT: 3.3(-3.9 to 10.5), p=0.36</p> <p>Complications and adverse events (n/%) ASD+PT: 3/5 DA: 2/3 ET: 3/4</p>
<p>Ketola et al 2009 [7]</p> <p>Prospective RCT</p> <p>1 surgeon</p>	<p>n=140</p> <p>Grade II subacromial impingement syndrome, symptoms for at least 3 months not relieved by conservative treatment (including NSAIDs, subacromial cortisone injections (59% patients)</p> <p>Mean duration of symptoms was 2.5 years.</p> <p>Recruited between June 2001 and July 2004</p>	<p>Arthroscopic acromioplasty followed by physiotherapy (ASD+PT) (n=70)</p> <p>Mean number of physiotherapy visits =6</p> <p>Baseline scores (mean VAS 0-10)</p> <p>Self-reported pain: 6.4</p> <p>Pain at night:</p>	<p>Supervised physiotherapy alone (PT) (n=70)</p> <p>14 patients crossed over to ASD</p> <p>Mean number of physiotherapy visits =7</p> <p>Baseline scores (mean VAS 0-10)</p> <p>Self-reported pain: 6.5</p> <p>Pain at night: 6.4</p> <p>Disability: 6.5</p> <p>Working ability: 5.9</p>	<p>At 24 months after randomisation: ASD+ET: n=68 /70 ET: n=66/70</p> <p>Self-reported pain (VAS 0-10) mean change from baseline ASD+PT vs PT: -3.9 vs -3.7, p=0.65</p> <p>Disability (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported</p> <p>Working ability (VAS 0-10) mean change from baseline ASD+PT vs PT: +2.3 vs +2.0, no p-value reported</p> <p>Pain at night (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported</p> <p>SDQ score (0-100) mean change from baseline ASD+PT vs PT: -53.1 vs -50.0, no p-value reported</p> <p>Reported painful days, mean change from baseline</p>

	63% female Mean age 47.1 years (23.3 to 60.0) Patients with full thickness rotator cuff tears were excluded	6.2 Disability: 6.3 Working ability: 5.7 Mean SDQ score: 78.0	Mean SDQ score: 82.5	ASD+PT vs PT: -55.0 vs -53.3, no p-value reported Proportion of pain free patients ASD+PT vs PT: 0.65 vs 0.64, p=0.90 Resource utilisation (based on complete data of patients who attended all follow-up visits, n=92) <ul style="list-style-type: none"> • Mean health care costs per patient ASD+PT vs PT: €2961 vs €1864 • Incremental cost: €1097 • Incremental effectiveness: 0.201 unit (1 unit =2 points on the 0-10 VAS) • For ASD+PT vs PT alone: ICER to achieve the MCID of 2 point reduction on the VAS (0-10) for pain = €5431 Given that observed (n=92) mean incremental effectiveness was 0.201 units, it is not clear that a between group MCID equivalent to a 2 point difference on the 0-10 VAS can be realised.
Ketola et al 2016 [8] RCT MRI of shoulder done at baseline and at 5 years Aim: To find out whether operative treatment (ASD) for shoulder impingement syndrome protects from later rotator cuff rupture and if it has an effect on muscle volume	As above	As above	As above	At 5 year f/up ASD+ET: n=57/70 (81%) ET: 52/70 (74%) Change in muscle volume Supraspinatus: ASD+ET vs PT: -7% vs -4%, p=0.6 Subscapularis ASD vs PT: no data reported, p=0.5 Infraspinatus ASD+ET vs PT: no data reported, p=0.9 % patients with fatty degeneration of the muscles at 5 years ASD+ET vs PT: 65% vs 54%, p=0.3 Number of patients who developed a full thickness tear of the supraspinatus tendon at 5 years: ASD+ET vs PT: 8 vs 7 % patients with thickened coracoacromial ligament at 5 years: ASD+ET vs PT: 44% vs 20%, p=0.02
Ketola et al 2017 [9]	As above	As above	As above	At mean time to final review 12.3 years (11.0 to 13.8), n=90/140 (64% of original group) ASD+PT: n=44/70 (63%) PT: 46/70 (66%) No significant difference between groups for: <ul style="list-style-type: none"> • Working status, ASD+PT vs PT: 19(43%) vs 14(30%), p=0.40 • Modified job to accommodate shoulder symptoms, ASD+PT vs PT: 4(9%) vs 10(22%), p=0.14 • No sick leave due to shoulder reason in previous year, ASD+PT vs PT: 43(98%) vs 44(96%), p=0.37

				<ul style="list-style-type: none"> Retired due to shoulder reasons, ASD+PT vs PT: 1(2%) vs 4(9%), p=0.34 Contralateral shoulder symptomatic, ASD+PT vs PT: 30(70%) vs 27(60%), p=0.23 Overall state of health compared to before treatment 'A lot better', ASD+PT vs PT: 23(56%) vs 24(52%), p=0.96 <p>Self-reported VAS for pain, mean(range): ASD vs PT: 2.8(0 to 10) vs 1.8(0 to 7), p=0.12</p> <p>Change in VAS for pain from 5 to 10 yrs, mean(range) ASD vs PT: 2.8(0 to 10) vs 1.8(0 to 7), p=0.14</p> <p>Change in VAS for pain from 0 to 10yrs, mean(range) ASD vs PT: -3.6(-10 to 5) vs -4.5(-10 to 3), p=0.18</p> <p>VAS for pain at night, mean(range) ASD vs PT: 2.5(0 to 10) vs 1.7(0 to 8), p=0.19</p> <p>VAS for disability, mean(range) ASD vs PT: 2.5(0 to 9) vs 2.0(0 to 8), p=0.41</p> <p>VA for working ability, mean(range) ASD vs PT: 7.5(0 to 10) vs 7.2(0 to 10), p=0.57</p> <p>SDQ score, mean(range) ASD vs PT: 23(0 to 100) vs 17(0 to 100), p=0.61</p> <p>Painful days per previous 3 months due to shoulder pain, mean(range) ASD vs PT: 18(0 to 90) vs 12(0 to 90), p=0.32</p> <p>Total days on which NSAIDS were consumed per previous 3 months due to shoulder pain, mean(range) ASD vs PT: 10(0 to 90) vs 7(0 to 85), p=0.47</p> <p>15D mean score ASD vs PT: 0.906 vs 0.886, p=0.38 Shoulder patients vs general population: 0.896 vs 0.922, p<0.001</p>
<p>Kukkonen et al 2014 [10]</p> <p>RCT</p> <p>3 hospitals in Finland</p>	<p>n=180 shoulders (n=173 patients)</p> <p>Non-traumatic symptomatic</p>	<p>Acromioplasty and physiotherapy (10 sessions) (ASD+PT)</p>	<p>Physiotherapy only (10 sessions) (PT)</p> <p>n=58</p>	<p>At one year, 167 shoulders available for analysis (7.2% drop out)</p> <p>PT: 55/58 ASD+PT: 57/59 ASD+RC+PT: 55/59</p> <p>Mean Constant score¹ at baseline and at one year</p>

¹ MCID=10.4 points [20]

Assessment at baseline, 3,6, and 12 months	supraspinatus tendon tear < 75% of tendon insertion	n=59	OR	<table border="1"> <tr> <th>Group</th> <th>baseline</th> <th>At one year</th> </tr> <tr> <td>PT</td> <td>57.1 (SD16.7)</td> <td>74.1(SD 14.2)</td> </tr> <tr> <td>ASD+PT</td> <td>59.6 (SD 13.3)</td> <td>77.2 (SD 13.0)</td> </tr> <tr> <td>ASD+RC+PT</td> <td>58.1 (SD13.2)</td> <td>77.9(SD 12.1)</td> </tr> </table>	Group	baseline	At one year	PT	57.1 (SD16.7)	74.1(SD 14.2)	ASD+PT	59.6 (SD 13.3)	77.2 (SD 13.0)	ASD+RC+PT	58.1 (SD13.2)	77.9(SD 12.1)							
	Group	baseline	At one year																				
PT	57.1 (SD16.7)	74.1(SD 14.2)																					
ASD+PT	59.6 (SD 13.3)	77.2 (SD 13.0)																					
ASD+RC+PT	58.1 (SD13.2)	77.9(SD 12.1)																					
<p>Mean duration of symptoms ranged from 26(SD 9.9) to 28(SD9.7) months.</p> <p>Recruited between October 2007- December 2012</p> <p>51% female Mean age 65 years</p>	29 patients (51%) also had biceps tenotomy	<p>Rotator cuff repair, acromioplasty and physiotherapy (10 sessions) (ASD+RC+PT) n=59</p> <p>23 patients (42%) also had biceps tenotomy</p>	<p>Constant sub scores at one year for physiotherapy vs both surgery groups combined In favour of ASD+PT with or without supraspinatus tendon repair</p> <ul style="list-style-type: none"> • Pain, p=0.0321 • Activities of daily living, p<0.0001 <p>No significant difference</p> <ul style="list-style-type: none"> • Range of movement, p=0.74 • Strength, p=0.76 • Patient satisfaction: PT(87%), ASD+PT (96%) & ASD+RC+PT (95%), p=0.14 <p>Cost of treatment</p> <table border="1"> <tr> <th>Group</th> <th>Mean cost of treatment</th> <th>Mean direct cost for the patients</th> <th>Mean indirect societal cost</th> </tr> <tr> <td>PT</td> <td>€2417 (SD 1443)</td> <td>€427</td> <td>€2130</td> </tr> <tr> <td>ASD+PT</td> <td>€4765 (SD 896)</td> <td>€486</td> <td>€4486</td> </tr> <tr> <td>ASD+RC+PT</td> <td>€5709</td> <td>€456</td> <td>€5461</td> </tr> <tr> <td></td> <td>p<0.0001</td> <td>p=0.96</td> <td>p<0.0001</td> </tr> </table> <p>Costs not generalisable to UK</p>	Group	Mean cost of treatment	Mean direct cost for the patients	Mean indirect societal cost	PT	€2417 (SD 1443)	€427	€2130	ASD+PT	€4765 (SD 896)	€486	€4486	ASD+RC+PT	€5709	€456	€5461		p<0.0001	p=0.96	p<0.0001
Group	Mean cost of treatment	Mean direct cost for the patients	Mean indirect societal cost																				
PT	€2417 (SD 1443)	€427	€2130																				
ASD+PT	€4765 (SD 896)	€486	€4486																				
ASD+RC+PT	€5709	€456	€5461																				
	p<0.0001	p=0.96	p<0.0001																				

Abbreviations: ASD: arthroscopic subacromial decompression, CI, confidence interval, DA: diagnostic arthroscopy, HrQoL: Health related quality of life, IQR: interquartile range, MCID: minimal clinically important difference, OSS: oxford shoulder score, PT: physiotherapy, pts: patients, RC: rotator cuff, RCT: randomised controlled trial, SD: standard deviation, SDQ, shoulder disability questionnaire, VAS: visual analogue scale, Vs: versus, wks: weeks, yrs: years

Terminology: For the purpose of this review, we have standardised key terms, even when an alternative term was used in the original publication.

- Physiotherapy (PT). PT will include written information and guidance on exercises to be conducted at home as well as a number of sessions of physiotherapy or supervised exercise therapy. Some studies used the term exercise therapy (ET).
- Diagnostic arthroscopy (DA). DA refers to the arthroscopic investigation of the joint, rotator cuff tendons and subacromial bursa, but does not involve any further intervention. It has been described in studies as a suitable 'sham' ASD or surgical placebo.
- Arthroscopic Subacromial Decompression (ASD). The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the subacromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it is may be mildly debrided or left alone [3].
- Shoulder impingement syndrome (SIS). SIS will be used to refer to shoulder pain which in various publications has also been referred to as subacromial

4.2 Safety

Adverse events or complications were only reported in two of the randomised controlled trials detailed in table 1.

