IMAGE-GUIDED HIGH VOLUME INTRA-ARTICULAR INJECTIONS (40MLS+) OF SALINE WITH OR WITHOUT CORTICOSTEROID AND/OR LOCAL ANAESTHETIC FOR THE TREATMENT OF PAINFUL JOINTS

Questions to be addressed

1. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?
2. In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, in partnership with Walsall CCG, Wolverhampton CCG and Dudley CCG, requested a rapid evidence review of the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, image-guided HIGH VOLUME intra-articular injections should be offered ONLY to patients who have failed to respond to conventional interventions, including intra-articular corticosteroid injections.
3. The Committee considers that there is sufficient evidence to suggest that image-guided HIGH VOLUME intra-articular injections is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous.
- Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. It can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis[a]. Other causes of joint pain include sports injuries, general sprains and strains, adhesive capsulitis, unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

[a] Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

- Despite the wide range of conditions and symptoms, different types of joint pain may share similar underlying mechanisms, manifestations, and potential treatments.
- Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes oral analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. Image-guided high volume intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are treatment options for adhesive capsulitis (frozen shoulder).

Clinical effectiveness

- We searched for studies that compared image-guided high volume injections to alternative treatment options and the only comparative studies identified were in patients with frozen shoulder. In this rapid evidence review, we report results from two systematic reviews of RCTs and one RCT (published subsequent to the systematic reviews) of the effectiveness of hydrodilatation (also referred to as arthrographic distension) with image-guided high volume injection in patients with adhesive capsulitis (frozen shoulder).
- The systematic review (with meta-analysis) by Saltychev et al (2018) evaluated the evidence on the effectiveness of hydrodilatation (HD) in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The total number of patients included in the review or meta-analysis was not reported.
    - The meta-analysis of seven of the RCTs showed that for hydrodilatation with corticosteroid versus intra-articular corticosteroids injection alone, there were statistically significant improvements in pain (p=0.00; numbers needed to treat (NNT)[b] = 12) and range of motion (p=0.01; NNT= 12) in favour of hydrodilatation. However, these did not translate to a difference in disability assessment between the two treatment arms (p=0.11).
    - The authors concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis. These results need to be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) and only a few outcome measures were reported.
- The systematic review conducted by Catapano et al (2018) to determine whether the combined intervention of hydrodilatation and corticosteroid injection expedites restoration of pain-free range of motion (ROM) compared to a control treatment of corticosteroid injection in patients with adhesive capsulitis included six RCTs involving 410 shoulders.
    - Two studies demonstrated statistically significant improvement in pain measured using the VAS with hydrodilatation and corticosteroid injection when compared to corticosteroid injection alone; one study at 12 weeks (p=0.002) and the other at one month (p=0.035).
    - Two studies demonstrated statistically significant improvement in favour of hydrodilatation with corticosteroid injection in ROM at 12 weeks (extension ROM p=0.03; external rotation ROM p=0.010 and abduction ROM p=0.005; internal rotation p=0.027) and one at one month (external rotation, p=0.005).

[b] NNT is the number of patients that need to be treated to achieve one patient with an improvement.

  - Two studies showed no difference between hydrodilatation with corticosteroid injection and corticosteroid injection alone.
  - In contrast to Saltychev et al, and despite considering some of the same studies (reported differently), Catapano et al concluded that combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM. These findings need to be interpreted with caution as the results were not consistent across the studies included and no meta-analysis was carried out.
- Gallacher et al carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)[c] differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)[d] and hydrodilatation (HD). Patients were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2013.
  - At six months after the intervention, both groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort (p= 0.023). The ACR and HD cohorts showed improvements in external rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group (p=0.03 and p=0.023 respectively). Significant improvement in EQ-5D[e] VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant.
  - The authors concluded that ACR is associated with significantly higher OSS at six months than HD however, significant improvement was observed in both groups. These findings need to be interpreted with caution as the study was small (n=50) so may not have been sufficiently powered to show any differences. In addition the fact that this was a patient-reported outcome measure may have introduced some bias especially as they were not blinded to their treatment.

Safety

- Both systematic reviews reported adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.
- Saltychev et al (2018) reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups based on three studies. No absolute numbers or proportions were reported.
- They reported one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid.
- Catapano et al (2018) reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only)

[c] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

[d] Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

[e] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

group. They state that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection with no further details.

- The RCT by Gallacher et al (2018) reported that there were no complications with either ACR or hydrodilatation.

Cost effectiveness

- No cost effectiveness studies of hydrodilatation compared to alternative treatment options were found. One systematic review attempted to assess the cost-effectiveness of different interventions used for frozen shoulder, including hydrodilatation (referred to arthrographic distension in the review); however, because of the paucity of evidence, the development of an economic model was not feasible (Maund et al 2012).
- Consequently, the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review.

Equity issues

- It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access or uptake compares to the rest of England.

1 Context

1.1 Introduction

Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis[f]. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments [1, 2].

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments [1]

Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy. If these fail, intra-articular steroid injection may be considered. High volume injection intra-articular injection (hydrodilatation) and arthroscopic capsular release (ACR) are considered treatment options for adhesive capsulitis (frozen shoulder) [3].

1.2 Existing national policies and guidance

There is no relevant published NICE Technology Appraisal Guidance (with statutory requirement for NHS organisations to make funding available), Clinical Guidelines or Quality Standards specifically for image-guided HIGH VOLUME intra-articular injections.

2 Epidemiology

Joint pain is one of the leading causes of disability worldwide [4].

A survey carried out by Duncan et al (2011) on the prevalence of arthritis and joint pain in the elderly in Scotland found that 63% of 803 respondents reported joint pain in the previous month. Women reported pain more often than men (68% versus 56%, p=0.001). The individuals who experienced pain were most likely to have knee pain (65%), followed by shoulder pain (31%) then lower back pain (28%), hip pain (25%) and hand pain (24%). Pain was more prevalent in women across all joint areas but the gender difference was only statistically significant for foot (p=0.002), neck ($p < 0.0001$), ankle ($p = 0.01$) and lower back pain ($p = 0.001$) [5].

[f] Pseudogout, also known as chondrocalcinosis, is a common joint disease caused by deposition of calcium pyrophosphate dihydrate (CPPD) crystals. Most often, it is asymptomatic, but it may simulate gout and osteoarthritis.

3 The interventions

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint usually into the glenohumeral (shoulder) joint. For the purpose of this rapid evidence review we will use the term hydrodilatation (HD). HD is generally carried out with a mixture of contrast medium, long acting anaesthetics, steroids, saline or air. However, because of the inherent compressibility of air, the procedure is more difficult than when saline is used. Dependent upon the contracted state of the joint capsule, HD usually occurs with an injection of between 10ml and 55ml of normal saline [6].

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). HD is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion. The risk of complications is thought to be low and treatment success is known after a couple of weeks [6, 7].

4 Findings

We searched Medline, Embase and Cochrane Library on the 19th September 2018 using the search strategy detailed in section 7 below. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews.

The search was limited to 2008 onwards and English only and we excluded letters, commentary, case reports and conference papers.

4.1 Evidence of effectiveness

We identified three systematic reviews of RCTs [8, 9, 10] of the effectiveness of hydrodilatation with image-guided high volume injection. All three systematic reviews focused on patients with adhesive capsulitis (frozen shoulder). Of the two SRs published in 2018 [8, 9] only one carried out a meta-analysis [8]. The health technology assessment (HTA) published in 2012, attempted to assess cost-effectiveness but without conducting a meta-analysis of pooled results [10]. We have not reported the clinical effectiveness outcomes reported in the HTA by Maund et al 2012 [10] as they have been superseded by the RCTs in the 2018 systematic reviews. However, the information on costs is reported as it is the only one identified. We also identified one relevant RCT published subsequent to these systematic reviews [3].

Earlier systematic reviews which considered the same RCTs as the recent, included systematic reviews with or without meta-analysis were excluded. Individual studies already included in the systematic reviews have not been reported separately. Non-comparative studies were excluded because they add little when there is RCT evidence.

4.1.1 Clinical effectiveness

The systematic review (with meta-analysis) by Saltychev et al (2018) [8] evaluated the evidence on the effectiveness of hydrodilatation with image-guided high volume injection in adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active and passive glenohumeral joint movements). They included 12 RCTs in the review and seven in the meta-analysis. The studies included in the meta-analysis compared hydrodilatation with corticosteroid with corticosteroid injection only. The authors stated that the volume of mixture injected for HD to occur varied from 20ml to 90ml in the studies included. The total number of participants was not provided but patient numbers in the studies varied between eight and 60. It was not clear whether the participants had failed other treatment. The authors report that most of the studies were of moderate quality.

The outcomes reported were change in pain severity, disability level and range of movement (ROM). A statistically significant improvement in pain using VAS[g] was reported for hydrodilatation with corticosteroid versus corticosteroids injection (mean difference (MD): 0.37 (95% CI 0.12 to 0.61), p=0.001; 5 studies, n=not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12. There was no information on the details of the VAS used. A statistically significant improvement in range of movement (ROM) based on pooled results from six studies of hydrodilatation with corticosteroid versus corticosteroids [MD: 0.38 (95% CI 0.07 to 0.69), p=0.01; 6 studies, n=not reported). The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement was 12. Importantly, the statistically significant difference between the two treatments for pain and for ROM, did not translate to any between group difference in disability assessment measured using SPADI[h] between hydrodilatation with corticosteroid and corticosteroids alone [MD: 0.20 (95% CI 0.-0.04 to 0.44), p=0.11; 4 studies, n=not reported].

Saltychev et al (2018) concluded that hydrodilatation has only a small, clinically insignificant effect when treating adhesive capsulitis [8]. These results should be interpreted with caution as they are from small studies (number of participants ranged from eight to 60) with only a few outcome measures reported. In addition, the participants were not blinded to their treatment and the assessors were not blinded to the treatment in two of the seven studies included in the meta-analysis.

Catapano et al (2018) [9] conducted a systematic review (no meta-analysis) to determine whether the combined intervention of hydrodilatation and corticosteroid injection(HD) expedites restoration of pain-free ROM compared to a control treatment of intra-articular corticosteroid injection(IAI) in patients with adhesive capsulitis. They included six RCTs (involving 410 shoulders), one of which only used 10ml of injection. The mean age of participants ranged from 51 to 61 years. In most of the studies participants were

[g] VAS: visual analogue score – the details of the score used was not reported.

[h] The Shoulder Pain and Disability Index (SPADI) was developed to measure current shoulder pain and disability in an outpatient setting. The SPADI contains 13 items that assess two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability.

symptomatic for at least three months. These studies were included in the review by Saltychev et al (2018) [8]. The authors report that the studies were of moderate quality.

Two RCTs (n = 100 shoulders and 90 shoulders respectively) demonstrated statistically significant improvement in pain in favour of treatment with HD compared to IAI: pain (VAS) at 12 weeks (HD 3.29 (SD 0.95) versus IAI 3.57 (SD 1.1), p=0.002), and the other at one month (HD 3.6 (SD 1.3) versus IAI 4.6(SD 1.1), p=0.035).

Three RCTs showed statistically and clinically significant improvement in ROM in favour of treatment with HD compared to IAI:

- at 12 weeks: abduction: (HD 114.4 (SD 30.1) versus IAI 82.7(SD 22.6), p=0.005); internal rotation (HD 55.4^0 (SD 18.2^0) versus IAI 48.4^0 (SD 10.8^0), p=0.027; n= 100 shoulders;
- at 12 weeks: (extension ROM p=0.03; external rotation ROM p=0.010; n= not reported - no detailed results were provided;
- at one month; external rotation (HD 36^0 (SD 9^0) versus IAI 28^0(SD 8^0), p=0.005 n= 90 shoulders;

In contrast, two studies demonstrated no benefit in any outcome measures with HD when compared to IAI alone.

The authors concluded that *"combining hydrodilatation with corticosteroid injection potentially expedites recovery of pain-free ROM"*. The greatest benefit appears to be within the first 3 months of intervention in the RCTs that showed improvement however, long term outcomes were not reported. These findings need to be interpreted with caution as studies were small, and they varied significantly regarding the volume of injection used. In addition, pain scores were reported by patients who were not blinded to their treatment.

Gallacher et al [3] carried out an RCT (n=50) to determine whether the Oxford Shoulder Score (OSS)[i] differs between patients with frozen shoulder treated with arthroscopic capsular release (ACR)[j] and hydrodilatation (HD).

Patients presenting with severe idiopathic frozen shoulder deemed suitable for surgical intervention by a consultant shoulder surgeon at a UK centre were randomised to ACR (n=25) or HD (n=25) between June 2013 and December 2016. Patients had had at least three months' duration of symptoms, and had failed a course of physiotherapy. The average age of the HD and ACR cohorts was 55.2 and 52.6 years, respectively. The primary outcome measure was OSS at six months, with secondary outcomes measures of the EuroQol-5D[k] visual analogue scale, external rotation, complications, and crossover rate also recorded.

---

[i] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

[j] Arthroscopic capsular release is an arthroscopic (keyhole) surgery that releases the tightness found in the capsule in cases of frozen shoulder. The aim of capsule release surgery is to restore movement in the shoulder

[k] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The

Six months after the intervention, 20 patients were available for follow-up in the HD cohort and 19 in the ACR cohort. Both groups demonstrated significant improvements in OSS from baseline, but the OSS was statistically and clinically significantly higher in the ACR cohort than the HD cohort (43.8 (95% CI, 42.2 to 45.2) versus 38.5 (95% CI, 34.6 to 42.4), p= 0.023). The ACR and HD cohorts both showed improvements in external rotation (47° versus 34°) and forward elevation (83° versus 71°), with the improvement in both outcomes being statistically and clinically significantly greater in the ACR group (p=0.03 and p=0.023 respectively). Significant improvement in EQ-5D VAS was also noted in each group, but the difference in improvement between the groups at any time point was not significant (10 versus 19.6 for ACR and HD, respectively, p= 0.053). Before the 6-month follow-up, four patients crossed over from HD to ACR; in contrast, one patient in the ACR cohort crossed over to HD. For the patients that crossed over from the HD group to the ACR group, the authors observed a mean 11.0 point improvement in the OSS at 6 weeks after HD compared with a 20.6 point improvement in the HD group that did not cross over. After ACR, the crossover patients then demonstrated a 28.0 point improvement in OSS from the baseline at 6 months.

Although significant improvement in OSS was observed in both groups, the results suggest that HD is inferior to ACR as it is associated with significantly lower OSS and change in ROM at six months follow-up. There was no difference in health-related quality of life between the two groups. These findings need to be interpreted with caution because the study was small (n=50) and therefore may not have been sufficiently powered to show any differences. It is unclear what criteria would be used to offer patients ACR in every day clinical practice. In addition the pain scores were reported by the patients who were not blinded to their treatment in fact four patients from the HD group crossed over to ACR before treatment was started. It is unclear whether the ROM assessors were blinded to the treatments.

Trials in progress
A search of clinicaltrials.gov did not identify any relevant ongoing trials.