In the CSAW RCT, six patients out of the 274 in the intention to treat analysis developed frozen shoulder (two in each of the three treatment populations (ASD+PT, DA+PT and no treatment). These were considered to be study related complications. There was no difference between the three treatment groups ($p > 0.9999$ for all comparisons) [4].

Of the 210 patients recruited to the FIMPACT RCT, adverse events were reported for 8 patients at 24 month follow-up. Six events were due to frozen shoulder: three had been treated with ASD, one with diagnostic arthroscopy only and two with physiotherapy. There was no difference between the three treatment groups for adverse events [6].

4.3 Summary of findings

Clinical Effectiveness.

Subacromial impingement syndrome (SIS).

Three well-conducted, randomised controlled trials compared ASD to conservative treatment for patients with SIS which had failed to respond to conservative treatment at 12 or 24 months [4,6,7]. Ketola et al (2009) compared ASD plus PT to PT alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both the three-arm studies compared ASD plus PT to diagnostic arthroscopy plus PT. However, in the UK based multicentre CSAW RCT, arthroscopic surgery was compared to no treatment at all, whereas in the FIMPACT RCT, the non-operative comparator included a home exercise regime as well as 15 physiotherapy visits.

ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. Two RCTs reported the difference in outcomes between ASD and diagnostic arthroscopy, with restricted physiotherapy support to both groups. There was no clinically significant difference at either 12-month follow-up in the CSAW RCT [4] or 24 months [6] for any of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test and 15D. The CSAW study attempted to blind study participants and hospital staff, so that they would not know whether they had had ASD or diagnostic arthroscopy. Subjects were assessed by an independent assessor, and remained clothed in order to conceal the treatment. This may have contributed to the apparent absence of difference in outcomes between the ASD and diagnostic arthroscopy only groups.

ASD plus physiotherapy versus no treatment. There was no clinically important difference for any outcomes measured at 12 months between ASD plus physiotherapy when compared to no treatment at all [4].

ASD plus physiotherapy versus physiotherapy. There was no clinically important difference for any outcomes measured at 24-month follow-up, irrespective of whether the comparator was a mean of 7 sessions [7] or 15 sessions of physiotherapy [6].

It should be noted that the variation in the non-operative treatments from no treatment at all [4] to 15 sessions of structured progressive physiotherapy with prescribed home exercises, should be treated as a potential confounder. In addition, subjects would have been aware of the treatment to which they had been allocated. All of the outcomes measured required some self-reporting, which may be influenced by prior perception that one treatment is better than another. These may have affected the reliability of these results.

Within each treatment group, all three trials showed clinically significant improvement at 12 or 24 months, when compared to baseline for the OSS, (modified) Constant score and pain.

Supraspinatus tear.

There was one RCT where 180 patients with a supraspinatus tear were treated with ASD and physiotherapy, or tendon repair, ASD and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the surgical procedure is more complex, the results are consistent with the studies that assessed the effectiveness of ASD for the management of shoulder impingement syndrome. It is not clear if the lack of benefit of surgery compared to physiotherapy alone is still apparent in the longer-term.

5 Equity issues

There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs.

For the period April 2017 to March 2018, patients registered with a GP in Wolverhampton CCG had the highest age and sex standardised rate at 116.7 per 10,000 population. In contrast, Sandwell and West Birmingham CCG had the lowest at 67.4 per 10,000 population. Both CCGs are considered outliers due to age sex standardised rates of elective ASD that are more than 3 standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access is not due to chance.

6 Activity and financial analysis

This section summarises SUS inpatient admissions for the three years from April 2015 to March 2018 inclusive. Data are presented for activity commissioned by Birmingham and Solihull CCG, Dudley CCG, Sandwell and West Birmingham CCG, Walsall CCG and Wolverhampton CCG (the Birmingham and Black Country CCGs), and show all elective and day case activity for Arthroscopic Subacromial Decompression (ASD) procedures for patients aged eighteen and over.

ASD procedures were defined based on guidance provided in the NHS Digital National Clinical Coding Standards [18], which advises the use of the following codes in combination to identify ASD procedures:

O29.1 Subacromial decompression
AND at least one of
Y76.7 Arthroscopic approach to joint or
W84.4 Endoscopic decompression of joint

In some cases, in addition to these procedures, a tenotomy (T70.2 Tenotomy NEC) is also carried out. These are reported in this section together with ASD procedures without tenotomy.

Further, ASD procedures, with or without tenotomy, may also be carried out in conjunction with rotator cuff procedures, as identified through the procedure codes below. These have been included in reporting shown here, and shown separately to ASD procedures with or without tenotomy, with no rotator cuff procedures.

Rotator cuff procedures:

T79.1 Plastic repair of rotator cuff of shoulder NEC
T79.4 Plastic repair of multiple tears of rotator cuff of shoulder
T79.8 Other specified repair of muscle
T79.9 Unspecified repair of muscle

The procedure code Z54.2 Rotator cuff of shoulder was also used to search for appropriate records.

A dataset of admissions where the combinations of procedures described above were found in either the primary procedure field or any of the subsequent six procedure code fields was produced, containing records for 5,938 admissions for Birmingham and Black Country CCGs between April 2015 and March 2018, and manually reviewed. As a result of this manual review, 1,144 admissions were excluded, as one or more of the procedures shown in Table 2 were present.

Table 2: Procedure codes excluded from analyses after manual review of data

Procedure codes excluded from analyses after manual review of data
O273: Repair of capsule and anterior labrum for stabilisation of glenohumeral joint
O274: Repair of capsule and posterior labrum for stabilisation of glenohumeral joint
O278: Other specified other stabilising operations on joint
T642: Transfer of tendon to tendon NEC
T645: Tenodesis
T658: Other specified excision of tendon
T691: Primary tenolysis
T701: Subcutaneous tenotomy
T709: Unspecified adjustment to length of tendon
T723: Release of constriction of sheath of tendon
T748: Other specified other operations on tendon
T793: Revisional repair of rotator cuff NEC
T794: Plastic repair of multiple tears of rotator cuff of shoulder
W283: Removal of internal fixation from bone NEC
W693: Partial synovectomy
W694: Open biopsy of synovial membrane of joint
W712: Open excision of intra-articular osteophyte
W771: Repair of capsule of joint for stabilisation of joint NEC
W781: Release of contracture of shoulder joint
W784: Limited release of contracture of capsule of joint
W802: Open debridement of joint NEC
W803: Open irrigation of joint NEC
W816: Capsulorrhaphy of joint
W817: Insertion of therapeutic spacer into joint
W833: Endoscopic shaving of articular cartilage
W836: Endoscopic excision of articular cartilage NEC
W847: Endoscopic repair of superior labrum anterior to posterior tear
W891: Endoscopic chondroplasty NEC
Y262: Plastic repair of organ NOC
Y272: Allograft to organ NOC
Y712: Secondary operations NOC
Y713: Revisional operations NOC
Z844: Patellofemoral joint

The main analyses presented here use the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC).

We attempted to include only admissions which matched the procedures relevant to the evidence selected for inclusion in this evidence review i.e. non elective ASD as the main procedure in adults with a diagnosis SIS or shoulder pain. Despite manual sifting of episodes, there may be some activity included in the dataset that should not be (and some excluded that should not be) due to factors such as coding errors, different permutations of coding for ASD, some of which are not clearly defined, ambiguous

coding, etc. It is unlikely that patients with a full thickness rotator cuff tear, unstable shoulder or frozen shoulder were included as we excluded the main procedures for these, even if they were accompanied by ASD.

We included episodes where the main procure was ASD, but this was accompanied by biceps tenotomy, a rotator cuff repair or acromioclavicular joint procedures for which we have not assessed the evidence. In all cases, these were combined with an ASD procedure.

To provide further contextual information, Table 3 shows a detailed breakdown of admissions by each category and subcategories of these. This shows that over the period April 2015 to March 2018 for all of the Birmingham and Black Country CCGs, there were 4,794 adult elective admissions for ASD procedures, of which 2,410 (50.3%) excluded rotator cuff procedures and 2,384 included rotator cuff procedures. Of those excluding a rotator cuff procedure, 284 included a tenotomy procedure, and of those including a rotator cuff procedure, 732 included a tenotomy.

Table 3: ASD elective admissions by category, all Birmingham and Black Country CCGs, April 2015 to March 2018

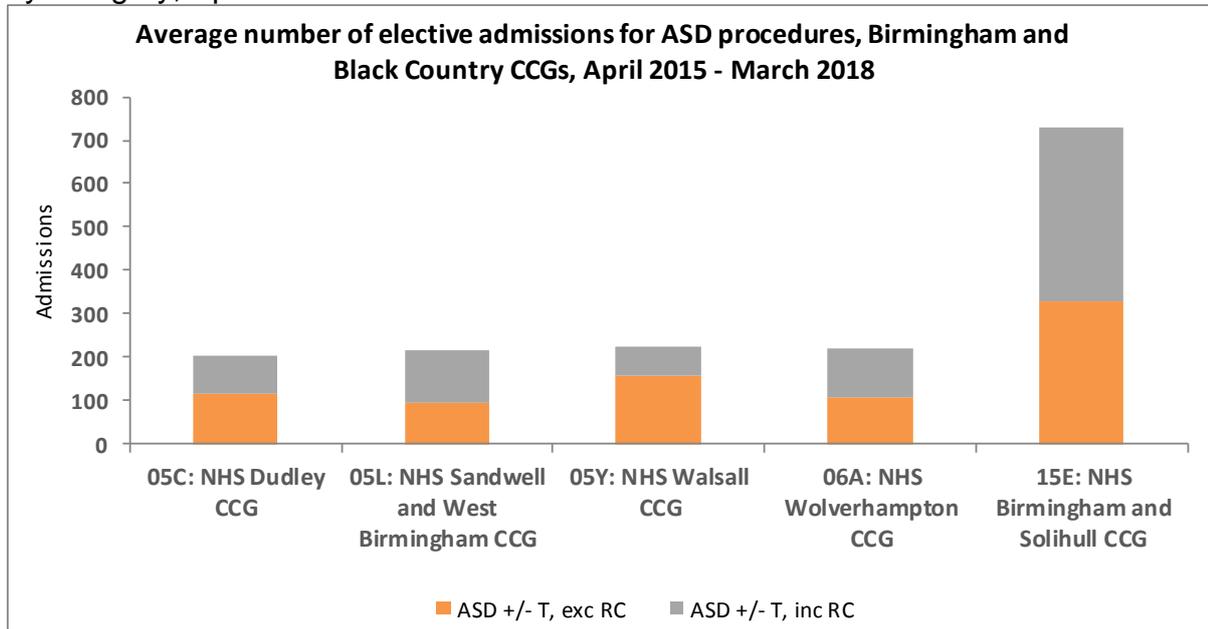
Procedure	Number of admissions
ASD without tenotomy, excluding rotator cuff	2,126
ASD with tenotomy, excluding rotator cuff	284
ASD with or without tenotomy, excluding rotator cuff	2,410
ASD without tenotomy, including rotator cuff	1,652
ASD with tenotomy, including rotator cuff	732
ASD with or without tenotomy, including rotator cuff	2,384
Total	4,794

Table 4 shows the number of elective admissions per year by CCG, by category (ASD +/- T, exc. RC and ASD +/- T, inc. RC), as well as the total elective admissions and average number of elective admissions per year by CCG. The highest average number of elective admissions per year over the period April 2015 to March 2018 was for Birmingham and Solihull CCG, with 730 elective admissions. This is also shown in Figure 1.