4.1.2 Cost-effectiveness

We identified one HTA which attempted to assess the cost-effectiveness of the different interventions for frozen shoulder.

However, Maund et al [10] were not able to report the cost-effectiveness of the different interventions for frozen shoulder including arthrographic distension due to a lack of reliable clinical effectiveness outcomes to populate a plausible, economic model.

As an alternative, the authors estimated average costs for the interventions from the perspective of the UK NHS, based on NHS reference costs (2008-9) and resource-use estimates obtained from clinical experts.

---

second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from “worst possible” to “best possible” health.

Critically none of the resource utilisation costs listed below take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

The authors estimated that the cost of arthrographic distension derived from NHS reference costs (high volume image-guided injection) was approximately £114.84 (£79.84 to £134.84), depending on the choice of steroid injection. They also reported the costs of other treatments used for frozen shoulder as follows;

- The costs for standard unguided steroid injection varied from £36.16 to £138.51 depending on the practitioner delivering the injection, the type of steroid used and where the practitioner is based (i.e. the setting). These costs suggest that a physiotherapist delivering treatment in a community setting is the cheapest option and a rheumatologist delivering treatment in a hospital setting is the most expensive.
- The estimated costs of standard guided steroid injection ranged from £299.68 to £475.56. These costs were mainly influenced by who delivered the injection; whether it's an orthopaedic surgeon, a rheumatologist or a radiologist.
- Physiotherapy treatment was estimated to cost between £98.75 and £126.75 dependent on setting. The addition of a steroid injection to physiotherapy presented a plethora of scenarios dependent on practitioner, steroid choice and setting; these costs range between £121.43 and £607.31.
- Manipulation under anaesthesia (MUA) was estimated to cost £1446 (£1,213 to £1,522) and capsular release £2,204 (£1,809 to £2,511), both of which included rehabilitation physiotherapy.

Table 1: Summary of systematic reviews of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options

Study	Patients	Intervention	Comparator	Outcomes
Saltychev et al 2018 [8] Finland Systematic review and meta-analysis of RCTs 12 RCTs in the SR 7 RCTs in the meta-analysis RCTs from different countries No UK studies included Search date – September 2017	Adults with adhesive capsulitis, frozen shoulder, painful stiff shoulder, or osteoarthritis (presence of pain with restriction of active & passive glenohumeral joint movements) Total number of patients not reported	Hydrodilatation Volume = 20 to 90ml Mixture = triamcinolone or methylprednisolone + contrast + normal saline ± local anaesthetic	Placebo, sham, other interventions, or no treatment as reported by individual study.	**PRIMARY OUTCOMES** **<u>Pain</u>** **hydrodilatation + corticosteroid vs corticosteroids (pooled results for 5 studies) –** Mean difference in **VAS** = 0.37 [95% CI 0.12 to 0.61 (p=0.00)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in pain scores was 12. **<u>Disability assessment</u>** **hydrodilatation + corticosteroid vs corticosteroids (Pooled results for 4 studies)** Mean difference in **SPADI** = 0.20 [95% CI 0.-0.04 to 0.44 (p=0.11)] **SECONDARY OUTCOMES** **<u>ROM</u>** **hydrodilatation + corticosteroid vs corticosteroids (pooled results for 6 studies)** Mean difference in **ROM** = 0.38 [95% CI 0.07 to 0.69 (p=0.01)], NNT= 12 - The number of patients that needed to be treated (NNT) in order to get a significant improvement in range of movement scores was 12. **ADVERSE EVENTS (3 studies)** Transient flushing or heat regulation disturbances, loss of sensation + motor control in injection arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope observed in both arms. One case of GH joint infection with HD + corticosteroid. **No further details provided.**
Catapano et al 2018 [9] Canada Systematic review without meta-analysis of RCTs from different countries 6 RCTs – 5 of the RCTs were also included in the meta-analysis by Saltychev et al 2018 One RCT used a total of 10ml therefore not high volume	Adults with adhesive capsulitis 410 shoulders Mean age 51 to 61 years In most of the studies participants have had symptoms for at least three months	Hydrodilatation with or without corticosteroid	Any	**PAIN - VAS (information on VAS score range for the different studies not reported)** Two of the relevant 5 studies reported statistically significant improvement in pain in favour of hydrodilatation (HD) relative to intra-articular injection (IAI); Three showed no difference At 12 weeks: IAI 3.57 (1.1) vs HD 3.29 (0.95) (p=0.002) Reza et al 2013 (100 shoulders) At 1 month: IAI 4.6(1.1) vs HD 3.6 (1.3) (p=0.035) Yoon et al 2016 (90 shoulders) **ROM** Three of the relevant 5 studies reported statistically significant improvement in ROM pain in favour of HD; Two showed no difference At 12 weeks 1) Extension ROM p=0.03; external rotation ROM p=0.01 (no details were provided Gam et al 1998 2) Abduction: IAI 82.7^0(22.6^0) vs HD 114.4^0 (30.1^0) p=0.005; Internal rotation: IAI 48.4^0 (10.8^0) vs HD 55.4^0 (18.2^0) p=0.027 Reza et al 2013 (100 shoulders)

				At 1 month External rotation: IAI 28^0(8^0) vs HD 36^0 (9^0) (p=0.005 Yoon et al 2016 (90 shoulders) It is not clear whether assessors were blinded to treatment **ADVERSE EVENTS – number of studies or patients not reported** Approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection.
Maund et al 2012 [10] UK Systematic review and **cost-effectiveness study** **No UK based studies included** 3 RCTs of arthrographic distension – all the RCTs were included in SR by Saltychev et al 2018	Adults with adhesive capsulitis	Arthrographic distension (with image-guided high volume injection) with or without corticosteroid and/or saline	Any	**Included studies have been considered in the reviews by Saltychev et al 2018 and Catapano et al 2018** **AVERAGE COST ESTIMATES FOR ARTHROGRAPHIC DISTENSION VERSUS ALTERNATIVE OPTIONS BASED ON NHS REFERENCE COSTS AND RESOURCE USE PROVIDED BY CLINICAL EXPERTS IN THE NHS** **£79.84 to £134.84** (Arthrographic distension with image-guided high volume injection) Vs standard unguided steroid injection £36.18 to £138.51 vs image-guided steroid injection £299.68 to £475.56 vs physiotherapy treatment alongside steroid injection £121.43 to £607.31 vs physiotherapy treatment only £98.75 to £126.75 vs Acupuncture £117.75 to £126.75 vs MUA £1,213 to £1,522 vs capsular release £1,809 to £2,511 The figures represent the range which depends on the setting, the professional delivering treatment or the choice of treatment e.g. steroid injection

Abbreviations: ACR – arthroscopic capsular release; EuroQol-5D VAS- EuroQOL-5D visual analogue scale[12]; HD – hydrodilatation; IAI – intra-articular injection; OSS[13] – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

[12] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

[13] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

Table 2: Summary of RCTs of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options

Study	Patients	Intervention	Comparator	Outcomes
Gallacher et al 2018 [3] UK RCT Single centre	Patients with severe idiopathic frozen shoulder for 3 months and had a failed course of physiotherapy n=50 (39 analysed) Recruited between June 2013 and December 2016 by consultant shoulder surgeon	Hydrodilatation into GH joint (1ml triamcinolone 80mg, 4ml 2% lidocaine, 40ml normal saline) n=25 (20 analysed) Mean age = 55.2 years Patients were unblinded to treatment	Arthroscopic capsular release n=25 (19 analysed) Mean age = 52.6 years Patients were unblinded to treatment	**Oxford shoulder score (OSS) at 6 months** Improvement from baseline with HD : 22.3 (95% CI, 16.6 to 27.5; p <0.01) Improvement from baseline with ACR: 26.5 (95% CI, 23.1 to 29.9; p< 0.01) **OSS at 6 months;** **ACR vs HD**: 43.8 [95% CI 42.2 to 45.2] vs 38.5 [95% CI 34.6 to 42.4], p=0.023 **Difference in improvement in EuroQOL-5D VAS at 6 months** (10 vs 19.6 for ACR and HD, respectively, p=0.053 **Improvement in external rotation at 6 months - ACR vs HD** (47° vs 34°) p=0.03 **Improvement in forward elevation at 6 months - ACR vs HD** (83° vs 71°) p=0.023 **Crossover** < 6-month follow-up, four patients from HD to ACR; one patient from ACR to HD. HD to the ACR group - mean 11.0-point improvement in the OSS at 6 weeks after HD vs 20.6-point improvement in the HD group that did not cross over. In crossover patients a 28.0-point improvement in OSS from the baseline at 6 months after ACR. **The authors found no complications to report**

Abbreviations: ACR – arthroscopic capsular release; EuroQol-5D VAS- EuroQOL-5D visual analogue scale[n]; HD – hydrodilatation; IAI – intra-articular injection; OSS[o] – Oxford Shoulder Score; VAS – visual analogue score; GH – glenohumeral; MUA – manipulation under anaesthesia; ROM – range of motion; SPADI - Shoulder Pain and Disability Index; VAS – visual analogue scale

[n] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. The first, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.
[o] The Oxford Shoulder Score (OSS) is a validated patient-reported outcome measure. The OSS questionnaire contains 12 items, each with five potential answers. Patients are asked to rate their symptoms between 1 (minimal symptoms) and 5 (severe symptoms). The combined total gives a minimum score of 12 and a maximum of 60.

4.2 Safety

Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups from three studies. They stated that one case of glenohumeral joint infection was reported in a patient treated with hydrodilatation and corticosteroid. No further details including the number of patients were provided.

Catapano et al [9] reported that side effects were equal among the combined (hydrodilatation with corticosteroid) intervention group and control (corticosteroid only) group. They stated that approximately 15% of patients in each group described transient loss of sensation, motor control of the arm, flushing, nausea, dizziness, pain and/or discomfort on injection. The authors indicate that these were typically rated as mild and spontaneously resolved completely, lasting only for a short period of time. However, no further details on the number of studies or patients were provided.

In the RCT of 50 patients, no complications were noted in either the ACR or hydrodilatation groups at six months follow-up [3].

4.3 Summary of findings

We identified three systematic reviews of RCTs [8, 9, 10] of hydrodilatation with high volume intra-articular injection for adhesive capsulitis, compared to alternative treatment options. The earliest of these also explored cost-effectiveness [10]. We also found one RCT [3] published subsequent to the systematic reviews. However, we have not reported clinical outcomes from the earliest systematic review as the studies have been superseded by those included in the most recent ones. The main outcomes measures reported include changes in pain scores and range of movement. Change in Oxford Shoulder Scores (OSS) and quality of life was reported.

Pain. Two systematic reviews (one with meta-analysis) reported significant improvements in pain scores using VAS with hydrodilatation with corticosteroid compared with corticosteroids injections alone. The findings from the systematic review (with meta-analysis) by Saltychev et al (2018) [8] was based on pooled results from five RCTs (p=0.00; NNT= 12) while those from Catapano et al (2018) [9] were from two out of five RCTs included in their review; one study at 12 weeks (p=0.002) and the other at one month (p=0.035).

Range of Movement. Significant improvements in range of movement were reported by two systematic reviews and one RCT. The findings reported by Saltychev et al were based on pooled results from six RCTs (p=0.01; NNT= 12) while those by Catapano et al were from two of five RCTs; one at 12 weeks (extension ROM p=0.03; external rotation ROM p=0.010 and abduction ROM p=0.005; internal rotation p=0.027) and one at one month (external rotation, p=0.005) in favour of the hydrodilatation group. Two RCTs included in Catapano et al showed no difference between hydrodilatation with corticosteroid injection and intra-articular corticosteroid injection alone. The RCT by Gallacher et al reported that the ACR and HD cohorts showed improvements in external

rotation and forward elevation with the improvement in both outcomes being significantly greater in the ACR group (p=0.03 and p=0.023 respectively).

Oxford Shoulder Score. The RCT by Gallacher et al reported that both the HD and ACR groups demonstrated significant improvements in OSS from baseline, but the OSS was significantly higher in the ACR cohort than the HD cohort (p= 0.023).

Quality of Life. Significant improvement in EQ-5D[p] VAS was also noted in both the HD and ACR groups in the RCT by Gallacher et al, but the difference in improvement between the groups at any time point was not significant.

These findings need to be interpreted with caution as they are all from small studies which may not have been sufficiently powered to show any meaningful differences. Also many of the outcomes measured were patient-reported; these patients were not blinded to their treatments, so this is likely to have introduced some bias.

Adverse events. Two systematic reviews [8, 9] reported on adverse events associated with hydrodilatation with corticosteroid and corticosteroid only intra-articular injections.

Based on three studies, Saltychev et al [8] reported that some transient adverse events such as flushing or disturbances in heat regulation, loss of sensation and motor control in the affected arm, loss of sleep, nausea, dizziness, after-pain and hypotensive syncope were observed with both the hydrodilatation with corticosteroid and corticosteroid only groups. They stated that there was one case of glenohumeral joint infection in a patient treated with hydrodilatation and corticosteroid. Catapano et al [9] reported similar adverse effects stating that approximately 15% of patients were affected. Neither of the reviews provided any further details

Cost Effectiveness. Maund et al [10] set out to carry out a cost-effectiveness analysis however, were unable to do so due to paucity of evidence. Instead the authors estimated average treatment costs from the perspective of the UK NHS for the interventions identified in the systematic review based on NHS reference costs and resource use provided by clinical advisers.

The costs estimated by the authors do not take into account the relative effectiveness for each intervention. They therefore shed no light on the relative cost effectiveness of any of the treatment options.

[p] EuroQol-5D (EQ-5D) is used to measure health-related quality of life; it measures a patient's health across five different domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D has two parts. First, the EQ-5D profile, asks patients to classify their health based on self-assessed levels of problems ("no", "some", "extreme") on the five dimensions. The second is the EQ-VAS, which asks patients to indicate their overall health on a vertical visual analogue scale, ranging from "worst possible" to "best possible" health.

5 Equity issues

It is unknown if there is variation in access to image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

6 Discussion and conclusions

Question 1

In adults with a painful joint, is image-guided HIGH VOLUME intra-articular injections clinically effective compared to alternative treatment options?

It is unclear whether treatment for joint pain with an image-guided HIGH VOLUME intra-articular injection is clinically effective compared to alternative treatment options.

Evidence from two systematic reviews of RCTS comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and ROM (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the ROM assessors were blinded to the treatments.

Question 2

In adults with a painful joint, is treatment with image-guided HIGH VOLUME intra-articular injections cost effective compared to alternative treatment options?

It is unclear whether image-guided HIGH VOLUME intra-articular injection is cost-effective compared to alternative treatment options. One study by Maundy et al (2012)[ref] attempted to establish the relative cost-effectiveness of image guided high volume intra-articular injections in painful joints but was unable to do so due to paucity of evidence data on the interventions.

7 Search Strategy

Search date: 19th September 2018

We searched PubMed, Embase and Cochrane Library – limiting to last 10years and English language. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

Search terms
Medline:

1. ((arthrograph* or arthroscop* or capsular or joint*) adj5 disten?ion).ti,ab.
2. (hydrodilat* or hydro-dilat*).ti,ab.
3. hvigi.ti,ab.
4. Injections, Intra-Articular/ or *Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high* or large) adj2 volume*).ti,ab.
9. 7 and 8
10. ((high volume* or large volume) adj5 (inject* or saline or steroid* or corticosteroid* or glucocorticoid* or cortiso* or hydrocortis* or triamcinolone or methylprednisolone or prednisolone or an?esthe*)).ti,ab.
11. 8 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic* or glenohumer* or gleno-humeral or shoulder or acetabul* or hip or tibiofem* or patellofem* or knee* or joint*) adj2 pain).ti,ab.
20. joint diseases/ or exp bursitis/ or femoracetabular impingement/ or patellofemoral pain syndrome/ or shoulder impingement syndrome/
21. exp Tendinopathy/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit* or degenerative arthri*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")

Embase:

1. ((arthrograph* or arthroscop* or capsular or joint*) adj5 disten?ion).ti,ab.
2. (hydrodilat* or hydro-dilat*).ti,ab.
3. hvigi.ti,ab.
4. ar.fs. or *Injections/
5. injection?.ti,ab.
6. (intraarticular or intra-articular).ti,ab.
7. 4 or 5 or 6
8. ((high* or large) adj2 volume*).ti,ab.
9. 7 and 8
10. ((high volume* or large volume) adj5 (inject* or saline or steroid* or corticosteroid* or glucocorticoid* or cortiso* or hydrocortis* or triamcinolone or methylprednisolone or prednisolone or an?esthe*)).ti,ab.
11. 9 or 10
12. exp joints/
13. hip/ or knee/ or elbow/ or shoulder/
14. 12 or 13
15. pain/ or exp back pain/ or chronic pain/
16. 14 and 15
17. exp Arthralgia/
18. arthralgi*.ti,ab.
19. ((sacroiliac or sacro-iliac or facet or zygapophyseal or acromioclavic* or glenohumer* or gleno-humeral or shoulder or acetabul* or hip or tibiofem* or patellofem* or knee* or joint*) adj2 pain).ti,ab.
20. exp elbow disease/ or exp shoulder disease/ or exp hip disease/ or exp knee disease/
21. exp Tendinitis/
22. exp OSTEOARTHRITIS/
23. (osteoarthrit* or degenerative arthri*).ti,ab. or arthritis.ti.
24. (frozen shoulder or bursitis or adhesive capsulitis or tennis elbow or tendinopath* or tendinitis).ti,ab.
25. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. 11 and 25
27. 1 or 2 or 3 or 26
28. limit 27 to (english language and yr="2008 -Current")
29. conference*.pt.
30. 28 not 29

Image-guided HIGH VOLUME intra-articular injections (40mls+) of saline with or without corticosteroid and/or local anaesthetic - Inclusion criteria for identification of relevant studies

Question	Population	Indication	Intervention	Comparator	Outcomes	Studies
In adults with a painful joint, what is the clinical and cost effectiveness of image-guided HIGH VOLUME intra-articular injections compared to alternative treatment options?	Adults with a painful joint	Pain management in degenerative joints	High-volume image guided injection (HVIGI) (40mls+) of saline with or without corticosteroid and/or local anaesthetic.	Any including: Standard volume intra-articular corticosteroid injection (image guided/not image guided) Conservative treatment with lifestyle modification and/or medication and/or physiotherapy	Clinical effectiveness including Pain Function/mobility QoL AE Cost effectiveness Subsequent arthroscopy Subsequent arthroplasty	Standard evidence review in order to be robust enough to influence/change clinical practice. SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies

Inclusion Criteria
Peer reviewed publications
English language

Exclusion Criteria
Abstracts
Letters
Commentaries
Conference papers
Case reports
Papers published more than 10 years ago
Papers published online subsequent to the search date

8 References

1. International Association for the Study of Pain (IASP). Treating people with joint pain. Global year against pain in the joint 2016; Fact sheet no 1. https://s3.amazonaws.com/rdcms-iasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/1.%20Patients%20and%20Joint%20Pain.pdf Last accessed 15 October 2018
2. NHS Choices [online] https://www.nhs.uk/conditions/joint-pain/ Last accessed 15 October 2018
3. Gallacher S, Beazley JC et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. Journal of Shoulder & Elbow Surgery. 2018 Aug; 27(8):1401-6.
4. Neogi T. Joint pain epidemiology. Global year against pain in the joint 2016; Fact sheet no 11. https://s3.amazonaws.com/rdcms-iasp/files/production/public/Content/ContentFolders/GlobalYearAgainstPain2/2016/FactSheets/English/11.%20Joint%20Pain%20Epidemiology.pdf Last accessed 15 October 2018
5. Duncan R, Francis RM et al. Prevalence of arthritis and joint pain in the oldest old: findings from the Newcastle 85+ Study. Age and Aging 2011; 40(6):752-5.
6. Georgiannos D, Markopoulos G et al. Adhesive Capsulitis of the Shoulder. Is there Consensus Regarding the Treatment? A Comprehensive Review. The open orthopaedics journal. [Review]. 2017; 11:65-76.
7. Buchbinder R, Green S et al. Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD007005.
8. Saltychev M, Laimi K et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. Scandinavian Journal of Surgery: SJS. 2018:1457496918772367.
9. Catapano M, Mittal N et al. Hydrodilatation with Corticosteroid for the Treatment of Adhesive Capsulitis: A Systematic Review. Pm & R. [Review]. 2018; 10(6):623-35.
10. Maund E, Craig D et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technology Assessment (Winchester, England). [Research Support, Non-U.S. Gov't Review]. 2012; 16(11):1-264.

4.

9 Clinician comments after 3 week consultation of the draft evidence review

Date	Clinician	Comments	SPH Response
04/12/2018	Mr. Samir Massoud Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham	In relation to the review of ultrasound guided Hydrodilatation for frozen shoulder, I agree that these are not likely to be more effective than steroid injection alone and are significantly more painful for patients.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
10/12/2018	Paresh Jobanputra (Cons Rheumatologist)	My experience in this area is limited. Given what is believed about the natural history of frozen shoulders, the only condition I consider for hydrodilation, a pathway of conservative therapy with or without clinical landmark based injection, perhaps repeated if necessary (either using clinical landmarks or US guidance) and only then considering surgical input seems reasonable.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
13/12/2018	Alison Jackson Clinical Team Leader (MSK) Musculoskeletal & Orthotics Good Hope and Solihull Hospitals	**Dear All** **Please see below information which has been compiled by a specialist physiotherapist working in UHB HGS physiotherapy injection service which provides US guided HV injections as well as US guided and blind injections. HGS US guided service has been operational for the delivery of HV shoulder joint injections since 2013: governance evidenced by PGD and relevant inclusion/exclusion criteria.** **Comments** • **Evidence review –** Agree the inclusion of relevant studies and appropriate summaries however additional studies incorporated below with summaries highlighted in yellow. 5. • **Current clinical practice – HV** shoulder joint injections are considered when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets, consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always	Thank you for your helpful feedback. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We deal with the additional studies separately below.

		followed up to review as part of this procedure. **6.** • **Clinical opinion -** Our clinical experience suggests that patients tolerate a guided shoulder distension procedure well and refer to an intense pressure feeling rather than pain. There have been no complications within our physiotherapy service and all have improved. I believe it works well particularly for patients with recalcitrant frozen shoulders, particularly females, in mid 50s and diabetic patients. Pain relief appears to be the most significant feature with variable movement improvement. This then allows tolerance of appropriate rehabilitation/stretching. I believe there are few risk factors, particularly when patients are appropriately screened pre procedure. It is easily performed as an outpatient procedure and patients often continue with their normal day with no restrictions. Cost effectiveness – (page 9 of the BSOL & Black Country HVIGI for joint pain Consultation Draft Nov 18 attachment) – no reference is made to the cost of physio led USG HV intra articular shoulder injection – only to palpation guided and we would encourage you to review this. I believe that physios are best placed to offer this safe, cost effective service as we assess and treat all aspects of the patients presenting problem from assessment to diagnosis, procedure and then rehab afterwards – a seamless service as suggested by Dr Jeremy Lewis's presentation at the 5th biennial Emirates physiotherapy conference in May 2016 "Don't want to be left out in the cold": Non-surgical management of Frozen Shoulder. The patient presents to the right person at the right time in their pathway therefore receiving the most appropriate management located in community or acute care settings.	We did not identify any cost-effectiveness studies on physiotherapy led USG high volume intra articular shoulder injection that met the PICO inclusion criteria.
11/12/2018	Physiotherapists BHH	I agree with the options for the commissioners on page 1 as we only use this for the shoulder joint when patients have failed other conservative treatments – hydro, stretches, acupuncture, palpation guided normal volume steroid/local injection – and this is only performed following full consultation with the patient, including information leaflets , consent, explanation of the procedure and its possible complications and intended benefits. Patients in physiotherapy are also always followed up to review as part of this procedure.	Thank you very much for these helpful comments and the one below. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

		With regard to clinical effectiveness, safety and cost implications – the following references 1. The effectiveness of ultrasound guided hydrodistension and physiotherapy in the treatment of frozen shoulder/adhesive capsulitis in primary care: a single centre service evaluation. Michael Bryant, Andrew Gough, James Selfe .First Published May 17, 2017 https://doi.org/10.1177/1758573217701063 Conclusions This service evaluation demonstrates that management of frozen shoulder stage II to III, as conducted by physiotherapists in a primary care setting utilizing hydrodistension and a guided exercise programme, represents an effective non-operative treatment strategy. Also details cost effectiveness when comparing with surgery or secondary care guided injection.	This service evaluation (not a clinical trial) was not included in the rapid evidence review because it did not meet the PICO inclusion criteria.
		2. Analysis of hydrodilatation as part of a combined service for stiff shoulder. Shoulder Elbow 2017 Jul;9 (3): 169-177 7. Rajendranath Sinha,1 Priyesh Patel,1 Nicky Rose,1 John Tuckett,2 Anurag N Banerjee,3 John Williams,1 Stephen Aldridge,1 and Paul Stuart2 8. Conclusions Hydrodilatation results in a significant improvement of symptoms in patients with adhesive capsulitis. An MDT approach has improved the management of the stiff and painful shoulder and markedly reduced the need for surgery – with table of figures over 4 years.	This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.)
		3. Effectiveness of Glenohumeral Joint Dilatation for Treatment of Frozen Shoulder: A Systematic Review and Meta-analysis of Randomized Controlled Trials Wei-Ting Wu, Ke-Vin Chang, Der-Sheng Han, Chung-Hsun Chang, Fu-Sui Yang & Chih-Peng Lin 9. Scientific Reports volume 7, Article number: 10507 (2017) | Download Citation	This systematic review and meta-analysis (Wu et al) was excluded from the rapid evidence review because it has been superseded by a later one (Saltychev et al 2018) which assessed all the trials included in Wu et al and more.
		10. 4. Frozen Shoulder: long term outcome following arthrographic distension. R Clement; A Ray; C Davidson; et al Acta Orthop. Belg 2013,79,368-374. Conclusions Arthrographic distension is safe and effective - including for diabetic patients. They reported long term improvement (12/12s+). The low number of patients requiring a second procedure makes it preferable to MUA.	This paper (not a comparative study) was not included in the rapid evidence review because non-comparative studies add little when there is RCT evidence. (Without a comparator we do not know whether changes observed might have occurred without the treatment.)

		11. 5. Information on shoulderdoc.co.uk about hydrodistension for frozen shoulder where their own data has " shown good results in selected patients" 12. 6. Dr Jeremy Lewis www.LondonShoulderClinic.com Shine foundation - some details of improvements and cost savings when procedure is performed by physiotherapists. 13. Anecdotally – I have performed 8 of these procedures this year to date. Patients tolerate it well and refer to an intense pressure feeling rather than pain. There have been no complications and all have improved to a varying degree. I believe it works well particularly for patients with recalcitrant frozen shoulders, particularly females, in mid 50s and diabetic patients. Pain relief appears to be the most significant feature with variable movement improvement. This then allows tolerance of appropriate rehabilitation/stretching. I believe there are few risk factors, particularly when patients are appropriately screened pre procedure. It is easily performed as an outpatient procedure and patients often continue with their normal day with no restrictions. There may be equity issues as this is only offered by the physio dept on the GHGH site. Cost effectiveness – page 9 – no reference is made to the cost of physio led USG HV intra articular shoulder injection – only to palpation guided. I believe that physios are best placed to offer this safe, cost effective service as we assess and treat all aspects of the patients presenting problem form assessment to diagnosis, procedure and then rehab afterwards – a seamless service as suggested by Dr Jeremy Lewis's presentation at the 5th biennial Emirates physiotherapy conference in May 2016 " Don't want to be left out in the cold": Non surgical management of Frozen Shoulder –	This article (not a clinical trial) was not included in the rapid evidence review because conference papers and articles not published in peer reviewed journals do not meet the PICO inclusion criteria This article (not a clinical trial) was not included in the rapid evidence review because conference papers and articles not published in peer reviewed journal do not meet the PICO inclusion criteria

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.

Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic for the treatment of joint pain

Questions to be addressed

1. In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection clinically effective compared to non-image guided intra-articular corticosteroid injection?
2. In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection cost effective compared to non-image guided intra-articular corticosteroid injection?

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 image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections to inform their decisions on commissioning policy development.

Options for commissioners:

3. The Committee considers that due to the lack of high quality evidence of clinical and cost effectiveness for image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections; its use should be considered a low priority.
4. The Committee recommend that image guided intra-articular corticosteroid injections should be offered ONLY to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of its clinical and cost effectiveness.
5. The Committee considers that there is insufficient evidence to suggest that image guided intra-articular corticosteroid injections are more or less effective than non-image guided intra-articular corticosteroid injections and therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.
6. The Committee recommends that image guided intra-articular corticosteroid injections should be promoted as the treatment of choice because there is sufficient evidence to suggest that it is associated with more injection accuracy which is likely to lead to better clinical outcomes and fewer complications and some evidence to suggest a greater reduction in pain/disability.

Summary

Background

- Osteoarthritis is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone.

- Osteoarthritis can affect most joints. The most commonly affected joints are the knees, hips and small joints of the hand.
- People with OA often have joint pain, stiffness, reduced participation in daily activities and poor quality of life.
- OA is a major source of disability owing to pain and loss of function. It is the most common form of joint disease and among the top 10 causes of disability worldwide.
- A range of lifestyle, pharmacological, non-pharmacological, and surgical interventions are used for controlling symptoms and improving function.
- Conventional therapies include the use of analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration.