Table 4: Number of elective admissions for ASD procedures by CCG, by category, April 2015 to March 2018

CCG	2015/16			2016/17			2017/18			All Years			Avg/yr		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	119	70	189	115	94	209	114	104	218	348	268	616	116	89	205
05L: NHS Sandwell and West Birmingham CCG	105	106	211	105	125	230	79	128	207	289	359	648	96	120	216
05Y: NHS Walsall CCG	144	85	229	166	70	236	160	50	210	470	205	675	157	68	225
06A: NHS Wolverhampton CCG	109	130	239	108	109	217	101	109	210	318	348	666	106	116	222
15E: NHS Birmingham and Solihull CCG	386	409	795	334	404	738	265	391	656	985	1204	2189	328	401	730
Grand Total	863	800	1663	828	802	1630	719	782	1501	2410	2384	4794	803	795	1598

Figure 3: Average number of elective admissions for ASD procedures by CCG per year, by category, April 2015 to March 2018



Figures 4 and 5 below show the trend in the number of elective admissions for the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC).

Figure 4: Number of elective admissions for ASD procedures with or without tenotomy with no rotator cuff procedures

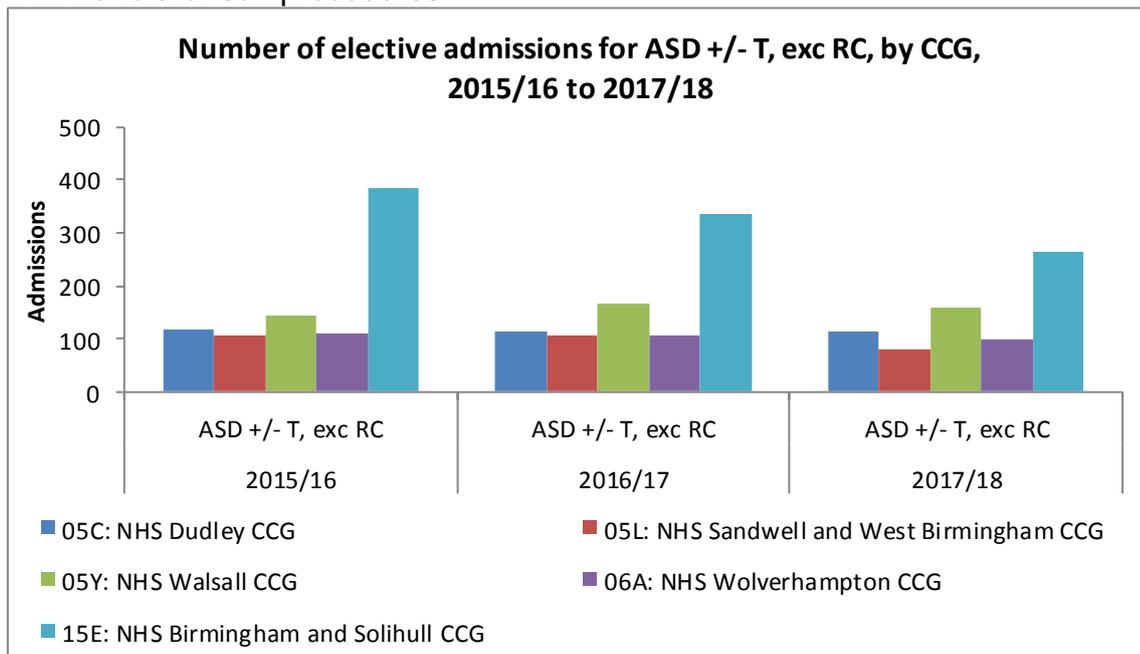


Figure 4 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with no rotator cuff procedures in all three years. However, the number of elective admissions per year has declined from 386 in 2015/16 to 285 in 2017/18. NHS Walsall had the second highest number of elective admissions in all three years.

Figure 5: Number of elective admissions for ASD procedures with or without tenotomy with rotator cuff procedures

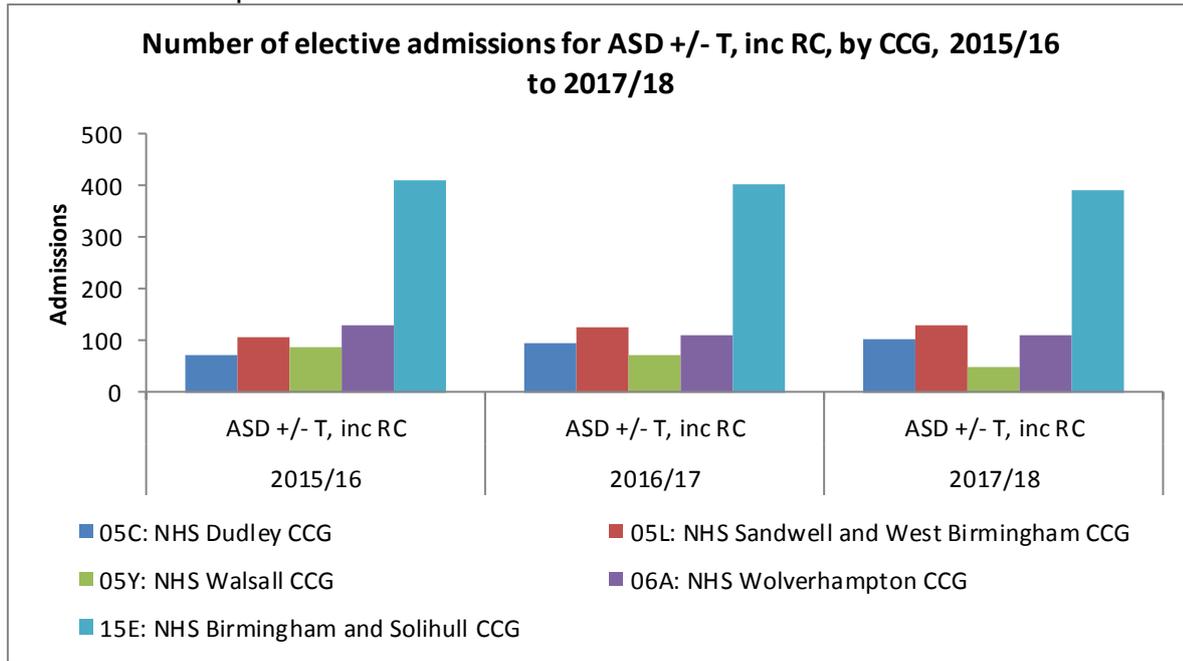


Figure 5 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with rotator cuff procedures in all three years. NHS Walsall CCG had a lower number of elective admissions in 2017/18 than in the previous two years.

Figures 6 and 7 below show the trend in the crude elective admission rate per 10,000 population for the categories of ASD procedures with or without tenotomy, with no rotator cuff procedures (ASD +/- T, exc. RC), and ASD procedures with or without tenotomy, with rotator cuff procedures (ASD +/-T, inc. RC).

Figure 6: Crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy with no rotator cuff procedures

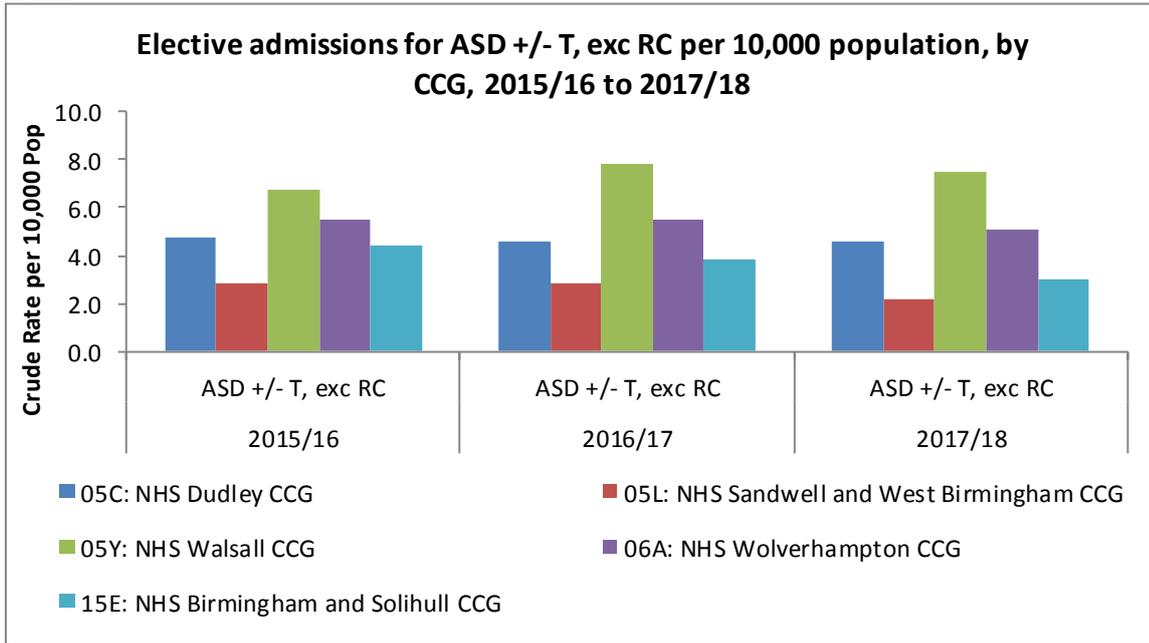


Figure 6 shows that NHS Walsall CCG had the highest crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy, with no rotator cuff procedures in all three years. NHS Sandwell and West Birmingham CCG had the lowest crude elective admission rate per 10,000 population in all three years and the rate decreased over this time period.