Clinical effectiveness

- We identified three studies of image guided intra-articular (IA) corticosteroid injections compared to non-image guided IA corticosteroid injections; one retrospective comparative study and two randomised single-blinded studies.
- Park et al (2015) retrospectively reviewed the medical charts of patients with acromioclavicular[a] (AC) joint degenerative OA who had been treated with ultrasound-guided (US) (n=50) or palpation-guided (n=50) AC joint IA corticosteroid injections between January 2012 and December 2013 at their outpatient clinic.
- The authors reported that the Shoulder Pain and Disability Index (SPADI)[b], Verbal Numeric pain Scale (VNS)[c] at rest (VNSar) and under local pressure (VNSlp), and the arm adduction test (VNSaat) all improved at one, three and six months after the injections in both groups ($p<0.05$).
- They also reported a statistically significantly greater improvement in the VNSlp score and SPDAI at six months and in the VNSaat score at three months and six months for the US-guided group compared with the palpation group ($p<0.05$).
- Given that the study was retrospective and conducted in one centre by a single physician (also one of the assessors), the potential for bias is substantial and therefore the results should be interpreted with caution.
- Nam et al (2013) carried out a randomised, prospective single-blinded clinical study (n=60) on the mid-term benefits and accuracy rate of US-guided versus palpation-guided IA injections for the treatment of distal radioulnar joint[d] (DRUJ) disorder.
- The authors reported that US-guided IA injections showed significantly higher accuracy (100%) than palpation-guided IA injections (75.8%) [$p<0.05$] in DRUJ disorder.
- They found that VNS, Disability of the Arm, Shoulder, and Hand questionnaire (DASH), Modified Mayo Wrist Score (MMWS), and range of movement (ROM) were improved at one, three and six months in both groups ($p<0.05$) but reported no significant difference in clinical outcome measures between the group receiving US-

[a] The acromioclavicular joint, or AC joint, is a joint at the top of the shoulder. It is the junction between the acromion (part of the scapula that forms the highest point of the shoulder) and the clavicle.

[b] The Shoulder Pain and Disability Index (SPADI) was developed to measure current shoulder pain and disability in an outpatient setting. The SPADI contains 13 items that assess two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability.

[c] Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score, *a five-point Likert scale of 3 (good) or 4 (excellent)* and 20 point improvement in the SPADI) at one, 3 and 6 months after the injections [14].

[d] The distal radioulnar joint is a joint between the two bones in the forearm; the radius and ulna, at the wrist.

guided injections and that receiving palpation-guided injections. However, they reported a positive correlation between pain/disability improvements and accuracy of IA injections at one, three and six months follow-up.

- These findings may not be generalisable because the palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. In addition, the relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show any difference in results between US-guided and palpation-guided injections.
- Both studies only included patients with BMI of less than 30kg/m^2; this does not necessarily represent the general OA population. The larger amounts of subcutaneous fat – the increased distance between the skin and bone in obese patients – are likely to have an effect on the accuracy of the injection, particularly for palpation-guided injections.
- Sibbitt et al (2011) reported the results from a single-blinded RCT (n=92) which addressed how sonographic needle guidance affects clinical outcomes of IA injection in patients with OA of the knee. Patients' pain was measured using the visual analogue scale (VAS) where 0cm signifies no pain and 10cm unbearable pain.
- The authors reported a significant reduction in pain mean scores (from a mean of 7.5 (±2.0) to 1.4 ±2.1 versus 7.8 ±1.8 to 2.4 ±2.1 with sonographic guidance relative to palpation guidance at two weeks (p=0.025) but this was not sustained at six months follow-up (p=1.0). They also reported superior duration of therapeutic effect in months [4.2± 1.9 versus 3.1± 2.1 (p=0.01)] and lower reinjection rates within 12 months [52% (24/46) versus 74% (34/46) (p=0.03)] with sonographic guidance. The authors also reported a significantly higher responder[e] rate with sonographic guidance of 67% (31/46) versus 33% (15/46) with palpation guidance, p=0.0004.
- These results should be interpreted with caution as participants were not blinded to their treatment and the details on the randomisation methods and concealment were not provided.

Safety

- Two of the three studies identified reported almost identical adverse effect profiles. They report that two and three patients in the US-guided group respectively and one patient (in each study) in the palpation-guided group complained of pain due to steroid-induced synovitis. In both studies skin atrophy and depigmentation were observed in two patients in the palpation group and in none in the US-guided group. There were no severe complications, such as septic arthritis, allergic reactions or ruptured tendons.
- The third study did not report adverse effects.

Cost-effectiveness

- We found one cost-effectiveness study of the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA.

[e] Responders were defined as those who had VAS <2cm

- Sibbitt et al (2011) aimed to assess the cost effectiveness of IA injection in patients with OA of the knee based on the results from a single-blinded RCT (n=92) which addressed whether sonographic needle guidance affects clinical outcomes.
- The authors reported a number of data on costs based on the USA Medicare system: cost per year if patient was treated at the physician's office as $173 ± $81 for palpation-guided IA injection compared with $460 ± $207 for sonographic guidance (p=0.0001); cost per year for patients treated in hospital outpatient clinic as $126 ± $58 for palpation-guided IA injection compared with $109 ± $49 for sonographic guidance (p=0.13).
- Cost per responder per year in a physician's office was reported as $531 ± $248 for palpation-guided IA injection compared with $1129 ± $307 for sonographic guidance (p=0.0001) and cost per responder per year in hospital outpatient clinic as $386 ± $180 versus $162 ± $73 respectively (p=0.0001). The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections.
- However it should be noted that the sonographic needle guidance procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing. The relevance of these results outside of the USA is therefore questionable.

Equity issues

- It is not known whether there is variation in access to image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

1 Context

1.1 Introduction

Osteoarthritis (OA) refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. It is the most common form of arthritis, and one of the leading causes of pain and disability worldwide. It is a chronic musculoskeletal disorder characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People with osteoarthritis often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by OA are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of osteoarthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of osteoarthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, OA is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic osteoarthritis; this might be thought of as 'joint failure'. This in part explains the extreme variability in clinical presentation and outcome that can be observed between people, and also at different joints in the same person [2].

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function (NICE 2012). Conventional therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

1.2 Existing national policies and guidance

There is no relevant NICE Technology Appraisal Guidance (with statutory requirement for NHS organisations to make funding available), clinical guidelines or quality standards specifically for the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections. However, NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.
- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

2 Epidemiology

OA is a major source of disability owing to pain and loss of function. It is the most common form of joint disease and among the top 10 causes of disability worldwide [4]. With aging of the population and increasing obesity, OA arises as a major public health problem and an important financial burden for the global economy [5].

In the UK, approximately 8.75 million people aged 45 years and over (33%) have sought treatment for OA. OA is more common in women (60% female, 40% male), and this difference is most apparent for hand and knee OA and among people over 50 years of age [6]. The risk of developing OA increases with age; one third of women and almost a quarter of men between 45 and 64 have sought treatment for OA, this rises to almost half of people aged 75 and over [7]. X-ray studies show that at least 50% of people older than 65 have evidence of OA [1].

The risk of developing OA throughout life increases with rising BMI [8]. People who are overweight or obese are respectively approximately 2.5 and 4.6 times more likely to develop knee OA than those of normal body weight [9]. This, along with the aging population, is contributing to the increasing number of people with OA.

Knee OA is more frequently observed in people with occupations that require squatting and kneeling, hip OA is associated with prolonged lifting and standing. Hand OA is more frequent in people with occupations requiring increased manual dexterity [10]. Genetic factors are thought to account for 60% of hand and hip OA and 40% of knee OA [11].

The total cost of OA to the UK economy is estimated at 1% of annual gross national product. In 1999/2000, 36 million working days were lost because of OA, costing the economy nearly £3.2 billion in lost production [1].

3 The interventions

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions including OA when first-line conservative therapies fail to provide adequate symptom relief [12].

Although osteoarthritis is generally thought to be of degenerative rather than inflammatory origin, there is evidence that an inflammatory component may be prese nt in at least some phases of the disease. Corticosteroids are known as potent anti-inflammatory agents that act through a variety of mechanisms [13].

Traditionally, intra-articular injections have been performed using anatomical landmarks to identify the correct trajectory for needle placement. However, different anatomical-guided injection techniques have yielded inconsistent intra-articular needle positioning due, in large part, to the fact that the physician cannot directly visualize the area of interest, and variations in anatomy are common. Incorrect needle placement has been partially associated with variable clinical outcomes. Furthermore, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis,

haemarthrosis, joint sepsis, necrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [12, 15]. However, it is controversial whether accuracy of needle placement has a significant impact on clinical outcome [12, 13].

The purpose of guidance during corticosteroid joint injections is to allow visualization, typically in real time, of the target anatomy so that the operator can achieve a more accurate and potentially safer and more effective injection [12, 13].

4 Findings

We searched Medline, Embase and Cochrane Library on the 14th September 2018 using the search strategy detailed in section 7 below. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews.

The search was limited to 2008 onwards and English language only and we excluded letters, commentary, case reports and conference papers.

4.1 Evidence of effectiveness

We did not find any systematic reviews of the clinical effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis. However we identified three studies; one retrospective comparative study and two randomised single-blinded studies [14, 15, 16] that met the PICO criteria for inclusion. Only comparative studies were included in this review.

> *We also identified one cost-effectiveness study of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA [16].*

4.1.1 Clinical effectiveness

We identified three studies of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections; one retrospective comparative study [14] and two randomised single-blinded studies [15, 16].

Park et al [14] retrospectively reviewed the medical charts of patients (n=100) with acromioclavicular (AC) joint degenerative OA who had undergone ultrasound (US) guided or palpation-guided AC joint IA corticosteroid injection between January 2012 and December 2013 at their outpatient clinic. Fifty patients had US guided IA corticosteroid injection and the other 50 had palpation-guided IA corticosteroid injection.

The authors reported that the Shoulder Pain and Disability Index (SPADI), Verbal Numeric pain Scale (VNS)[f] at rest (VNSar) and under local pressure (VNSlp), and the arm adduction test (VNSaat) improved at one, three and six months after the injections compared to before injection in both groups (p<0.05). They also reported a statistically significantly greater improvement in the VNSlp score at six months [baseline scores 6.10 ± 0.93 vs 6.02 ± 0.89; at 6 months: 2.29 ± 1.06 vs 2.83 ± 0.64 (p<0.05)] and SPADI at six months [baseline scores 51.50 ± 6.64 vs 52.88 ± 7.96; at 6 months: 27.44 ± 6.07 vs 30.63 ± 5.59 (p<0.05)] and in the VNSaat score at three months and six months [baseline scores 5.68 ± 0.99 vs 5.64 ± 0.92; at 3 months:2.50 ± 0.71 vs 2.85 ± 0.78 (p<0.05); at 6 months: 2.20 ± 0.98 vs 2.79 ± 1.06 (p<0.05)] for the US-guided group compared with the palpation-guided group. Please refer to table 1 for details.

The authors concluded that US-guided AC joint IA injection for the treatment of symptomatic AC joint OA resulted in better pain and functional status improvement than palpation-guided IA injection at the 6-month follow-up. However, these results need to be interpreted with caution as the treatment was carried out by a single physician in one centre and therefore may not be generalisable. As this is a retrospective chart review, the participants' information and recorded results may not have been accurate. The participants were not randomised, they chose their preferred intervention, and both the participants and the assessors (one of whom was the physician) were not blinded (they were aware of which intervention was used). In addition all the participants had BMIs of less than 30kg/m^2. All of these are likely to have introduced bias to the study.

Nam et al [15] conducted a randomised, prospective single-blinded clinical study (n=60) on the mid-term benefits and accuracy rate of US guided versus palpation guided intra-articular (IA) injections for the treatment of distal radioulnar joint (DRUJ) disorder. Participants were randomly assigned to undergo US-guided or palpation-guided IA injection.

The authors reported that US-guided IA injections showed significantly higher accuracy (100%) than palpation-guided IA injections (75.8%) into the DRUJ (p<0.05). They found that the primary outcome (Disability of the Arm, Shoulder, and Hand questionnaire (DASH)) and the secondary outcomes (VNS[g], Modified Mayo Wrist Score (MMWS), and range of movement (ROM)) all improved at one, three and six months in both groups but observed no significant difference in clinical outcome measures between the group receiving US-guided injections and the group receiving palpation-guided injections. However they observed a positive correlation between pain improvements and accuracy of IA injections at follow-up. DASH scores at baseline were 44.0 ± 8.5 vs 46.3 ± 10.2 for accurate vs inaccurate injections respectively; and scores at 6 months were 15.3 ± 4.1 vs 19.9 ± 2.3 (p<0.05) in favour of accurate injections. This is in contrast to DASH scores for US-guided versus palpation-guided injections with baseline scores of 44.3 ± 8.6 vs

[f] Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score and 20 point improvement in the SPADI) at one, 3, and 6 months after the injections.
[g] A successful outcome required a five-point Likert scale of 3 (good) or 4 (excellent) and a reduction on the VNS of >50 % and DASH of >15 points at 1, 3, and 6 months after the injection.

44.1 ± 8.9 and six months scores of 16.3 ± 4.1 vs 15.5 ± 4.4 (p=NS[h]). Please refer to table 1 for details.

These results need to be interpreted with caution for a number of reasons. The study was not double-blinded (only the assessors were blinded) and lack of blinding could have resulted in bias, particularly if a difference had been anticipated by patients. The palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. The relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show a difference between the two groups. All the participants had BMIs of less than 30kg/m^2; this is not necessarily representative of the general OA population. The larger amounts of subcutaneous fat in obese patients are likely to have an effect on the accuracy of the injection.

Sibbitt et al (2011) reported the results from a single-blinded RCT (n=92) which addressed how sonographic needle guidance affects clinical outcomes of IA injection in patients with OA of the knee. Patients' pain was measured using the visual analogue scale (VAS) where 0cm signifies no pain and 10cm, unbearable pain.

The authors reported a significant reduction in pain mean scores with sonographic guidance relative to palpation guidance at two weeks (p=0.025) but this was not sustained at six months follow-up (p=1.0) (baseline pain mean scores were 7.5±2.0 versus 7.8±1.8 for the sonographic guidance versus palpation guidance groups respectively; scores at two weeks were 1.4± 2.1 versus 2.4±2.1). They also reported superior duration of therapeutic effect in months [4.2± 1.9 versus 3.1± 2.1 (p=0.01)], lower reinjection rates within 12 months [52% (24/46) versus 74% (34/46) (p=0.03)] and longer time to next procedure (reinjection or referral to surgery) [7.1± 3.2 versus 6.0± 2.8 (p=0.08, not significant)] with sonographic guidance. The authors also reported a significantly higher responder[i] rate with sonographic guidance of 67% (31/46) versus 33% (15/46) with palpation guidance (p=0.0004).

These results should be interpreted with caution as participants were not blinded to their treatment and no details of the randomisation methods used or concealment were provided.

Trials in progress
A search of clinicaltrials.gov identified two trials both of which have been discontinued.

- NCT01032720 – This was a randomised trial to determine if ultrasound-guided knee steroid injections are more effective than sham ultrasound knee steroid injections for the treatment of osteoarthritis. This study, which recruited 33 participants, was terminated in February 2012; no further details are available [17].
- NCT02104726 – This was an open label study to compare relative efficacy of intraarticular steroid injection using anatomic landmarks versus a fluoroscopy guided technique in decreasing knee osteoarthritis pain one month after the procedure. The

[h] NS = not statistically significant
[i] Responders were defined as those who had VAS <2cm

trial, which did not recruit any participants, was withdrawn in July 2016; no further details are available [18].

4.1.2 Cost-effectiveness

We found one cost-effectiveness study of the use of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections conducted in the USA.

Sibbitt et al [16] reported the results from an RCT which addressed whether sonographic needle guidance affects clinical outcomes and used these to determine the cost effectiveness of IA injection in patients with OA of the knee.

The authors reported a number of data on costs: cost per year if patient was treated in the physician's office as $173 ± $81 for palpation-guided IA injection compared with $460 ± $207 for sonographic guidance (p=0.0001); cost per year for patients treated in hospital outpatient clinic as $126 ± $58 for palpation-guided IA injection compared with $109 ± $49 for sonographic guidance (p=0.13).

> *Cost per responder per year in a physician's office was reported as $531 ± $248 for palpation-guided IA injection compared with $1129 ± $307 for sonographic guidance (p=0.0001) and cost per responder per year in hospital outpatient clinic as $386 ± $180 for palpation guidance versus $162 ± $73 for sonographic guidance (p=0.0001). The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections.*

These results should be interpreted with caution for the following reasons: very little information was provided and there was no information on the method of randomisation or concealment. The study was conducted in the USA and costings were based on the Medicare reimbursement system which is not universally applicable. The costs not supported by the system were omitted from the costings e.g. sonographic guidance provided in hospital outpatients were not reimbursed and hence the potential cost for this was not reflected in the calculations. This certainly would have skewed the cost difference between the two study arms. It is unclear how relevant these resources and costs are to the NHS in England.

Table 1: Summary of studies of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis

Study	Patients	Intervention	Comparator	Outcomes
Park et al 2015 [14] Seoul, Republic of Korea Retrospective comparative study (chart review)	Patients with OA of AC joint who had palpation or US guided IA corticosteroid between January 2012 & December 2013 n=100	US guided AC joint IA steroid injection (n=50) mixture of 0.5% lidocaine (1ml) + triamcinolone 20 mg/mL (0.5 ml) + radiographic contrast material (0.5 ml) Men: 11 (22%) Women: 39 (78%) Age: 57.8 ± 8.4 years BMI(kg/m^2): 22.9 ± 1.9 FU: 6.5 ± 2.3 months (Mean±SD)	Palpation (P) guided AC joint IA steroid injection (n=50) mixture of 0.5% lidocaine (1ml) + triamcinolone 20 mg/mL (0.5 ml) + radiographic contrast material (0.5 ml) Men: 12 (24%) Women: 38 (76%) Age: 59.1 ± 8.5 years BMI(kg/m^2): 22.8 ± 2.1 FU: 6.6 ± 2.2 months (Mean±SD)	**Successful (accurate) Injection as determined by the presence of contrast dye in the joint cavity by radiography (US vs P)** 96% (48/50) vs 60.5% (31/50) (p<0.05) **SPADI (US vs P)(Mean±SD)** Baseline 51.50 ± 6.64 vs 52.88 ± 7.96 At one month: 23.88 ± 4.57 vs 25.30 ± 7.56 (p=NS) At 3 months: 25.71 ± 5.01 vs 28.12 ± 6.75 (p=NS) At 6 months: 27.44 ± 6.07 vs 30.63 ± 5.59 (p<0.05) **VNSar (US vs P)** Baseline 5.16 ± 0.79 vs 5.02 ± 0.80 At one month: 2.16 ± 0.96 vs 2.18 ± 0.80 (p=NS) At 3 months: 2.45 ± 0.83 vs 2.56 ± 0.56 (p=NS) At 6 months: 2.47 ± 0.90 vs 2.29 ± 0.75 (p=NS) **VNSlp (US vs P)** Baseline 6.10 ± 0.93 vs 6.02 ± 0.89 At one month: 2.82 ± 0.69 vs 2.94 ± 0.89 (p=NS) At 3 months: 2.52 ± 0.86 vs 2.94 ± 0.89 (p=NS) At 6 months: 2.29 ± 1.06 vs 2.83 ± 0.64 (p<0.05) **VNSaat (US vs P)** Baseline 5.68 ± 0.99 vs 5.64 ± 0.92 At one month: 2.64 ± 0.78 vs 2.94 ± 0.89 (p=NS) At 3 months:2.50 ± 0.71 vs 2.85 ± 0.78 (p<0.05) At 6 months:2.20 ± 0.98 vs 2.79 ± 1.06 (p<0.05) **All (at rest, under local pressure, and the arm adduction test) of the VNS and SPADI after the injection improved significantly from baseline at one, 3, and 6 months in both groups (p<0.05 for each before vs after injection comparison).** Successful treatment (significant pain relief) was defined as > 50% improvement in the VNS score and 20 point improvement in the SPADI) at one, 3 and 6 months after the injections. **Safety – US vs P** Steroid-induced synovitis – 3 vs 1 Skin atrophy and depigmentation – 0 vs 2 No p values reported

Study	Patients	Intervention	Comparator	Outcomes
Nam et al 2013 [15] Seoul, South Korea Randomised, prospective, single-blinded study	Patients with DRUJ disorder n=60 (57 analysed)	US guided IA injection of 0.5ml Omnipaque + 1% lidocaine (0.25ml) + triamcinolone 20mg (0.5ml) into the DRUJ n=28 Mean age: 52.9 years Male: 10 Female: 18	Palpation guided IA injection of 0.5ml Omnipaque + 1% lidocaine (0.25ml) + triamcinolone 20mg (0.5ml) into the DRUJ n=29 Mean age: 54.1 years Male: 11 Female: 18	**Clinical outcome by method of injection guidance** **Primary outcome (US vs P)** **DASH** Baseline 44.3 ± 8.6 vs 44.1 ± 8.9 Score at one month: 21.1 ± 4.5 vs 22.8 ± 4.8 (p=NS) Score at 3 months: 12.8 ± 2.3 vs 14.17 ± 3.5 (p=NS) Score at 6 months: 16.3 ± 4.1 vs 15.5 ± 4.4 (p=NS) **Secondary outcome (US vs P)** **VNS** Baseline 6.5 ± 1.0 vs 6.4 ± 0.9 Score at one month: 2.6 ± 0.8 vs 3.0 ± 0.9 (p=NS) Score at 3 months: 2.7 ± 1.0 vs 3.1 ± 0.8 (p=NS) Score at 6 months: 3.3 ± 1.1 vs 3.5 ± 0.7 (p=NS) **MMWS** Baseline 56.5 ± 6.4 vs 55.3 ± 5.1 Score at one month: 73.6 ± 3.1 vs 72.6 ± 4.1 (p=NS) Score at 3 months: 83.9 ± 3.2 vs 82.2 ± 3.4 (p=NS) Score at 6 months: 80.1 ± 5.0 vs 81.0 ± 4.1 (p=NS) **ROM** Pronation Baseline 63.4 ± 4.5 vs 63.6 ± 5.2 Score at one month: 83.5 ± 3.7 vs 82.1 ± 3.8 (p=NS) Score at 3 months: 82.7 ± 5.7 vs 80.1 ± 4.3 (p=NS) Score at 6 months: 80.3 ± 4.5 vs 79.4 ± 3.8 (p=NS) Supination Baseline 63.5 ± 4.5 vs 63.4 ± 5.9 Score at one month: 82.0 ± 3.4 vs 81.4 ± 3.5 (p=NS) Score at 3 months: 84.7 ± 5.4 vs 83.2 ± 4.3 (p=NS) Score at 6 months: 85.4 ± 5.6 vs 83.7± 4.5 (p=NS) **All outcomes after the injection improved significantly from baseline at one, 3 and 6 months in both groups but there were no significant differences in clinical outcome between the US guided and the palpation guided groups.** A successful outcome required a five-point Likert scale of 3 (good) or 4 (excellent) and a reduction on the VNS of >50 % and DASH of >15 points at 1, 3, and 6 months after the injection.

Study	Patients	Intervention	Comparator	Outcomes
				Successful (accurate) injection as determined by the presence of contrast dye (Omnipaque) in the joint cavity by radiography (US vs P) 100% (28/28) vs 75.8% (22/29) (p<0.05) **Clinical outcome by accuracy of injection** **Primary outcome (Accurate vs Inaccurate)** **DASH** Baseline 44.0 ± 8.5 vs 46.3 ± 10.2 Score at one month: 21.3 ± 4.3 vs 26.6 ± 5.6 (p<0.05) Score at 3 months: 12.8 ± 2.5 vs 18.6 ± 1.4 (p<0.05) Score at 6 months: 15.3 ± 4.1 vs 19.9 ± 2.3 (p<0.05) **Secondary outcome (Accurate vs Inaccurate)** **VNS** Baseline 6.4 ± 1.0 vs 6.6 ± 0.5 Score at one month: 2.6 ± 0.7 vs 4.1 ± 0.4 (p<0.05)) Score at 3 months: 2.8 ± 0.9 vs 3.3 ± 0.9 ((p<0.05) Score at 6 months: 3.3 ± 0.9 vs 4.0 ± 0.0 (p<0.05) **MMWS** Baseline 56.0 ± 6.0 vs 55.3 ± 3.9 Score at one month: 73.4 ± 3.7 vs 70.7 ± 1.5 (p<0.05) Score at 3 months: 83.6 ± 3.2 vs 79.0 ± 1.6 (p<0.05) Score at 6 months: 80.8 ± 4.7 vs 78.4 ± 2.0 (p=NS) **ROM** <u>Pronation</u> Baseline 63.7 ± 4.6 vs 62.1 ± 6.5 Score at one month: 83.3 ± 3.7 vs 78.9 ± 1.3 (p<0.05) Score at 3 months: 86.7 ± 5.7 vs 81.1 ± 1.7 (p<0.05) Score at 6 months: 84.3 ± 4.8 vs 77.4 ± 2.1 (p<0.05)) <u>Supination</u> Baseline 63.6 ± 5.1 vs 62.1 ± 6.5 Score at one month: 82.2 ± 3.4 vs78.4 ± 1.4 (p<0.05) Score at 3 months: 85.9 ± 5.2 vs 80.8 ± 1.3 (p<0.05) Score at 6 months: 83.2 ± 4.6 vs 76.7± 2.5 (p<0.05) **All outcomes after the injection improved significantly from baseline at one, 3, and 6 months in both groups. There was a statistically significant improvement in the VNS, DASH and ROM in the accurate injection group compared with the inaccurate injection group at one, 3 and 6 months but not the MMWS at 6 months.**

Study	Patients	Intervention	Comparator	Outcomes
				Safety – US vs P Steroid-induced synovitis – 2 vs 1 Skin atrophy and depigmentation – 0 vs 2 No p values reported
Sibbitt et al 2011 [16] New York, USA Single-blinded RCT and cost-effectiveness study	Non-effusive knees with OA n=92	Sonographic image guided injection (80mg triamcinolone) enhanced with one-handed mechanical syringe. n=46	Palpation guided anatomic landmark injection (80mg triamcinolone). n=46	**Pre-procedure baseline pain on VAS scores – mean (SD) (P vs US)** 7.8 (1.8) vs 7.5 (2.0) (p=0.45) **Pain at 2 weeks using VAS scores (P vs US)** 2.4 ± 2.1 vs 1.4 ± 2.1 (p=0.025) – 42% difference **Pain at 6 months using VAS scores (P vs US)** 6.3± 2.9 vs 6.3± 2.6 (p=1.0) **Duration of therapeutic effect (months) (P vs US)** 3.1± 2.1 vs 4.2± 1.9 (p=0.01) **Time to next procedure (reinjection or referral to surgery) (P vs US)** 6.0± 2.8 vs 7.1± 3.2 (p=0.08) **Reinjection within 12 months (P vs US)** 74% (34/46) vs 52% (24/46) (p=0.03) **Referral to surgery within 12 months (P vs US)** 7% (3/46) vs 4% (2/46) (p=0.7) **Responders at 2 weeks (P vs US)** 33% (15/46) vs 67% (31/46) p=0.0004 **Cost per year - physician's office (P vs US)** $173 ± $81 vs $460 ± $207 (p=0.0001) **Cost per year – hospital outpatient (P vs US)** $126 ± $58 vs $109 ± $49 (p=0.13) **Cost per responder per year - physician's office (P vs US)** $531 ± $248 vs $1129 ± $307 (p=0.0001) **Cost per responder per year – hospital outpatient (P vs US)** $386 ± $180 vs $162 ± $73 (p=0.0001) Responders were defined as those who had VAS <2cm VAS goes from 0- to 10cm; where 0cm is no pain and 10cm unbearable pain. VAS<2cm is regarded as asymptomatic and significant pain is defined as >5cm

Study	Patients	Intervention	Comparator	Outcomes
				Details of data on those treated in the physicians' office and in hospital outpatients were not provided. Ultrasound guided procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing.

Abbreviations: AC joint - acromioclavicular joint; BMI – body mass index; DASH - Disability of the Arm, Shoulder and Hand questionnaire; DRUJ - distal radioulnar joint; FU - follow-up; IA - intra-articular; MMWS - Modified Mayo Wrist Score; NS – not significant; OA - osteoarthritis; P – palpation; ROM - range of motion; SD – standard deviation; SPADI - Shoulder Pain and Disability Index; US - ultrasound; VAS - visual analogue scale; VNS - Verbal Numeric pain Scale; VNSar - Verbal Numeric pain Scale at rest; VNSlp - Verbal Numeric pain Scale under local pressure; VNSaat - Verbal Numeric pain Scale arm adduction test

4.2 Safety

The study by Park et al [14] reported that three patients in the US-guided group and one patient in the palpation group complained of pain due to steroid-induced synovitis. Skin atrophy and depigmentation were observed in two patients in the palpation group and none in the US-guided group. There were no severe complications, such as septic arthritis or allergic reactions.

Due to the retrospective nature of the study, it is possible that some of the adverse effects experienced by the patients were not documented.

Nam et al [15] also reported almost identical safety issues “two patients in US-guided group and one patient in the palpation group complained of pain due to steroid-induced synovitis. Skin atrophy and depigmentation were observed in two patients in the palpation group, none in the US-guided group. There were no severe complications, such as septic arthritis, allergic reactions and tendon ruptures”.

4.3 Summary of findings

We did not find any systematic reviews. However, we identified three clinical effectiveness studies, one of which assessed the cost-effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections in patients with osteoarthritis. The cost-effectiveness study was conducted in the USA.

The retrospective study by Park et al [14] reported statistically significant improvements in patients with OA of the AC joint in all outcome measures at one, three and six months after the injections in both the US and the palpation-guided groups. They also reported a statistically significantly greater improvement in two of the four outcome measures (VNSlp score and SPDAI) at six months and in one of the four measures (VNSaat score) at three months and six months for the US-guided group compared with the palpation group. However, it is unclear what the clinical relevance of the differences observed in these outcome measures is. In addition, given that the participants chose their preferred intervention, the study was retrospective and conducted in one centre by a single physician (also one of the assessors), the potential for bias is substantial and therefore the results should be interpreted with caution.