Figure 7: Crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy with rotator cuff procedures

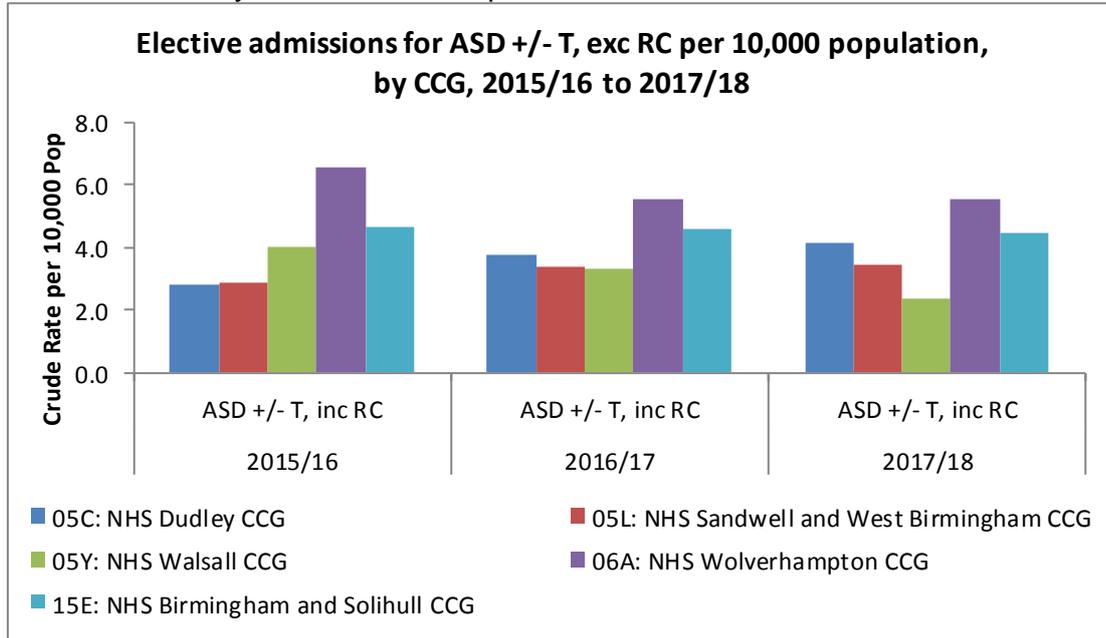


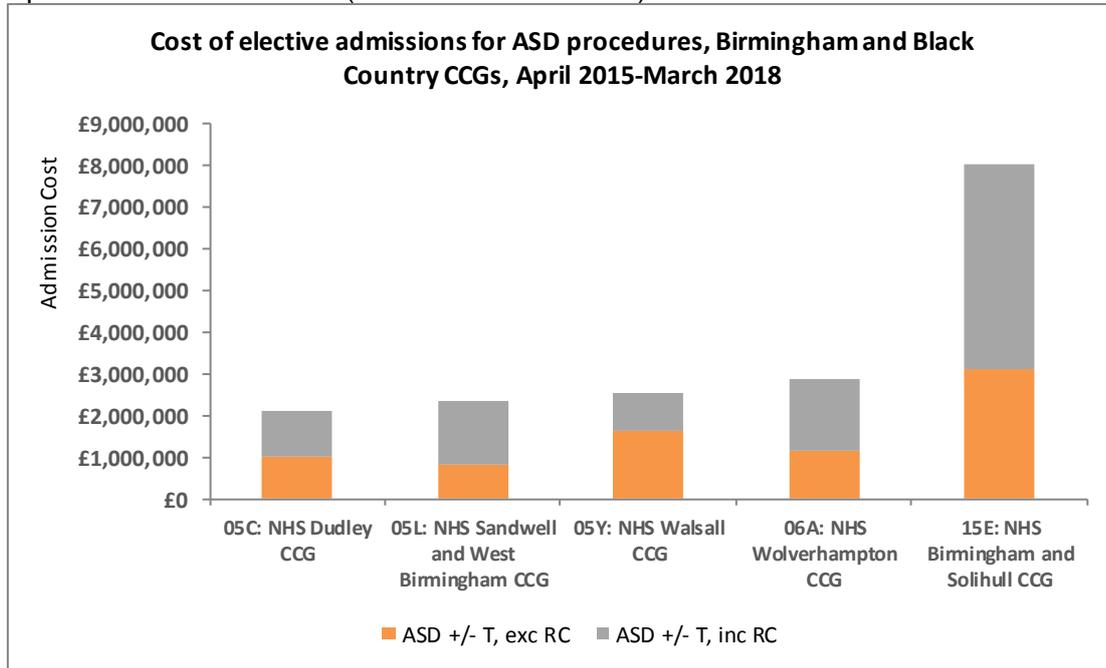
Figure 7 shows that NHS Wolverhampton CCG had the highest elective admission rate for ASD procedures with or without tenotomy, with rotator cuff procedures in all three years. However, the crude elective admission rate was lower in 2017/18 and in 2016/17 than it was in 2015/16.

Table 5 shows the cost of elective admissions per year by CCG, by category, as well as the total national tariff cost, including MFF, for 2018/19 applied to all years of elective admissions and average number of elective admissions per year by CCG. This shows that the total cost of elective admissions for ASD procedures during the period April 2015 to March 2018 for all Birmingham and Black Country CCGs was £17,963,651 based on 2018/19 costs.

Table 5: National tariff cost of elective admissions for ASD procedures by CCG, by category, by financial year, April 2015 to March 2018 (2018/19 national tariff)

CCG	2015/16			2016/17			2017/18			All Years			Avg/yr		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	£329,731	£285,419	£615,150	£346,640	£384,478	£731,118	£341,532	£428,539	£770,071	£1,017,903	£1,098,436	£2,116,339	£339,301	£366,145	£705,446
05L: NHS Sandwell and West Birmingham CCG	£292,901	£428,327	£721,228	£309,804	£529,379	£839,183	£244,988	£545,856	£790,844	£847,693	£1,503,561	£2,351,255	£282,564	£501,187	£783,752
05Y: NHS Walsall CCG	£484,769	£378,163	£862,932	£589,786	£318,840	£908,626	£552,215	£227,916	£780,130	£1,626,770	£924,919	£2,551,689	£542,257	£308,306	£850,563
06A: NHS Wolverhampton CCG	£391,997	£633,876	£1,025,872	£401,146	£555,138	£956,285	£376,082	£529,609	£905,692	£1,169,225	£1,718,624	£2,887,849	£389,742	£572,875	£962,616
15E: NHS Birmingham and Solihull CCG	£1,201,857	£1,675,283	£2,877,141	£1,066,014	£1,657,158	£2,723,172	£848,802	£1,607,404	£2,456,206	£3,116,674	£4,939,845	£8,056,519	£1,038,891	£1,646,615	£2,685,506
Grand Total	£2,701,256	£3,401,068	£6,102,324	£2,713,390	£3,444,994	£6,158,384	£2,363,620	£3,339,323	£5,702,943	£7,778,266	£10,185,385	£17,963,651	£2,592,755	£3,395,128	£5,987,884

Figure 8: National tariff cost of elective admissions for ASD procedures by CCG, by category, April 2015 to March 2018 (2018/19 national tariff)



The number of elective admissions for ASD procedures by primary diagnosis is given in Table 6 and Figure 9. These show that 2,095 (44%) admissions related to a primary diagnosis of M754: impingement syndrome of shoulder; 1,996 (42%) admissions related to M751: rotator cuff syndrome; 230 (5%) admissions related to M199: arthrosis, unspecified. Other procedures accounted for the remaining 10%.

Table 6: Number of elective admissions for ASD procedures by primary diagnosis, by category, April 2015 to March 2018

Primary Diagnosis description	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	% of Total
M754: Impingement syndrome of shoulder	1553	542	2095	44%
M751: Rotator cuff syndrome	302	1694	1996	42%
M199: Arthrosis, unspecified	179	51	230	5%
Other	376	97	473	10%
Grand Total	2410	2384	4794	100%

Figure 9: Number of elective admissions for ASD procedures by primary diagnosis, by category, April 2015 to March 2018

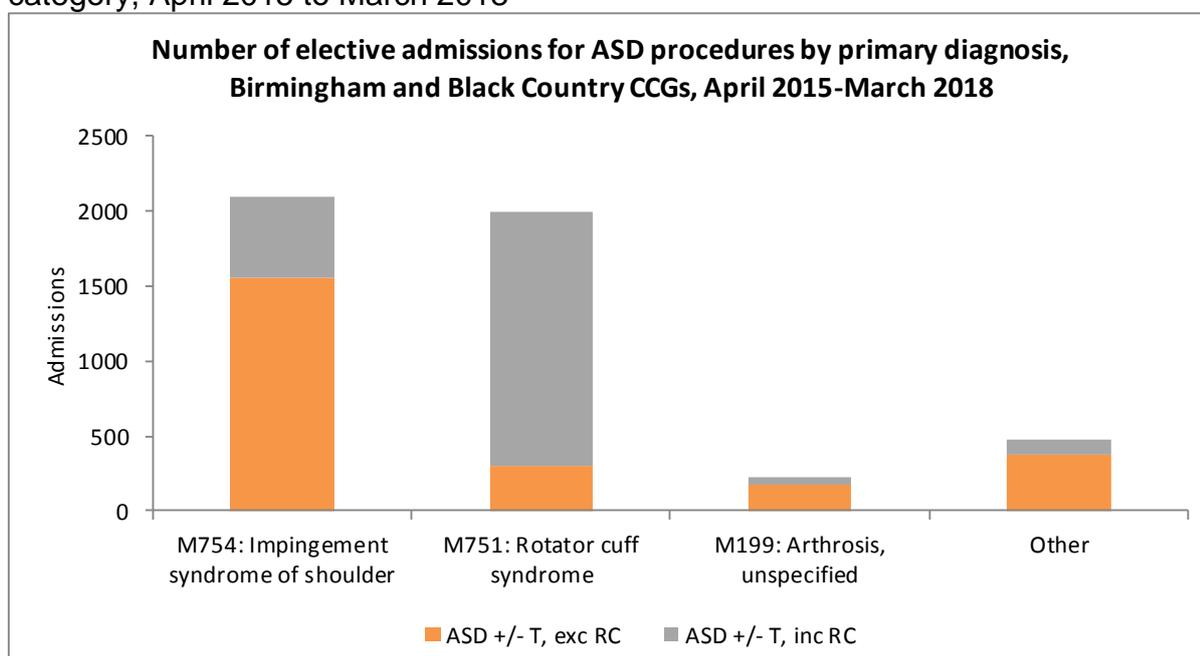
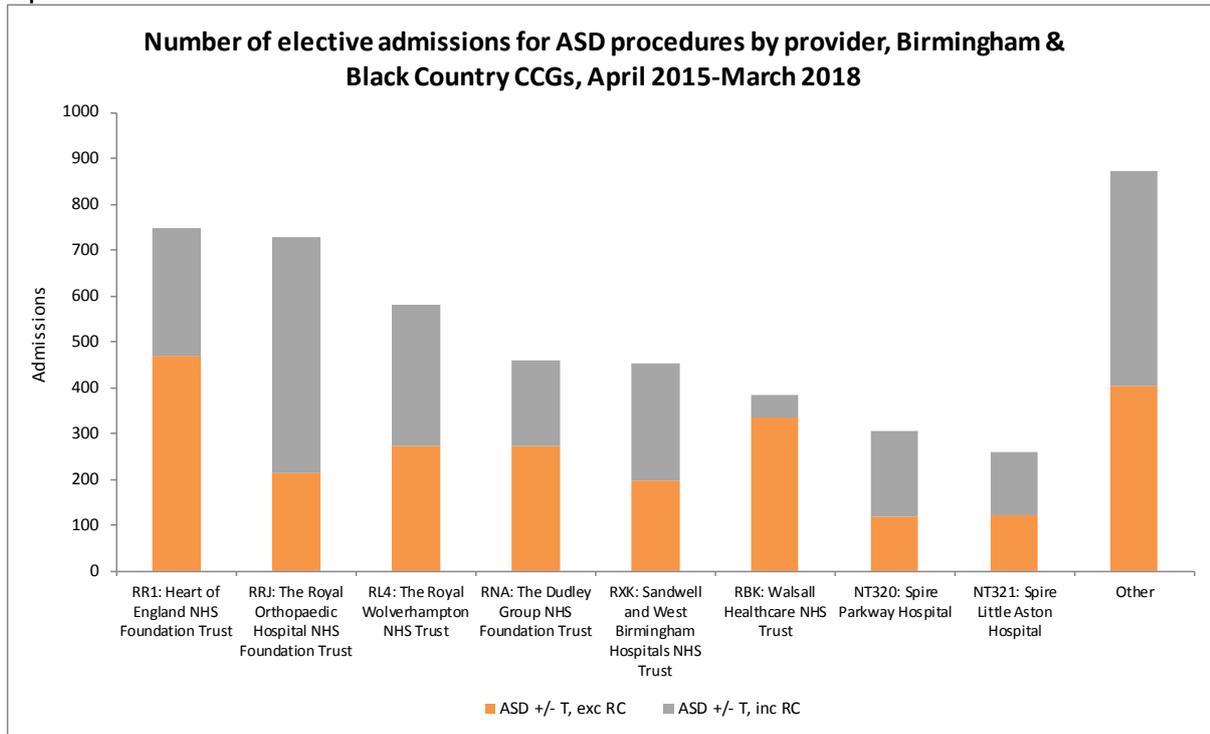


Table 7 and Figure 10 give the number of elective admissions for ASD procedures by provider. This shows that 750 procedures (16%) were carried out at the Heart of England NHS Foundation Trust; 728 procedures (15%) at the Royal Orthopaedic Hospital NHS Foundation Trust; and 581 (12%) at the Royal Wolverhampton NHS Trust on behalf of the Birmingham and Black Country CCGs. These three providers accounted for 43% of all the elective ASD activity commissioned by the CCGs between April 2015 and March 2018.

Table 7: Number of elective admissions for ASD procedures by provider, by category, April 2015 to March 2018

Provider	ASD +/- T, exc RC	ASD +/- T, inc RC	Grand Total	% of Total
RR1: Heart of England NHS Foundation Trust	469	281	750	16%
RRJ: The Royal Orthopaedic Hospital NHS Foundation Trust	216	512	728	15%
RL4: The Royal Wolverhampton NHS Trust	275	306	581	12%
RNA: The Dudley Group NHS Foundation Trust	272	187	459	10%
RXK: Sandwell and West Birmingham Hospitals NHS Trust	198	256	454	9%
RBK: Walsall Healthcare NHS Trust	337	47	384	8%
NT320: Spire Parkway Hospital	118	187	305	6%
NT321: Spire Little Aston Hospital	122	139	261	5%
Other	403	469	872	18%
Grand Total	2410	2384	4794	100%

Figure 10: Number of elective admissions for ASD procedures by provider, by category, April 2015 to March 2018

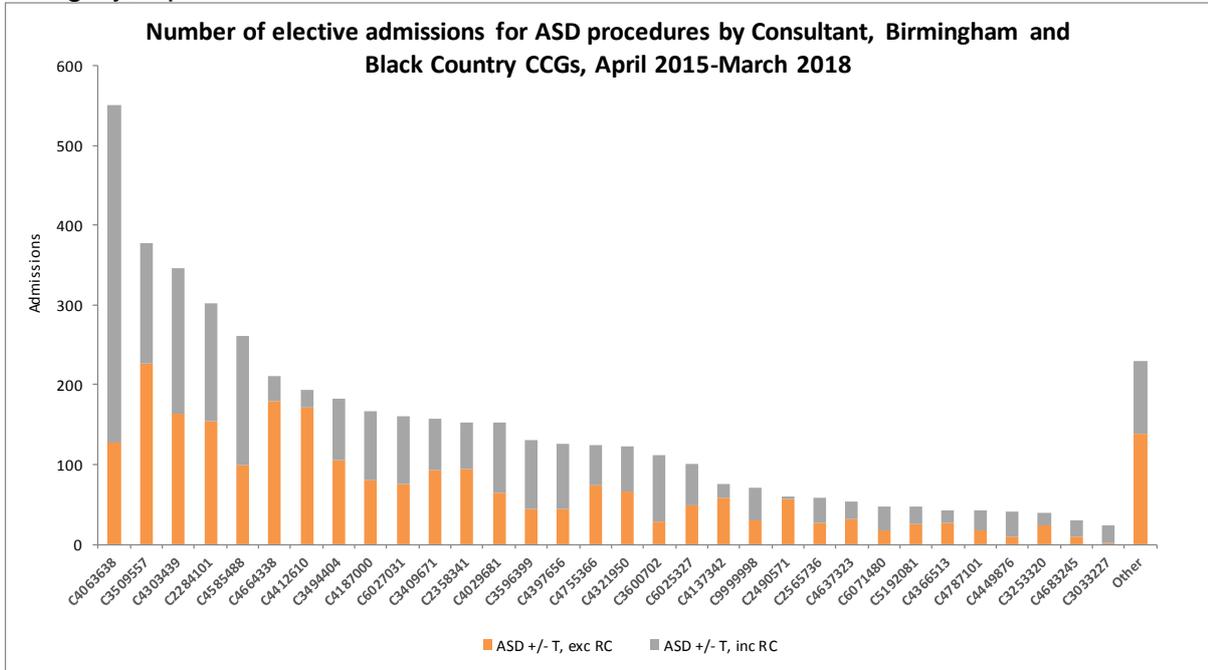


ASD is not a highly specialised shoulder procedure; the operations performed over the three-year period were undertaken by at least 32 different Consultants (Figure 11). The Consultants carrying out the largest number of ASD procedures are identified through the codes listed in Table 8 below. 51% of all the procedures performed over three years were undertaken by the top eight consultant codes, all of whom performed over 150 ASD procedures over the three-year period.

Table 8: Number of elective admissions for ASD procedures by consultant code, by category, April 2015 to March 2018

Consultant Code	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	% of Total
C4063638	127	424	551	11%
C3509557	226	152	378	8%
C4303439	163	183	346	7%
C2284101	155	148	303	6%
C4585488	99	163	262	5%
C4664338	180	31	211	4%
C4412610	171	23	194	4%
C3494404	106	76	182	4%
C4187000	80	87	167	3%
C6027031	75	85	160	3%
C3409671	93	65	158	3%
C2358341	95	57	152	3%
C4029681	64	88	152	3%
C3596399	44	86	130	3%
C4397656	44	82	126	3%
C4755366	74	51	125	3%
C4321950	66	57	123	3%
C3600702	28	83	111	2%
C6025327	49	52	101	2%
C4137342	58	18	76	2%
C9999998	30	41	71	1%
C2490571	57	3	60	1%
C2565736	26	32	58	1%
C4637323	32	21	53	1%
C6071480	17	31	48	1%
C5192081	25	22	47	1%
C4366513	26	17	43	1%
C4787101	18	24	42	1%
C4449876	9	32	41	1%
C3253320	23	16	39	1%
C4683245	9	21	30	1%
C3033227	2	22	24	1%
Other	139	91	230	9%
Grand Total	2410	2384	4794	100%

Figure 11: Number of elective admissions for ASD procedures by consultant code, by category, April 2015 to March 2018

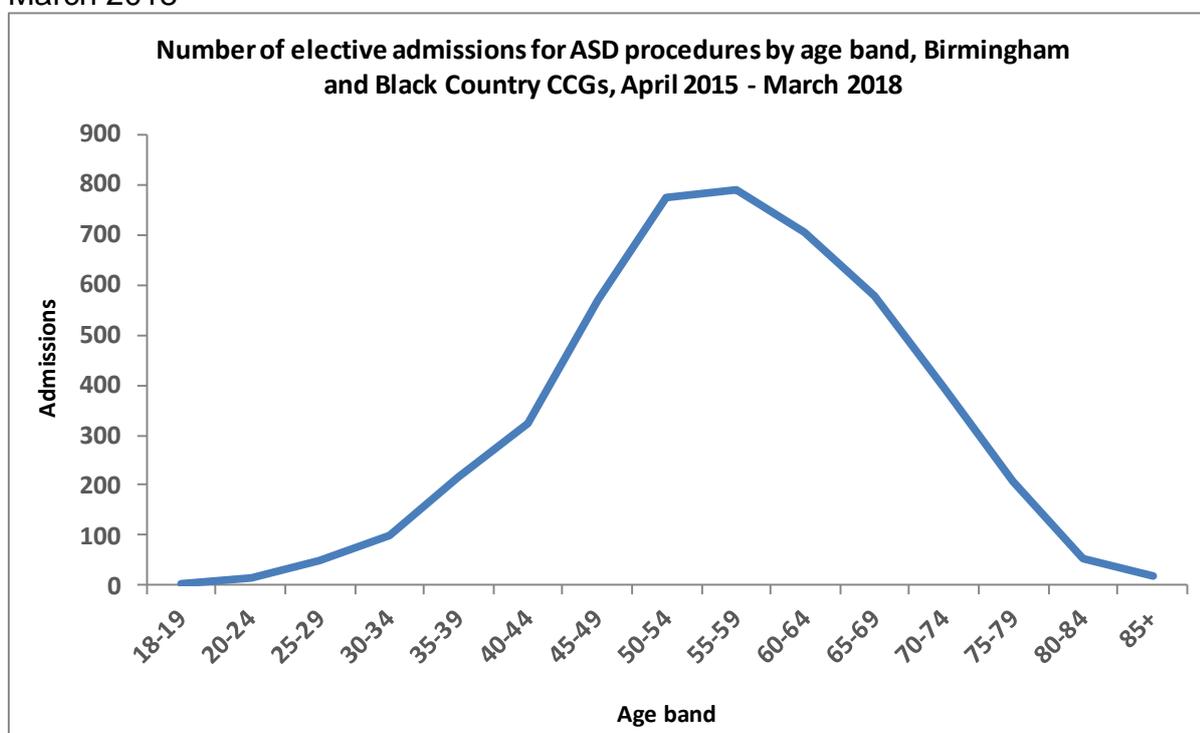


The number of elective admissions for ASD procedures by age band is given in Table 9 and Figure 12. These show that 47% of admissions are for patients aged 50 to 64, with a further 24% of admissions occurring in those aged 45 to 49 or 65 to 69.

Table 9: Number of elective admissions for ASD procedures by age band, April 2015 to March 2018

Age Band	Number of Admissions	% of Admissions	Cumulative % of Admissions
18-19	4	0%	0.1%
20-24	14	0%	0.4%
25-29	50	1%	1.4%
30-34	100	2%	3.5%
35-39	214	4%	8.0%
40-44	322	7%	14.7%
45-49	571	12%	26.6%
50-54	772	16%	42.7%
55-59	788	16%	59.1%
60-64	705	15%	73.8%
65-69	578	12%	85.9%
70-74	394	8%	94.1%
75-79	209	4%	98.5%
80-84	55	1%	99.6%
85+	18	0%	100.0%
Grand total	4794	100%	100.0%

Figure 12: Number of elective admissions for ASD procedures by age band, April 2015 to March 2018



Crude rates of admissions per 10,000 population are given in Table 10. These vary from 5.61 admissions per 10,000 population for Sandwell and West Birmingham CCG, to 10.63 admissions per 10,000 population for Wolverhampton CCG for the period April 2017 to March 2018.