The randomised prospective single-blinded clinical study by Nam et al [15] reported significantly higher accuracy (100%) with US-guided than with palpation-guided IA injections (75.8%) in patients with DRUJ disorder. They found that all clinical outcome measures were improved at one, three and six months in both the groups receiving US-guided injections and those receiving palpation-guided injections but found no significant difference between the groups. However, they reported a positive correlation between pain improvements and accuracy of IA injections at six months follow-up. These findings may not be generalisable because the palpation-guided IA injection was given by an experienced physician (seven years) which may not always be the case in clinical settings. This may have affected the accuracy rate. In addition, the relatively small number of inaccurate injections means that the study may not have been sufficiently powered to show any difference between the two types of injection guidance.

Both studies only included patients with BMI of less than 30kg/m^2; this does not necessarily represent the general OA population. The distance between the skin and bone in obese patients is likely to have an effect on the accuracy of the injection.

Sibbitt et al [16] reported the results from an RCT as well as the cost effectiveness of IA injection in patients with OA of the knee. The authors reported significant pain reduction with sonographic guidance relative to palpation guidance at two weeks which was not sustained at six months follow-up. They also reported superior duration of therapeutic effect with sonographic guidance compared to palpation guidance and a lower rate of reinjection within 12 months with sonographic guidance. However, there is potential for bias in the results reported because participants were not blinded to the treatment they received.

The authors reported a number of data on costs based on the USA Medicare system: for patients treated in the physician's office they reported a significantly lower cost per patient per year and cost per responder per year for palpation-guided IA injection compared with sonographic guidance. In contrast, for patients treated in hospital outpatient clinic, they reported a significantly lower cost per responder per year with sonographic guidance compared with palpation guidance, but no difference in cost per patient per year for the two groups.

The authors concluded that the use of sonographic guidance in hospital outpatient clinics modestly reduced the cost per patient per year and cost per responder per year relative to palpation guided injections. However it should be noted that the sonographic needle guidance procedure in hospital outpatients is not reimbursed by Medicare so the authors only included $2 per procedure for each mechanical syringe and hence the true costs were missing. The relevance of these results outside of the Medicare system is therefore questionable.

5 Equity issues

It is not known whether there is variation in access to image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections for patients with osteoarthritis across providers in the NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, and Walsall, Wolverhampton and Dudley CCGs areas, or how access compares to the rest of England.

6 Discussion and conclusions

Question 1

In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection clinically effective compared to non-image guided intra-articular corticosteroid injection?

.

We did not find any high quality evidence to support the clinical effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections, although some lower quality evidence was found.

Evidence from a low quality study (retrospective chart review) [14] suggests that US guided intra-articular corticosteroid injections for osteoarthritis of the AC joint significantly improves some clinical outcome measures (VNSlp score and SPADI score at six months and VNSaat score at three months and six months)[j] compared to palpation guided intra-articular corticosteroid injections. The clinical relevance of the difference seen in these outcome measures is uncertain. In addition, a moderate quality study (single-blinded RCT) [16] also suggests that sonographic guided intra-articular corticosteroid injections significantly improves pain relative to palpation guided injections in patients with osteoarthritis of the knee after two weeks (although this was not sustained at six months follow-up), reduces reinjection rates within 12 months and increases the time to the next procedure. However, the lack of blinding of the participants to the treatments they received means that there was potential for bias in the results.

These findings conflict with those from a moderate quality prospective single-blinded randomised controlled study [15] which reported no difference in the clinical outcomes measured between US guided and palpation guided IA corticosteroid injections for patients with DRUJ disorder.

Evidence from this study of DRUJ injections [15] suggests that US guided IA corticosteroid injections into the DRUJ have a higher accuracy rate relative to palpation guided IA corticosteroid injections (100% versus 75%; $p<0.05$). The authors also suggest a positive correlation between accuracy and improvement in clinical outcomes measured ($p<0.05$). However, the study may not have been sufficiently powered to show any differences between outcomes for US guided compared to palpation guided injections due to the relatively small number of inaccurate injections in the latter group.

Question 2
In adults with a painful joint due to osteoarthritis, is image guided intra-articular corticosteroid injection cost effectiveness compared to non-image guided intra-articular corticosteroid injection?

We did not find any high or moderate quality evidence to support the cost-effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections.

> *We found one cost-effectiveness study of sonographic guided versus palpation guided IA corticosteroid injections in patients with osteoarthritis of the knee based on an RCT conducted in the USA. The study based its costs on the Medicare reimbursement system which is unique to the USA. It is therefore unclear how these results relate to the NHS in England.*

.

[j] SPADI - Shoulder Pain and Disability Index; VNSlp - Verbal Numeric pain Scale under local pressure; VNSaat - Verbal Numeric pain Scale arm adduction test

7 Search Strategy

Search date: 14th September 2018

We searched Medline, Embase and Cochrane Library, limited to 2008 onwards and English only. We also ran a search of TRIP database and NICE Evidence search with similar limits and restricting to Evidence Reviews. We excluded letters, commentary, case reports and conference papers.

Search terms
Medline:

1 exp Adrenal Cortex Hormones/
2 Injections, Intra-Articular/
3 1 and 2
4 ((intraarticular or intra-articular or inject*) adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
5 ((intraarticular or intra-articular or injection*) adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
6 3 or 4 or 5
7 (imag* adj5 guid*).ti,ab.
8 (ultraso* or ultra-so* or sonogra* or doppler or fluoroscop*).ti,ab.
9 exp Ultrasonography/
10 7 or 8 or 9
11 6 and 10
12 (imag* adj3 guid* adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
13 ((steroid* or corticosteroid* or glucocorticoid*) adj5 imag* adj3 guid*).ti,ab.
14 (imag* adj3 guid* adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
15 ((triamcinolone or methylprednisolone or prednisolone) adj5 imag* adj3 guid*).ti,ab.
16 11 or 12 or 13 or 14 or 15
17 (comment or editorial or letter or news or "review").pt. or case report.ti.
18 16 not 17
19 limit 18 to (english language and yr="2008 -Current")
20 limit 11 to "reviews (maximizes specificity)"
21 limit 20 to (english language and yr="2008 -Current")
22 19 or 21

Embase

1 exp corticosteroid/ar
2 ((intraarticular or intra-articular or inject*) adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
3 ((intraarticular or intra-articular or injection*) adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
4 1 or 2 or 3
5 (imag* adj5 guid*).ti,ab.
6 (ultraso* or ultra-so* or sonogra* or doppler or fluoroscop*).ti,ab.
7 *exp echography/

8 5 or 6 or 7
9 4 and 8
10 (imag* adj3 guid* adj5 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.
11 ((steroid* or corticosteroid* or glucocorticoid*) adj5 imag* adj3 guid*).ti,ab.
12 (imag* adj3 guid* adj5 (triamcinolone or methylprednisolone or prednisolone)).ti,ab.
13 ((triamcinolone or methylprednisolone or prednisolone) adj5 imag* adj3 guid*).ti,ab.
14 9 or 10 or 11 or 12 or 13
15 (conference* or comment or editorial or letter or news or "review").pt. or case report.ti.
16 14 not 15
17 limit 16 to (english language and yr="2008 -Current")
18 limit 9 to "reviews (maximizes specificity)"
19 limit 18 to (english language and yr="2008 -Current")
20 17 or 18

Table 2: Inclusion criteria for identification of relevant studies

Question	Population	Indication	Intervention	Comparator	Outcomes	Studies
In adults with a painful joint, what is the clinical and cost effectiveness of image guided intra-articular corticosteroid injections compared to non-image guided intra-articular corticosteroid injections?	Adults with a painful joint (exclude : inflammatory joint conditions - RA, gout, psoriatic arthritis)	Pain management in degenerative joints due to osteoarthritis	Image guided therapeutic intra-articular joint injections with corticosteroids with/without local anaesthetic Exclude: arthrocentesis for any reason	Non image-guided intra-articular joint injections with corticosteroids	Clinical effectiveness including Pain Function/mobility QoL AE Cost effectiveness Subsequent arthroplasty	Standard evidence review in order to be robust enough to influence/change clinical practice. SRMA SR of RCTS RCT SR Prospective cohort studies Retrospective cohort studies Cost effectiveness studies

Inclusion Criteria
Peer reviewed publications
English language

Exclusion Criteria
Abstracts
Letters
Commentaries
Conference papers
Case reports
Papers published more than 10 years ago
Papers published online subsequent to the search date

8 References

1. National Institute for Health and Clinical Excellence (NICE). Final Scope Osteoarthritis: the care and management of osteoarthritis. London, UK :NICE; 2012 https://www.nice.org.uk/guidance/cg177/documents/osteoarthritis-update-final-scope2 Last accessed 27 September 2018
2. National Institute for Health and Clinical Excellence (NICE). Osteoarthritis: the care and management of osteoarthritis. Clinical Guideline 177. London, UK: NICE; 2014
3. Griesser MJ, Harris JD et al. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. J Bone Joint Surg Am 2011; 93: 1727-1733
4. Cross M, Smith E, et al. The global burden of hip and knee osteoarthritis: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis. 2014; 73(7):1323–30.
5. Ayhan E, Kesmezacar H, Akgun I. Intraarticular injections (corticosteroid, hyaluronic acid, platelet rich plasma) for the knee osteoarthritis. World Journal of Orthopedics 2014; 5(3): 351–361.
6. National Institute for Health and Clinical Excellence (NICE). NICE Clinical Knowledge Summaries (CKS): Osteoarthritis: Prevalence. London, UK: NICE; April 2015.Online. Available: https://cks.nice.org. uk/osteoarthritis#!backgroundsub:2. Last accessed 27 September 2018
7. Arthritis Research UK, Osteoarthritis in General Practice. 2013.
8. Wluka A, Lombard C, and Cicuttini F. Tackling obesity in knee osteoarthritis. Nature Reviews Rheumatology 2013; 9(4): 225-235.
9. Kearns K, Dee A et al. Chronic disease burden associated with overweight and obesity in Ireland: the effects of a small BMI reduction at population level. BMC Public Health 2014; 14(143)
10. Clemence P, Nguyen C et al. Risk factors and burden of osteoarthritis. Annals of Physical and Rehabilitation Medicine 2016 59 (3): 134–138.
11. Spector T and MacGregor A. Risk factors for osteoarthritis: genetics. Osteoarthritis and Cartilage 2004; 12: 39-44.
12. Berkoff DJ, Miller LE, Block JE. Clinical utility of ultrasound guidance for intra-articular knee injections: a review. Clin Interv Aging. 2012; 7:89-95
13. Jüni P, Hari R et al. Intra-articular corticosteroid for knee osteoarthritis. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD005328
14. Park KD, Kim TK et al. Palpation versus ultrasound-guided acromioclavicular joint intra-articular corticosteroid injections: a retrospective comparative clinical study. Pain Physician. 2015;18(4):333–341
15. Nam SH, Kim J et al. Palpation versus ultrasound guided corticosteroid injections and short-term effect in the distal radioulnar joint disorder: A randomized, prospective single-blinded study. Clin Rheumatol 2013; 12:1807-1814.
16. Sibbitt WL Jr, Band PA et al. A randomized controlled trial evaluating the cost-effectiveness of sonographic guidance for intra-articular injection of the osteoarthritic knee. J Clin Rheumatol. 2011; 17(8):409–415.
17. Fraenkel L. Ultrasound (US)-Guided Versus Sham Ultrasound Corticosteroid (CS) Knee Injections. https://clinicaltrials.gov/ct2/show/NCT01032720
18. John Hopkins University. "Blind" vs. Fluoroscopy-Guided Steroid Injections for Knee Osteoarthritis. https://clinicaltrials.gov/ct2/show/NCT02104726

19. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National clinical guideline for care and management in adults. London: Royal College of Physicians (UK), 2008
20. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilage 2013; 21: 1145-1153.

9 Clinician comments after 3 week consultation of the draft evidence review

Date	Clinician	Comments	SPH response
	Jamie Arbuthnot Consultant Trauma & Orthopaedics Good Hope & Solihull Hospital	Can you confirm that this is image guided injections as a treatment rather than as a diagnostic measure please?	Yes, we can confirm that the rapid evidence review relates to image guided injections as a treatment. We will clarify this in the title of the document.
28/11/2018	Mr Andrew M Pearson Executive Medical Director & Consultant Orthopaedic Surgeon The Royal Orthopaedic Hospital NHS Trust	Thank you for sending me the details of this consultation. I have listed some of my personal observations below which you and your team may or may not find helpful in arriving at a decision. 1. Patients should always be managed with pharmacological and lifestyle modifications before referral to secondary care for any type of injection 2. Injections can be used for diagnostic or therapeutic purposes. Particularly in the case of patients with lower back and hip joint pain a hip injection can be useful in differentiating pain arising from the hip and back. 3. Whether image-guidance is required when undertaking a joint injection depends very much on which joint if being injected. For example the knee joint never requires the use of image guidance to be sure that the injection is performed intra-articularly. But in the hip joint it always requires the use of image-guidance to be sure that the injection is in the right place. 4. I see far too many patients in secondary care who have allegedly had joint injections conducted in primary care where the outcome is questionable, but where I have little confidence that the injection actually entered the joint as intended.	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We have clarified in the title that the review relates to injections for treatment rather than diagnostic purposes. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-

		5. I areas where there are important structures nearby, such as the hand, it is important that intra-articular injections are supported by image-guidance. I would be very happy to be involved in any way that I can in order to help further with this consultation	articular injections in the hand.
04/12/2018	Mr. Samir Massoud Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham	Thanks, The review of injections for arthritis is difficult to comment on because of lack of evidence. As far as I know, ultrasound guided injection of the subacromial space for impingement is much more common than these injections and may be worth investigating as these are fairly simple to do without ultrasound guidance. This would be a more likely source of savings. In my practice, more than 90% of shoulder injections are done in my clinic at the ROH with no ultrasound guidance.	Thank you very much for these helpful comments. This was a review of intra-articular joint injections, and hence injections into the subacromial space were not within scope of this review. We will include your comments in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
06/12/2018	Geoff Naylor Clinical Director Planned Care BSOL	Bsol CCG have data suggesting quite a lot of these injections are done by a select few of orthopaedic surgeons mainly in the independent sector on the NHS ECN contract. Not just for the shoulder, but also CMC joint injection injections	Thank you very much for your comment. We will include it in section 9 of the report so that it is available for discussion with the rest of the rapid evidence review.
06/12/2018	William Goude Walsall Healthcare NHS Trust	I agree that making decisions based on 3 low power studies, none of which look at sub acromial or CMCJ injections is not	Thank you very much for these helpful comments and clinical opinion. We will

		possible. My personal practice is to perform the majority of sub acromial injections in the clinic, but if it is an important diagnostic test (e.g if the patient has symptoms from the cervical spine etc as well) I will get the injection ultrasound guided. As upper limb surgeons we are probably confident to perform these injections ourselves in the clinic, but this may not be the case for our juniors or some of our colleagues.	include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. This was a review of intra-articular joint injections, and hence injections into the sub acromial space were not within scope of this review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand/CMCJ.
06/12/2018	Mike Craigen Consultant Orthopaedic and Hand surgeon Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust	Thank you for your request. I am a hand surgeon managing problems in the elbow wrist and hand and therefore have no experience of high volume intraarticular injections as these would be inappropriate in these areas. As to image guided joint injections this has been my standard practice for all my consultant career, normally using x ray but occasionally using ultrasound. You seem to have found the few studies that are published. The rationale is that if the injection fails to resolve the symptoms one possible explanation is failure to inject into the joint (easy to do in the hand and wrist), a problem avoided if image guidance is used. In addition you don't seem to have made any comment on the complications of injecting steroid outside the joint, including fat necrosis and tendon injury, again a higher risk in the hand due to the number of tendons in close proximity. I would support a recommendation that injections in the hand	Thank you very much for these helpful comments and clinical opinion. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand. We will include your comments in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

		and wrist should be performed under image guidance although I would prefer under x ray by an specialist in that area would be my preferred choice. I would be happy to provide further input.	
06/12/2018	*Richard Dias* *Clinical Director, Trauma & Orthopaedics* *Consultant Orthopaedic Hand & Upper Limb Surgeon* *Honorary Senior Lecturer, University of Birmingham*	I agree with Samir that subacromial space injections for impingement are easy to do without ultrasound guidance. I suspect it is the physiotherapists that use ultrasound for these injections. I totally agree with Mike Craigen that all injections into the hand and wrist should be done under image guidance. In clinical practice we often see patients who have had blind injections to the small joints of the hand with no benefit at all and the lack of confidence in further injections.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. This was a review of intra-articular joint injections, and hence injections into the subacromial space were not within scope of this review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the hand.
06/12/2018	Mr. Rajive Jose Consultant, Hand Surgery Burns & Plastics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham,	My practice is the same as Mike Craigen and I echo his comments regarding injections in the hand.	Thank you for your comment. Please see comments above.

06/12/2018	Mr. Mark Brewster Hand Surgery - Consultant Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham	I must admit that I perform almost all injections without USS or XR I do use XR for CMCJ and STT but all soft tissue injections, wrist joint/TFCC and MCPJs injection I do in the clinic with anatomical guidance only.	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.
06/12/2018	Mr. Alastair Marsh Consultant Orthopaedic Trauma Surgeon Clinical Lead Major Trauma Service Trauma & Orthopaedics - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital Birmingham	You have done a few though Mike! The important thing is that the joints that are difficult to get into, you do with guidance. Most common reasons for joint injections to not work are wrong joint or not in joint to start with. As a foot and ankle Surgeon I use xray guidance almost always so that I have the confidence that I have placed it where I want it. It also reduced the risk of fat necrosis in the foot and plantar plate rupture around the toes. It allows me to see the joint as well to confirm stability as well.	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the ankle or foot.
06/12/2018	Paul Parker University Hospitals Birmingham NHS Foundation Trust	I just guess where the hip is..... Or not.....	
06/12/2018	Seyed A Ali Trauma & Orthopaedic Consultant University Hospitals Birmingham NHS Foundation Trust Selly Oak Hospital	I completely agree with Alastair Marsh. Being a Foot & Ankle Surgeon, I always use X-ray guidance to inject small joints of the foot for reasons mentioned by Alastair. Thank you.	Thank you very much for your helpful comment and clinical opinion. We will include it in section 9 of the report so it is available for discussion with the rest of the rapid evidence review.

			We found no studies of the comparative effectiveness of image guided versus palpation guided intra-articular injections in the ankle or foot.
10/12/2018	Paresh Jobanputra (Rheumatology) University Hospitals Birmingham NHS Foundation Trust	Evidence review: The focus of the review is rather narrow but I suspect the search strategy is sufficiently accurate in terms of the literature for osteoarthritis. However since a large number of injections are done for shoulder pain, and one might argue that much rotator cuff disease is due to AC joint OA, a broader perspective should have been taken to allow the commissioners to make a more informed decision. There are more studies for shoulder pain and several systematic reviews. We should also bear in mind that injections for OA, however they are delivered, have limited efficacy so evidence from systematic reviews of these should have been described to give commissioners a broader perspective. Current clinical practice: I suspect there is considerable practice variation both in primary care and in secondary care. We do not have a local protocol for this but I believe that many hard pressed clinicians are asking for radiology-based injections because of time pressures and also a prevalent belief that the latter are more effective. It would seem appropriate to commission a clear physiotherapy based triage pathway for patients with isolated joint pains such as knee pain, shoulder pain and hand osteoarthritis. Clinical opinion: I suspect that all injections for OA have a large placebo element so a pragmatic approach whereby clinical landmark-based injections done by an experienced practitioner in an appropriate setting, as a first step, is	Thank you very much for these helpful comments and clinical opinion. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review. Regarding shoulder pain, separate rapid evidence reviews were carried out on the effectiveness of high volume joint injections and on the effectiveness of subacromial decompression.

		sensible. It seems reasonable to consider an US guided injection in resistant cases especially if these could avoid more invasive therapy. The definition of 'resistant' needs care bearing in mind that, for established OA, injections have limited efficacy. I can only speculate about the number of patients but, given the prevalence of shoulder pain (including AC OA), knee pain (including all grades of OA) and hand pain (DIP and CMC joint disease), I suspect the population burden and consultations in primary care and secondary care are substantial.	
12/12/2018	Michael Waldram SOH Trauma Consultant SOH Trauma Trauma - University Hospitals Birmingham NHS Foundation Trust Queen Elizabeth Hospital, Queen Elizabeth Medical Centre	I have been in Consultant Hand surgery practice for 35 yrs I entirely echo the comments of Mike Craigen	Thank you for your comment. Please see comments above.
12/12/2018	Munawar Shah Walsall Healthcare NHS Trust	I am upper limb consultant for nearly 17 years have been injecting 90% without xray or US however I do have US available to me in clinic and hence use it when required but agree with rest	Thank you very much for these helpful comments. We will include them in section 9 of the report so that they are available for discussion with the rest of the rapid evidence review.

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.

January 2019

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.

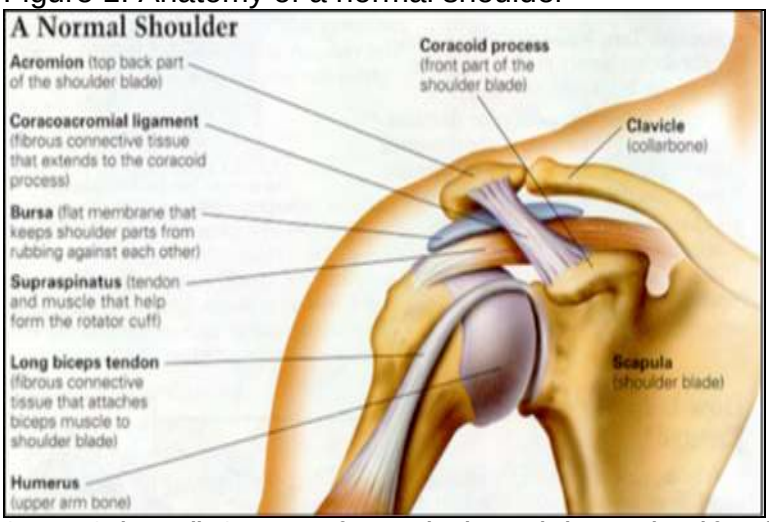
1 Context

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.ortho-md.com/procedures/impingement_syndrome.html

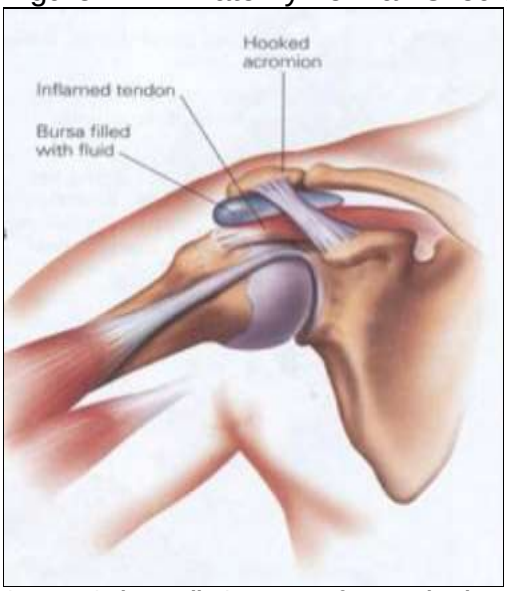
Shoulder impingement occurs when the tendon rubs or catches on the acromion and the subacromial bursa. Shoulder impingement can start suddenly or come on gradually. As illustrated in figure 2 below, it may occur if

•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.ortho-md.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 the 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
Beard et al 2018 [4] **CSAW trial** Multicentre, randomised, pragmatic parallel group, placebo controlled, three group trial 32 hospitals, 51 surgeons in the UK	n=313 adults Mean age 53.4 yrs 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]. Completed non-operative management including physiotherapy that includes a remedial exercise programme and at least one steroid injection Recruited Sept 2014 to June 2015 Excluded: full thickness rotator cuff tear Baseline Scores: Mean (SD), n (if reported) **Oxford Shoulder Score**	ASD plus physiotherapy (4 sessions) (ASD+PT) (n=106) 6 pts had surgery to the acromioclavicular joint or the long head of biceps [22] 6 months' post randomisation, 24(23%) pts had not yet received treatment 12 months' post randomisation, 19(18%) pts had not yet received treatment Median time to treatment: 90 days (IQR 58-123)	a. Investigational arthroscopy plus physiotherapy (4 sessions) (DA+PT) (n=103) 6 months' post randomisation, 43 (42%) pts had not received treatment 12 months' post randomisation, 35 (34%) pts had not yet received treatment Median time to treatment: 82 days (IQR56-134) b. No treatment (re-assessment appointment at 3 months only) (n=104) 6 months' post randomisation, 12 (12%) pts had not been reassessed 12 months' post randomisation, *26(25%)*pts had not	**Primary outcome: Oxford Shoulder Score** 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 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 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 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 • At 6 and 12 months, all groups had better mean OSS compared to baseline. **Modified Constant-Murley Score** 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 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 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

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

	ASD+PT: 25.2 (8.5) n=106 DA+PT: 26.7 (8.8), n=103 No treatment: 25.5 (8.3), n=104 **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 **PainDETECT** ASD+PT: 11.7 (6.6) n=105 DA+PT: 11.0 (5.9) No treatment: 11.9(6.6), n=100 **HADS Depression** ASD+PT: 5.0 (3.8) n=105 DA+PT: 5.0 (3.7) n=102) No treatment: 5.7(4.2), **HADS Anxiety** ASD+PT: 6.3 (4.3) DA+PT: 6.3 (4.2) No treatment: 6.9(4.5) **EQ VAS** ASD+PT: 65.8 (19.4) DA+PT: 69.7 (19.2) No treatment: 64.4(23.2) **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)		been reassessed Median time to treatment: 217 days (111-262)	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 **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 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 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 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 **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 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 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 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

				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 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 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 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 **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 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 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 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 **EQ-5D-3L Index** Mean (SD), n at 6 months ASD+PT: 0.65(0.29), n=89

				DA+PT: 0.67(0.26), n=93 No treatment: 0.52(0.36), n=89 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 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 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 Complications (study related) ASD+PT: 2 DA+PT: 2 no treatment: 2 Complications (unrelated) ASD+PT: 1 DA+PT: 2
Paavola et al 2018 [6] FIMPACT Multicentre, three group, randomised, double blind sham controlled trial 3 orthopaedic clinics in Finland	n=210 at first randomisation n=193 after 2nd randomisation (n=17 excluded) Adults aged 35 to 65 years Symptoms of shoulder impingement syndrome (concomitant grade I or II) for more than 3 months, unresponsive to conventional conservative treatment, partial thickness RCT were	ASD within 12 wks after randomisation+ one visit to physiotherapist /home exercises (ASD+PT) (n=59)	a. Diagnostic Arthroscopy within 12 wks after randomisation + one visit to physiotherapist /home exercises (DA+PT) (n=63) b. PT within 2 weeks - 15 physiotherapy sessions +home exercises (n=71)	At 2 years f/up ASD+PT: n=59 DA+PT: n=59 PT: n=68 **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 **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 **Constant-Murley Score** Mean (95%CI) ASD+PT: 77.9(73.7 to 82.3) DA+PT: 73.7(69.5 to 78.0)

	included in the study Recruited 1 Feb 2015 to 25 June 2015 Full or partial thickness tears (grade III/IV) were excluded Baseline, 3,6,12,24 months after randomisation. Data and analysis reported at 24 months only.			ASD+PT vs DA: 4.3(-20. to 10.5), p=0.18 **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 **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 **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 **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 **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 **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 **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 **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 **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

				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 **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 **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 **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 **Complications and adverse events (n/%)** ASD+PT: 3/5 DA: 2/3 ET: 3/4
Ketola et al 2009 [7] Prospective RCT 1 surgeon	n=140 Grade II subacromial impingement syndrome, symptoms for at least 3 months not relieved by conservative treatment (including NSAIDs, subacromial cortisone injections (59% patients) Mean duration of symptoms was 2.5 years. Recruited between June 2001 and July 2004	Arthroscopic acromioplasty followed by physiotherapy (ASD+PT) (n=70) Mean number of physiotherapy visits =6 Baseline scores (mean VAS 0-10) Self-reported pain: 6.4 Pain at night:	Supervised physiotherapy alone (PT) (n=70) 14 patients crossed over to ASD Mean number of physiotherapy visits =7 Baseline scores (mean VAS 0-10) Self-reported pain: 6.5 Pain at night: 6.4 Disability: 6.5 Working ability: 5.9	At 24 months after randomisation: ASD+ET: n=68 /70 ET: n=66/70 Self-reported pain (VAS 0-10) mean change from baseline ASD+PT vs PT: -3.9 vs -3.7, p=0.65 Disability (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported Working ability (VAS 0-10) mean change from baseline ASD+PT vs PT: +2.3 vs +2.0, no p-value reported Pain at night (VAS 0-10) mean change from baseline ASD+PT vs PT: -4.2 vs -3.8, no p-value reported SDQ score (0-100) mean change from baseline ASD+PT vs PT: -53.1 vs -50.0, no p-value reported Reported painful days, mean change from baseline

	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) • 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: • 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

				• 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 heath compared to before treatment 'A lot better', ASD+PT vs PT: 23(56%) vs 24(52%), p=0.96 Self-reported VAS for pain, mean(range): ASD vs PT: 2.8(0 to 10) vs 1.8(0 to 7), p=0.12 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 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 VAS for pain at night, mean(range) ASD vs PT: 2.5(0 to 10) vs 1.7(0 to 8), p=0.19 VAS for disability, mean(range) ASD vs PT: 2.5(0 to 9) vs 2.0(0 to 8), p=0.41 VA for working ability, mean(range) ASD vs PT: 7.5(0 to 10) vs 7.2(0 to 10), p=0.57 SDQ score, mean(range) ASD vs PT: 23(0 to 100) vs 17(0 to 100), p=0.61 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 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 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
Kukkonen et al 2014 [10] RCT 3 hospitals in Finland	n=180 shoulders (n=173 patients) Non-traumatic symptomatic	Acromioplasty and physiotherapy (10 sessions) (ASD+PT)	Physiotherapy only (10 sessions) (PT) n=58	At one year, 167 shoulders available for analysis (7.2% drop out) PT: 55/58 ASD+PT: 57/59 ASD+RC+PT: 55/59 Mean Constant score[i] at baseline and at one year