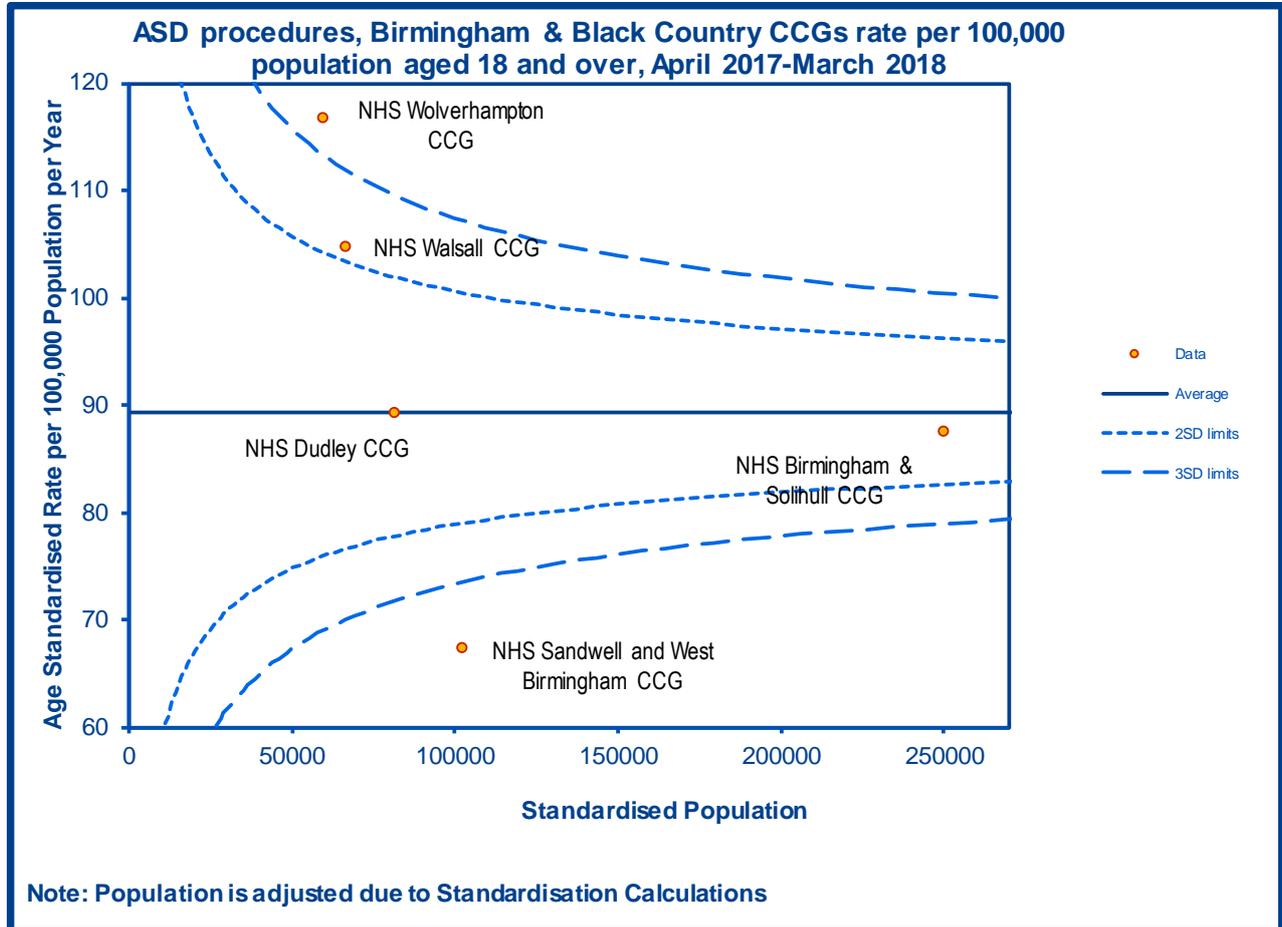
Table 10: Crude elective admission rates per 10,000 population by CCG and financial year, 2015/16 to 2017/18

CCG	2015/16			2016/17			2017/18			All Years		
	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total	ASD +/- T, exc RC	ASD +/- T, inc RC	Total
05C: NHS Dudley CCG	4.77	2.81	7.57	4.61	3.77	8.38	4.57	4.17	8.74	13.95	10.74	24.69
05L: NHS Sandwell and West Birmingham CCG	2.85	2.88	5.72	2.85	3.39	6.24	2.14	3.47	5.61	7.84	9.74	17.58
05Y: NHS Walsall CCG	6.77	4.00	10.77	7.81	3.29	11.10	7.53	2.35	9.88	22.11	9.64	31.75
06A: NHS Wolverhampton CCG	5.52	6.58	12.10	5.47	5.52	10.98	5.11	5.52	10.63	16.09	17.61	33.71
15E: NHS Birmingham and Solihull CCG	4.39	4.66	9.05	3.80	4.60	8.40	3.02	4.45	7.47	11.21	13.71	24.92

Figure 13 below is a funnel plot showing age standardised ASD elective admissions (with or without tenotomy, and with or without rotator cuff procedures) for the period April 2017 to March 2018. The funnel plot methodology calculates standard deviations around the mean of the five CCGs. This shows that Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population, and Sandwell and West Birmingham CCG had the lowest at 67.4 per 100,000 population. The rate for Birmingham and Solihull CCG was 87.5, for Dudley CCG was 89.3 and for Walsall CCG was 104.7 per 100,000 population. Please note that the y-axis starts at 60 in figure 13 below.

The mean is the mean age standardised rate per 100,000 population of the five CCGs, based on elective admissions from April 2017 to March 2018. It should be noted that the mean is reflective of the number of hospital admissions during that year. The ideal age standardised rate per 100,000 population for ASD procedures, taking into account the evidence of clinical and cost effectiveness, is unknown.

Figure 13: Age standardised elective admission rates per 100,000 population by CCG, April 2017 to March 2018



7 Discussion and conclusions

What is the evidence of clinical and cost effectiveness of arthroscopic subacromial decompression, compared to conservative treatment, in adults with impaired function and pain in the affected shoulder joint?

Clinical Effectiveness.

Shoulder Impingement Syndrome.

We found three randomised controlled trials which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two

of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 physiotherapy visits.

- ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test, 15D and patient satisfaction.
- ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].
- ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively).

Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score^j and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus tear.

There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

^j The authors of the CSAW RCT refer to the modified Constant Score but it is not clear how it differs from the Constant Score (also called the Constant-Murley Score). Both the CSAW study publication [4] and the CSAW study protocol [19] reference the 1987 Constant-Murley Score publication [13].

Cost Effectiveness.

We found no studies generalisable to the NHS which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Activity and Variation.

There is significant variation in access to ASD elective admissions across the five Birmingham and Black Country CCGs. For the period April 2017 to March 2018, Wolverhampton CCG had the highest age standardised rate at 116.7 per 100,000 population compared to Sandwell and West Birmingham CCG which had the lowest at 67.4 per 100,000 population. Both CCGs are outliers due to age standardised rates of elective ASD that are more than three standard deviations from the mean of the CCGs. This indicates that there is a high degree of confidence that the variation in access among the five CCGs is not due to chance.

The mean shown on the funnel chart is the mean age standardised rate per 100,000 population of the five CCGs for ASD procedures, based on elective admissions from April 2017 to March 2018. It should be noted that the mean is reflective of the number of hospital admissions during that year. The ideal age standardised rate per 100,000 population for ASD procedures, taking into account the evidence of clinical and cost effectiveness, is unknown, but if the CCGs consider that elective ASD procedures as described in this review are of limited clinical value, then the mean shown on the funnel chart is too high.

Issues that arise from the evidence and data review.

Evidence selection: The search for relevant comparative evidence was initially wide and not restricted to any indication. However, we restricted the selection of papers for inclusion to comparator studies which included a non-operative treatment and ASD as the primary intervention. The only comparator studies which met both the intervention and comparator criteria were for shoulder impingement syndrome or supraspinatus tendon tear.

Data selection: The data in the activity section of this report was selected to most closely match the indications, interventions and comparators in the included RCTs. We allowed inclusion of biceps tenotomy, partial rotator cuff tear repair or acromioclavicular joint surgery if they were combined with ASD only. We excluded any episodes which were associated with non-elective or emergency care. It was clear from the manual sifting of activity data that ASD is commonly coded as an adjunctive procedure with more complex shoulder operations. This, combined with the variation in coding means that the data will not be a completely accurate fit with the evidence to which it relates. However, the data will give an indication of the number and cost of these procedures across the five CCGs.

Indication: Three RCTs reported results for ASD with physiotherapy compared to non-operative management. All patients had a diagnosis of non-traumatic SIS, all had failed to respond to conservative treatment including physiotherapy and oral analgesia. The proportion of patients who had had at least one cortisone injection was not reported in

one study [6], whilst 59% [7] and 100% [4] of participants had had at least one steroid injection in the other two studies. The mean duration of symptoms was reported in two studies: 18 months [6] and 2.5 years [7] but not reported in the CSAW RCT [4]. All three studies excluded patients who had a full thickness tear of the rotator cuff. The proportion of participants who had a partial tear (grade I or II tear of the rotator cuff) was not reported in two of the RCTs. In the CSAW RCT, operative diagnosis was reported; 55/172 patients who received surgery had a partial thickness tear (31/89 allocated to ASD, 22/80 allocated to diagnostic arthroscopy only and 2/24 patients initially allocated to no treatment. The results from all three RCTs are not limited to those patients with isolated impingement syndrome.

Intervention: As described at the start of this review, the standard ASD procedure is antero-inferior acromioplasty and excision of the coracoacromial ligament and the subacromial bursa. All the studies allowed patients with SIS and a partial/small full-thickness tear of the rotator cuff to be included but they did not consistently report the proportion of patients in whom this was repaired. In addition, there was additional variation between studies to the standard ASD procedure as a small number of patients also had surgery to the acromioclavicular joint and to the long head of biceps (tenotomy) [4]. It is uncertain if these adjunct procedures occurred in either of the two Finnish RCTs [6,7]. It is also unclear to what extent these additional procedures might require additional recovery time and if this could affect outcomes such as pain and function.

Physiotherapy: In the three studies of patients with SIS, all patients who were allocated to ASD also received physiotherapy. However, the variation between the PT regimes ranged from one session of physiotherapy for guidance and instructions on home exercises (FIMPACT)[6], to 'up to' 4 physiotherapy appointments (CSAW)[4] and a mean of 6 physiotherapy sessions in the RCT by Ketola et al [7].

Physiotherapy was also the comparator to surgery in two of the RCTs for SIS but the mean number of seven sessions in one RCT [7] was far less than in the FIMPACT RCT where the comparator was 15 sessions as well as home exercises [6].

Uncertainty: Given that all the patients with SIS in these three RCTs had already failed to achieve an adequate response to conservative treatment (which included physiotherapy), it is not clear from these studies if the results warrant further intervention with physiotherapy.

- All three RCTs showed clinically meaningful improvement from baseline after no treatment at 12 months or PT at 24 months for the OSS, Constant score and pain.
- This indicates that some patients' will experience improvement in symptoms over time measured by the OSS, CS and pain scores, without any treatment at all.
- There was no analysis of the comparative effectiveness of the different comparators – no treatment, seven sessions of physiotherapy or 15 sessions of physiotherapy.
- There is insufficient evidence from these studies to justify the incremental costs of 15 sessions of physiotherapy compared to other non-operative alternatives.
- The relative clinical and cost effectiveness between all the non-operative treatment options remains uncertain.

Lack of blinding of patients and assessors may have biased the results in favour of surgery due to perception that no treatment or physiotherapy (which has previously failed) might be an inferior treatment option. All the RCTs attempted to limit the impact of lack of blinding by using independent assessors for data collection, and in some instances insisting that patient's shoulders remained clothed. However, this would not correct for subjective self-reported outcomes for pain, activities of daily living, quality of life and elements of composite scores such as the OSS or the Constant Score. This may have contributed to the observed statistically significant differences between ASD plus PT, compared to no treatment, which were not large enough to meet the MCID for OSS and Constant score at both 6 and 12 months. We noted that the MCIDs reported in the RCTs were referenced, increasing confidence that MCID reflected outcomes which are meaningful to patients.

Despite the lack of blinding to the treatment allocation, the potential bias did not result in clinically significant better outcomes for people receiving ASD compared to those receiving conservative treatment for SIS, even though they had already previously failed to respond adequately to conservative management.

Though not clinically significant, the results of the CSAW and FIMPACT studies [4,6] where ASD was statistically significantly better than no treatment and better than physiotherapy alone but not better than sham ASD (DA), suggests that the reasons why ASD was better than no treatment or than physio was not due to the ASD (otherwise it would also have been better than sham ASD), but due to something else eg placebo effect due to lack of blinding or due to the lack of physio in the no treatment group in CSAW[4].

8 Search Strategy

Search date: 16th August, updated 22nd October 2018

We searched for subacromial decompression on Medline, Embase and Cochrane – limiting to English and 2008 onwards. We also ran a search of TRIP database and NICE Evidence with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

The search identified publications with any arthroscopic shoulder procedures. The abstracts and titles were then sifted to select those that met the criteria in the PICO table below. Where there was ambiguity in the PICO criteria, the reviewer also referred to the wording of the research question for this evidence review, which specified that the intervention of interest was arthroscopic subacromial decompression.

Medline and Embase

Searches

▲

1 Shoulder Pain/

- 2 Shoulder Impingement Syndrome/
- 3 Rotator Cuff Injuries/
- 4 Osteoarthritis/ and Shoulder Joint/
- 5 Bursitis/ and Shoulder Joint/
- 6 ((shoulder* or subacromial or sub-acromial) and (adhesive capsulitis or bursitis)).ti,ab.
- 7 ((shoulder* or subacromial or sub-acromial) adj5 (pain or osteoarthritis or arthritis or impinge*)).ti,ab.
- 8 (rotator cuff adj2 (tear? or injur*)).ti,ab.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 Arthroscopy/
- 11 Therapeutic Irrigation/ and arthroscop*.mp.
- 12 Debridement/ and arthroscop*.mp.
- 13 (arthroscop* adj5 (lavage or irrigat* or debride* or decompress* or resurfac*)).ti,ab.
- 14 (arthroscop* and (lavage or irrigat* or debride* or decompress* or resurfac*)).ti.
- 15 10 or 11 or 12 or 13 or 14
- 16 9 and 15
- 17 (comment or editorial or letter or news or "review").pt. or case report.tw.
- 18 exp animals/ not humans.sh.
- 19 17 or 18
- 20 16 not 19
- 21 limit 16 to "reviews (maximizes specificity)"
- 22 20 or 21
- 23 limit 22 to (english language and yr="2008 -Current")

Inclusion criteria for identification of relevant studies

Population	Indication	Intervention	Comparator	Outcomes	Studies
Adults with impaired function and pain in the affected shoulder joint	Adhesive capsulitis Partial thickness rotator cuff tear Impingement syndrome of the shoulder Osteoarthritis	Arthroscopic subacromial decompression including: arthroscopic lavage, debridement, labral resurfacing [Likely procedure codes: • Diagnostic arthroscopic exam on shoulder +/- biopsy (as sole proc) W8820	Conservative treatment with lifestyle modification and/or medication and/or physiotherapy	Clinical effectiveness including Pain Function/mobility QoL Safety Cost effectiveness Subsequent arthroplasty	SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies

	<ul style="list-style-type: none"> • Therapeutic arthroscopy of the shoulder W8603 • Resurfacing arthroplasty of shoulder W5060] <p>Exclude : stabilisation procedures including labral(SLAP) tear/tendon repair)</p>			
<p>Inclusion Criteria Peer reviewed publications, English language</p> <p>Exclusion Criteria Abstracts, Letters, Commentaries, Conference papers, Case reports, Papers published more than 10 years ago</p>				

9 References

1. NHS choices. Shoulder Pain. <https://www.nhs.uk/conditions/shoulder-pain/>
2. Artus M, Holt T and Rees J. The painful shoulder: an update on assessment, treatment, and referral. British Journal of General Practice. 2014;64(626), e593-e595.
3. Chipchase LS, O'Connor DA, Costi JJ, Krishnan J (2000) Shoulder impingement syndrome: preoperative health status. J Shoulder Elbow Surg 9:12–15
4. Beard DJ, Rees JL, Cook JA CSAW Study Group et al. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet 2018;391:329-38.
5. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, Carr A. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. Rheumatology (Oxford). 2006;45(2):215-21.
6. Paavola M, Malmivaara A, Taimela S et al. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial. BMJ 2018;362:k2860
7. Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? a two-year randomised controlled trial. J Bone Joint Surg Br 2009;91:1326-34

8. Ketola S, Lehtinen J, Rousi T et al. Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with non-operative treatment? Subgroup analysis involving 140 patients at 2 and 5 years in a randomised study. *Acta Orthop* 2015;86:641-46
9. Ketola S, Lehtinen J, Elo P et al. No difference in long-term development of rotator cuff rupture and muscle volumes in impingement patients with or without decompression. *Acta Orthop* 2016;87(4):351-55
10. Ketola S, Lehtinen J, Arnala I. Arthroscopic decompression not recommended in the treatment of rotator cuff tendinopathy. *Bone Joint J* 2017;99-B:799-805
11. Kukkonen J, Joukainen A, Lehtinen J et al. Treatment of non-traumatic rotator cuff tears. *Bone Joint J* 2014;96-B:75-81
12. Longo UG, Vasta S, Maffulli N, Denaro V. Scoring systems for the functional assessment of patients with rotator cuff pathology *Sports Med Arthrosc Rev.* 2011;19(3):310-20.doi: 10.1097/JSA.0b013e31820af9b6.
13. Christiansen DH1, Frost P, Falla D, Haahr JP, Frich LH, Svendsen SW. Responsiveness and Minimal Clinically Important Change: A Comparison Between 2 Shoulder Outcome Measures. *J Orthop Sports Phys Ther.* 2015 Aug;45(8):620-5.
14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;214:160–164
15. Mathieson S, Lin C. PainDETECT Questionnaire Clinimetrics. *Journal of Physiotherapy* 2013 Vol. 59
16. Stern AF. Questionnaire Review: The Hospitals Anxiety and Depression Score. *Occupational Medicine* 2014;64:393–394
17. EuroQol Research Foundation 2018. EQ-5D Instruments. <https://euroqol.org/eq-5d-instruments/>. Accessed 19.11.2018
18. National Clinical Coding Standards OPCS-4 (2017) - NHS Digital <https://hscic.kahootz.com/gf2.ti/f/762498/27837541.1/.../-/NCCSOPCS42017.pdf>
19. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. *Psychol Med* 1988;18:1007–1019
20. Beard D, Rees J, Rombach I et al. The CSAW Study (Can Shoulder Arthroscopy Work?)—a placebo-controlled surgical intervention trial assessing the clinical and cost effectiveness of arthroscopic subacromial decompression for shoulder pain: study protocol for a randomised controlled trial. *Trials.* 2015; 16: 210
21. Kukkonen J, Kauko T, Vahlberg T et al Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. *J Shoulder Elbow Surg* 2013;22:1650–1655
22. Salaffi F, Stancati A, Silvestri CA et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain* 2004;8:283-91
23. Beard DJ, Carr AJ, Cook JA et al. Can Shoulder Arthroscopy Work? (CSAW) trial – Authors' reply. *Lancet.* July 28, 2018

10 Clinician comments after three week consultation of the draft evidence review

	Clinician	Comment	SPH response
4 Dec 2018	Samuel Chan, Consultant Shoulder & Elbow Surgeon, Trauma & Orthopaedics, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust	<p>Thank you for the opportunity to contribute my thoughts.</p> <p>With regard to the clinical problem of subacromial impingement and the role of decompression surgery, I agree with the findings of the studies referenced and that the majority do not require surgical decompression, if the problem is isolated to impingement alone. The clinical problem is that there are other structural causes of pain that may be addressed during arthroscopic shoulder surgery including ACJ pathology, long head of biceps pathology and cuff tear pathology. All these other pathologies have been excluded from the referenced studies to allow better definition of subacromial impingement and to try to standardise outcomes. Unfortunately, subacromial impingement as an isolated entity is uncommon, and one which I do not tend to list for surgery without a prolonged trial of physiotherapy +/- steroid injection. In reality, the referenced studies are only relevant to handful of cases per year in my clinical practice.</p> <p>In this cohort of cases, patients with prolonged symptoms are usually keen to try surgical decompression as conservative measures have</p>	<p>Thank you for these helpful comments.</p> <p>All 3 RCTs [4, 6,7] included patients with a partial thickness rotator cuff tear. In the CSAW RCT, 55/172 patients who received surgery had a partial thickness tear (31/89 allocated to ASD, 22/80 allocated to diagnostic arthroscopy only and 2/24 patients initially allocated to no treatment). The results from these RCTs are not limited to those patients with isolated impingement syndrome.</p> <p>We note your comment that isolated subacromial impingement is rare. Whilst coding procedures is not always accurate, we note (table 3 above) that there were 2126 ASD procedures performed without tenotomy or any rotator cuff tear repair) between April 2015 and March 2018. Table 6 indicates that in the 2410 patients who had ASD +/- tenotomy (284/2410 had ASD+tenotomy), the primary diagnosis was M754: Impingement syndrome of the shoulder. No related diagnoses were reported.</p> <p>The only trial to compare ASD to no treatment at all was the CSAW RCT [4]. This did show a statistically significant improvement at both 6 months and 1 year in OSS for both ASD and diagnostic arthroscopy only when compared to no treatment (see below). However, the size of the difference was less than 6 points on the OSS and therefore did not meet the criteria</p>

failed – and anecdotally, these patients have done well post surgery.

On the flip side, patients can present to clinic with imaging showing pathology in the shoulder and are listed accordingly. These patients may not have a cuff tear on long head of biceps pathology intra-operatively and end up only having a subacromial decompression. Unfortunately, any imaging modality is not 100% specific or sensitive. It is difficult to change the treatment algorithm in this group, as if they are symptomatic, I would normally recommend proceeding with arthroscopic surgery. It would be inappropriate to not fund surgery for this cohort of

required to be considered clinically important [12]. All patients had improved OSS at 6 and 12 months (including those who received no treatment). It is not clear to what extent the improvement in OSS observed in the ASD and diagnostic arthroscopy groups might be attributable to post-operative physiotherapy or placebo effect.

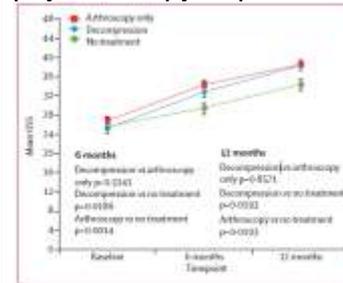


Figure 2: Oxford Shoulder Score in the intention-to-treat analysis. Data are mean (95% CI) shown at follow-up timepoints. OSS-Oxford Shoulder Score.

Beard et al 2018 [4].

The three RCTs were also at risk of recruiting patients with additional pathology, as you describe in your clinical practice. As stated above, the results apply to patients with subacromial pain with or without a partial rotator cuff tear.

We have reviewed the guideline (http://www.bess.org.uk/application/files/2914/8127/3402/Subacromial_Shoulder_Pain.pdf) and note that it recommends that, *“In the absence of a rotator cuff tear, if impingement*

	<p>patients.</p> <p>In light of the CSAW trial, the British Shoulder & Elbow Society have tried to engage with NICE to develop and update the pathway, but unfortunately, there is little inclination to do that at this stage. At the moment, it is probably most helpful to refer you to the Subacromial shoulder pain pathway developed by the British Shoulder & Elbow Society in conjunction with the British Orthopaedic Association:</p> <p>http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf</p> <p>It is easily accessible and useful for the framework of managing shoulder pain.</p>	<p><i>symptoms fail to resolve with conservative treatment, subacromial decompression surgery (acromioplasty) is recommended.”</i></p> <p>This recommendation appears to conflict with the results from the 3 RCTs which suggest that in patients who have already failed conservative treatment, that ASD plus physiotherapy does not result in a clinically significant difference when compared to diagnostic arthroscopy (12 and 24month follow up)[4,6], physiotherapy only (24 month follow up) [6,7] or no treatment (12 month follow up)[4].</p> <p>The guideline then explains that “<i>Subacromial decompression (acromioplasty) surgery aims to excise the bony spur on the antero-inferior surface of the acromion. The operation also involves excision of bursal tissue on the under surface of the acromion and release of the coraco-acromial ligament. The procedure aims to increase the volume of the subacromial space, thereby reducing the mechanical attrition and painful irritation of the rotator cuff tendons.</i>”</p> <p>If increasing the subacromial space is effective, this does not explain why there was no clinically significant difference at either 12-month follow-up [4] or 24 months [6] between ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy. This was consistent for all of the outcomes measured: Oxford Shoulder Score (OSS), Constant score, pain, depression and anxiety, health-related quality of life, simple shoulder test and 15D as well as patient satisfaction with the allocated treatment.</p>
--	---	--

<p>04 Dec. 2018</p>	<p>Mr. Samir Massoud, Consultant Trauma & Orthopaedics , Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust</p>	<p>Thanks,</p> <p>Totally agree with the analysis for ASD for shoulder impingement. However, I would caution against including ASD+/ tenotomy and cuff repair in this analysis as the primary procedure in this situation is the cuff repair not ASD.</p> <p>The evidence presented in the supraspinatus tear study indicates similar results at 1 year. However, this is misleading as degenerative cuff tears increase in size with time if not repaired and the results of ASD alone and physiotherapy in that situation are likely to deteriorate in the future whereas the results of cuff repair+ASD will be maintained in the long term. The larger size tears resulting from not repairing the rotator cuff are less likely to heal after future repair, may become irreparable and occasionally lead to patients requiring a muscle transfer or reverse shoulder replacement. The results of all these procedures are not as good as supraspinatus repair. I would be very concerned if this work gives the impression that cuff repairs are not necessary.</p> <p>It is interesting to see, provided the populations treated are similar, what proportion of patients in different practices are treated with ASD+/-tenotomy versus Cuff repair+ASD+/- tenotomy.</p> <p>I am not sure whether you have enough data to</p>	<p>Thank you for these helpful comments.</p> <p>We agree that the Kukkonen et al study focused on the hypothesis that <i>“rotator cuff repair yields superior results compared with the other treatment modalities”</i>[10].</p> <p>The study by Kukkonen et al [10] found that a one year follow up, there was no difference in outcome measured using the Constant score between those groups of patients treated with ASD+physiotherapy, ASD+RC repair+physiotherapy or 10 sessions of physiotherapy alone. However the RCT was limited to only 1 year follow up and not designed to establish the proportion of degenerative cuff tears which might become larger or irreparable.</p> <p>The long term outcomes for these patients with a symptomatic but untreated supraspinatus tears<75% was out of scope of this review.</p> <p>In addition, as this is a single, relatively small (n=180) RCT for this population with partial supraspinatus tears, some degree of caution about the interpretation of the results is reasonable. The scope of this review did not include systematic review of the effectiveness of supraspinatus tear repair.</p> <p>The data is available for further analysis should that be agreed.</p> <p>As far as we are aware, outpatient data is less sophisticated than HES and attendance is likely to only be recorded as a T&O outpatient attendance. The existence of an MSK referral hub may be able to provide further insight; this may require clinical audit.</p>
-----------------------------	---	---	---

		analyse what proportion of patients seen in outpatients with diagnosis of Shoulder impingement are treated with ASD and what non-operative measures they had prior to surgery. This would give a more accurate picture of current practice.	
14 Dec. 2018	Nigel Featherstone - combined response from UHB/HGS (not already received)	<p>Mr Kalogrinanitis - considered low clinical value and not offered to patients.</p> <p>Mr Cooper - had already been issued by CCG to Shoulder surgeons but recirculating again for comments</p> <p>Mr Spurrier - supports comments by Mr Chen. Isolated impingement is rare, but there is a subset of patients who fail conservative management and do well with decompression surgery. However the majority of decompression surgery patients I have seen have had other pathology to address, which may have gone untreated had decompression not been funded by the relevant commissioner</p>	<p>We note your comment that isolated SIS is rare. However, as stated above the three RCTs did not exclude patients with partial rotator cuff tears. Whilst coding procedures is not always accurate we note (table 3 above) that there were 2126 ASD procedures performed without tenotomy or any rotator cuff tear repair) between April 2015 and March 2018. Table 6 indicates that in the 2410 patients who had ASD +/- tenotomy (284/2410 had ASD+tenotomy), the primary diagnosis was M754: Impingement syndrome of the shoulder</p>

Appendix 1: Glossary of outcome measures used in the trials included in this review.

The Oxford Shoulder Score (OSS) is a patient-based questionnaire used to assess shoulder pain. It is a condition-specific questionnaire, completed unaided by the patient. It consists of 12 questions exploring pain (4 questions) and function (8 questions). Each item is scored from 1 to 5, from least to most difficulty or severity, and combined to produce a single score with a range from 12 (least difficulties) to 60 (most difficulties). [11].

The minimal clinically important difference (MCID) for the OSS in patients with SIS is 6 points [12].

Visual Analogue Scale (VAS) for Pain (VAS 0-100). In the FIMPACT RCT, patients rated the intensity of pain during activity and pain at rest at the actual time of assessment using a Visual Analogue Scale (VAS) (100 mm). Shoulder pain was assessed on a 100 mm scale ranging from 0 (no pain) to 100 (worst imaginable pain).

The MCID for pain measured using VAS(0-100) was 15 points [18].

Visual Analogue Scale (VAS) for Pain (VAS 0-10). In the RCT by Ketola et al [7], patients self-reported pain a Visual Analogue Scale (VAS) ranging from 0 to 10 with 0 indicating a high level of pain and 10 representing no pain.

The MCID for pain measured using VAS(0-10) was 2 points [21].

The Constant-Murley Score, also known as the Constant Score (CS) consists of both objective (range of motion (40 points) and strength (25 points)) and subjective patient reported measurements (pain (15 points), workload and leisure time activities (20 points)), which are summarised in a score between 0 and 100. A higher score indicates better shoulder function.

The total possible score is 100 points, indicating an asymptomatic and healthy person, while the worst score is 0 points.

The MCID for the Constant Score in patients with SIS is 11 points [12].

PainDETECT. The questionnaire consists of seven questions that address the quality of neuropathic pain symptoms; it is completed by the patient and no physical examination is required. The first five questions ask about the gradation of pain, scored from 0 to 5 (never = 0, hardly noticed = 1, slightly = 2; moderately = 3, strongly = 4, very strongly = 5). Question 6 asks about the pain course pattern, scored from -1 to 2, depending on which pain course pattern diagram is selected. Question 7 asks about radiating pain, answered as yes or no, and scored as 2 or 0 respectively. The final score between -1 and 38, indicates the likelihood of a neuropathic pain component. A score of 12 indicates that pain is unlikely to have a neuropathic component (< 15%), while a score of 19 suggests that pain is likely to have a neuropathic component (> 90%). A score between these values indicates that the result is uncertain.

The Simple Shoulder Test (SST) was developed to assess functional impairment of the patient's activities of daily living. The SST consists of 12 questions with yes (1) or no (0) response options. The maximum SST score is 12 indicating normal shoulder function, minimum score of 0 points refers severely diminished shoulder function.

The MCID for the SST in rotator cuff disease is 2 points [6].

The Shoulder Disability Questionnaire (SDQ) was developed to evaluate functional status limitation throughout self-assessment by patients with soft-tissue shoulder disorders. It consists of sixteen items with three answer options: Yes, No and Not Applicable (NA) with the meaning that the activity of the particular item had not been performed in the previous 24 hours. The ratio of the affirmative answers over the number of the applicable items is multiplied by 100 so the result is a percentage between 0 (no functional limitations) and 100 (affirmative answer to all applicable items). The SDQ is reported to have a good responsiveness and it is able to discriminate accurately between self-rated clinically stable and improved subjects [12].

HADS. Depression and anxiety was measured using the HADS (Hospital Anxiety and Depression Scale), a fourteen-item scale; seven of the items relate to anxiety (0-21 points) and seven relate to depression (0-21 points) [15]. Higher scores indicate a greater likelihood of depression or anxiety. For both scales, scores of less than 7 indicate non-cases; scores of 8 to 14 indicate mild to moderate anxiety or depression, whilst scores of 15 or more indicate severe anxiety or depression.

Health related quality of life (HRQoL). The EQ-5D is a standardized instrument designed to measure health-related quality of life (HRQoL) [16]. The EQ-5D consists of two parts: a descriptive system and the EQ-VAS. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression for which there are 3 levels of severity in the EQ-5D-3L. The EQ-VAS records the patient's self-rated health on a vertical visual analogue scale.

The 15D instrument is a generic health-related quality of life (HRQoL) instrument comprising 15 dimensions concerning breathing, mental function, speech, vision, mobility, usual activity, vitality, hearing, eating, excretion, sleeping, distress, discomfort and symptoms, depression and sexual activity. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at that moment (the best level being 1 and the worst level being 5). A set of utility or preference weights is used in an addition aggregate formula to generate a single index number, the utility or 15D score. The maximum 15D score is 1 (no problems on any dimension) and the minimum score is 0 (being dead) [6].

Patient satisfaction and responder analysis. Patients' global assessment of satisfaction to the treatment was assessed on a VAS scale ranging from 0 (completely disappointed) to 100 (completely satisfied) with the question: 'Are you satisfied with the treatment you have received?'. In addition, patient satisfaction with the treatment outcome was elicited (using a 5 item scale) at each follow-up time point with the question 'How satisfied are you with the outcome of your treatment?'. Participants who reported very

satisfied or satisfied were categorised as 'Responders' and patients who responded very dissatisfied or dissatisfied were categorised 'Non-responders' [6].

Return to previous leisure activities. At each follow-up, participants were asked to respond to the following question: 'Have you been able to return to your previous leisure activities?' ('yes' or 'no') [6].

Competing Interest

All SPH authors have completed the ICMJE uniform disclosure form (www.icmje.org/coi_disclosure.pdf) and declare: grants from Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

Terms of Use

This document has been produced by SPH for Solihull CCG, Birmingham CrossCity CCG and Birmingham South Central CCG. It must not be distributed or accessed or used for commercial purposes without prior written permission from SPH. The purpose of this document is to review and summarise published evidence relating to clinical interventions. The findings may be applicable to the development of commissioning policy, but commissioning policy development is undertaken by NHS commissioners taking into account a wide range of other factors. SPH is not responsible for the development of commissioning policy. Use of this document is subject to agreement that SPH is fully indemnified against any liability that may arise through use of the information within this document.

© NHS Solutions for Public Health 2019

Solutions for Public Health owns on creation, the copyright associated with the interpretation and appraisal of the referenced material. The copyright protected material may be reproduced free of charge in any format or medium subject to the necessary permission provided it is reproduced accurately and not used in a misleading context. If any of the copyright items produced are being copied to others, the source of the material must be identified and the copyright status acknowledged.