[i] MCID=10.4 points [20]

<table>
<tr>
<td>Assessment at baseline, 3,6, and 12 months</td>
<td>supraspinatus tendon tear< 75% of tendon insertion

Mean duration of symptoms ranged from 26(SD 9.9) to 28(SD9.7) months.
Recruited between October 2007- December 2012

51% female
Mean age 65 years</td>
<td>n=59

29 patients (51%) also had biceps tenotomy</td>
<td>OR

Rotator cuff repair, acromioplasty and physiotherapy (10 sessions) (ASD+RC+PT)
n=59

23 patients (42%) also had biceps tenotomy</td>
<td>
<table>
<tr><td>Group</td><td>baseline</td><td>At one year</td></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>
Constant sub scores at one year for physiotherapy vs both surgery groups combined
In favour of ASD+PT with or without supraspinatus tendon repair
• Pain, p=0.0321
• Activities of daily living, p<0.0001
No significant difference
• Range of movement, p=0.74
• Strength, p=0.76
• Patient satisfaction: PT(87%), ASD+PT (96%) & ASD+RC+PT (95%), p=0.14

Cost of treatment
<table>
<tr><td>Group</td><td>Mean cost of treatment</td><td>Mean direct cost for the patients</td><td>Mean indirect societal cost</td></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>
Costs not generalisable to UK
</td>
</tr>
</table>

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

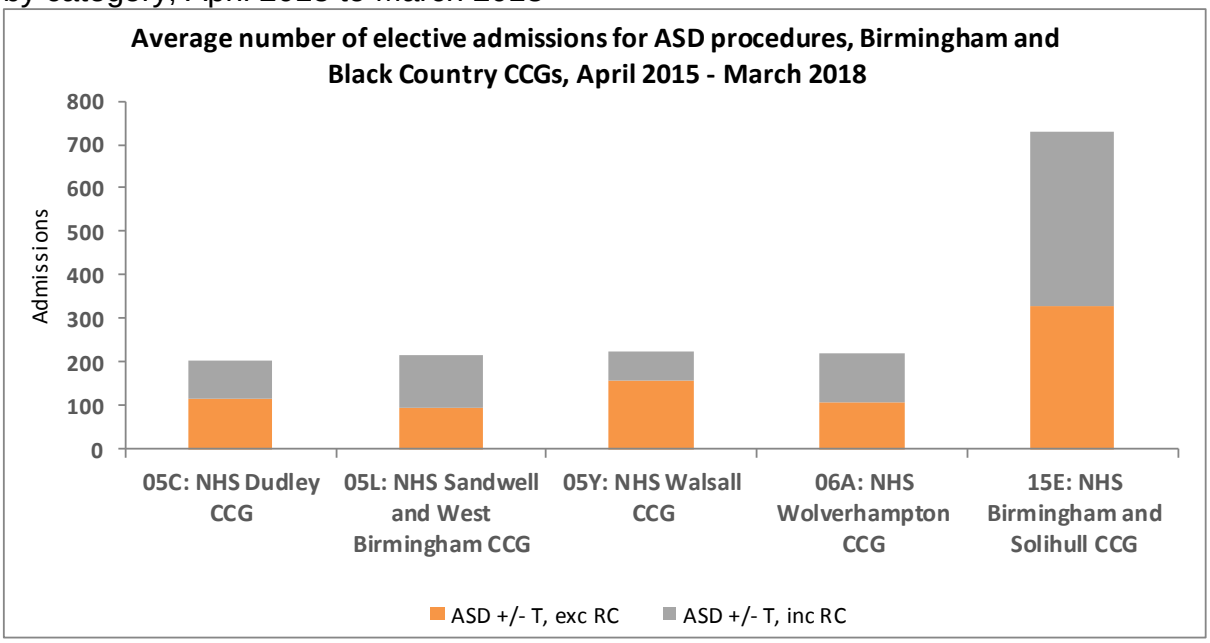
Procedure	Number of admissions
ASD without tenotomy, excluding rotator cuff	2,126
ASD with tenotomy, excluding rotator cuff	284
ASD with or without tenotomy, excluding rotator cuff	2,410
ASD without tenotomy, including rotator cuff	1,652
ASD with tenotomy, including rotator cuff	732
ASD with or without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

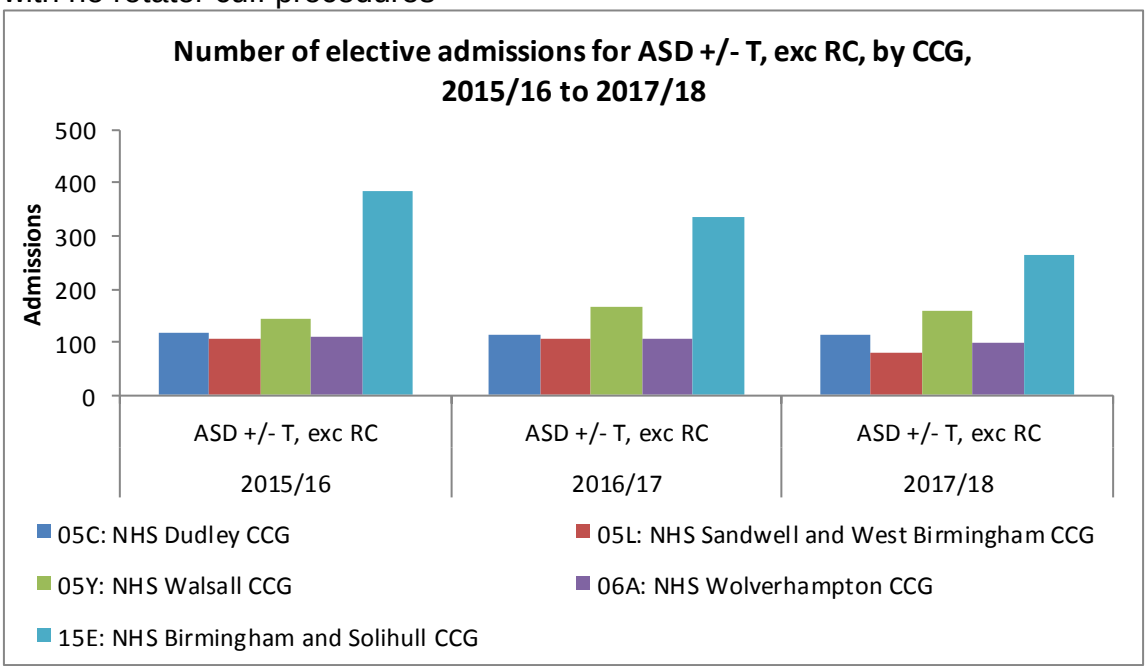


Figure 4 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with no rotator cuff procedures in all three years. However, the number of elective admissions per year has declined from 386 in 2015/16 to 285 in 2017/18. NHS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

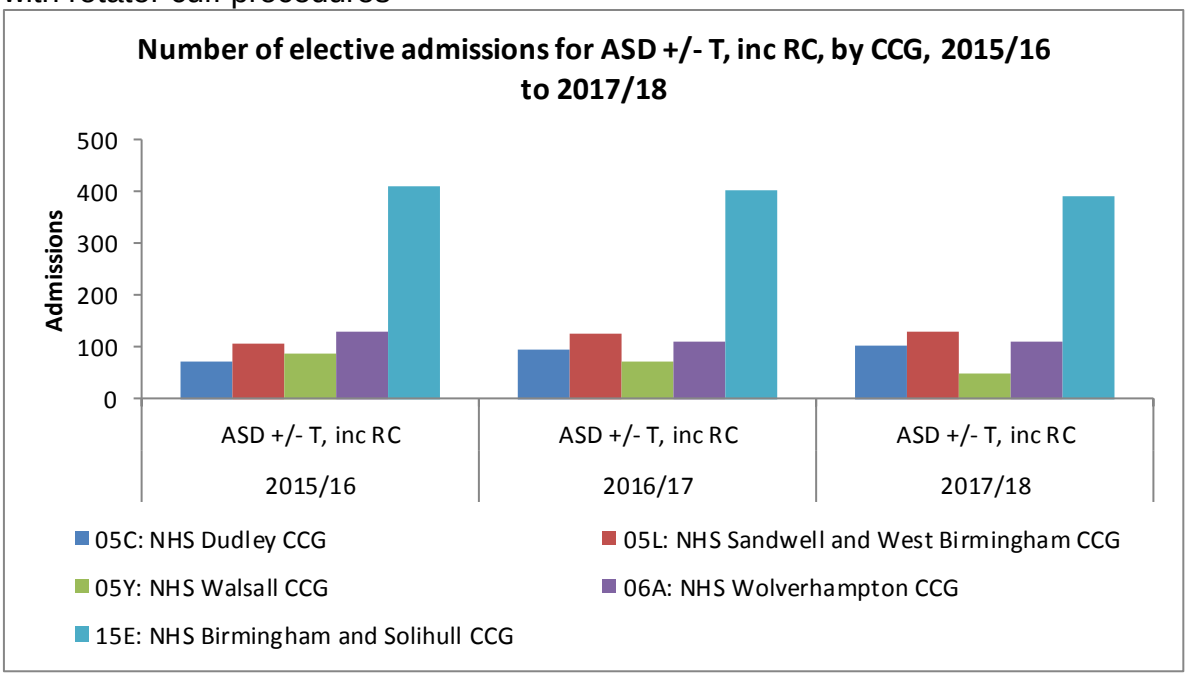


Figure 5 shows that NHS Birmingham and Solihull CCG had the highest number of elective admissions for ASD procedures with or without tenotomy with rotator cuff procedures in all three years. NHS Walsall CCG had a lower number of elective admissions in 2017/18 than in the previous two years.

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

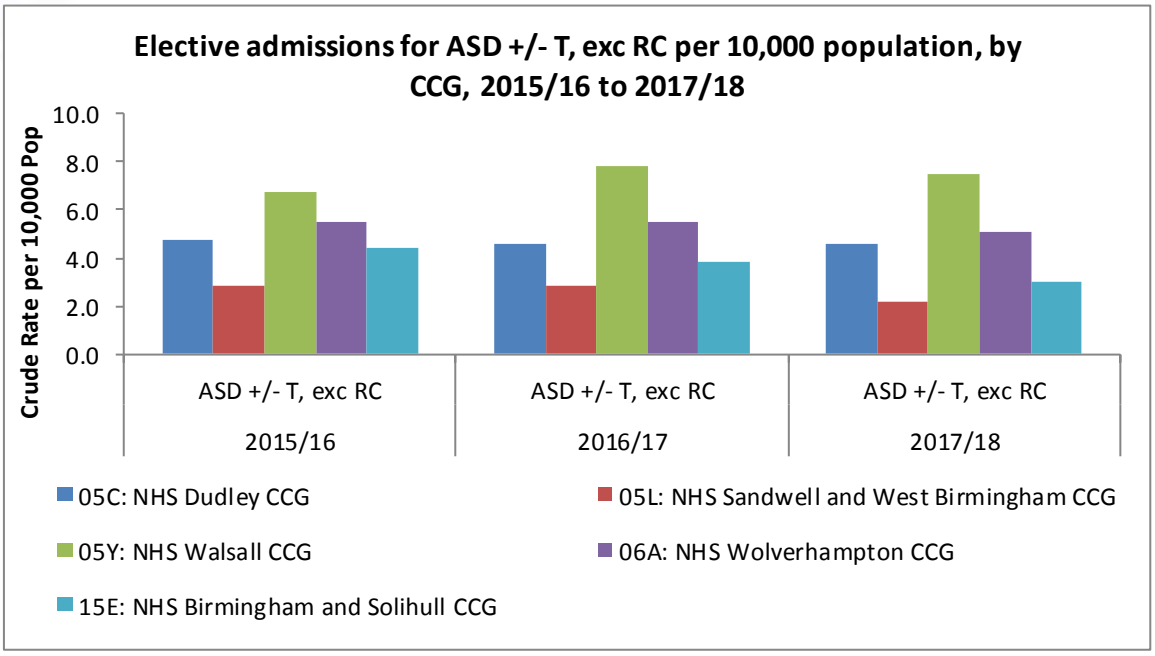


Figure 6 shows that NHS Walsall CCG had the highest crude elective admission rate per 10,000 population for ASD procedures with or without tenotomy, with no rotator cuff procedures in all three years. NHS Sandwell and West Birmingham CCG had the lowest crude elective admission rate per 10,000 population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

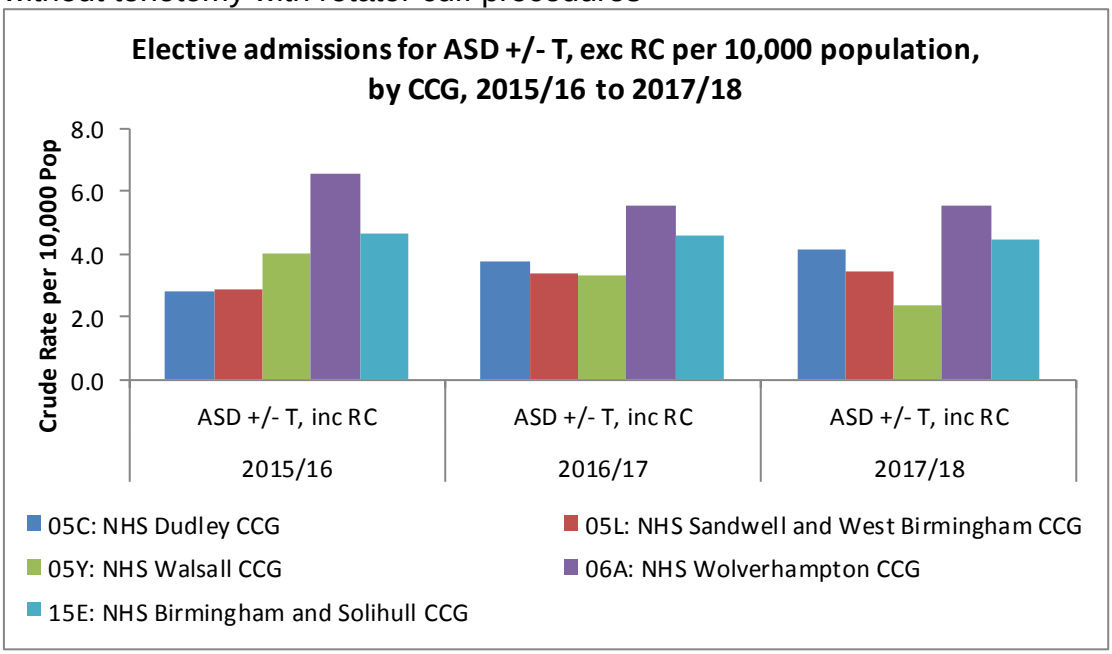


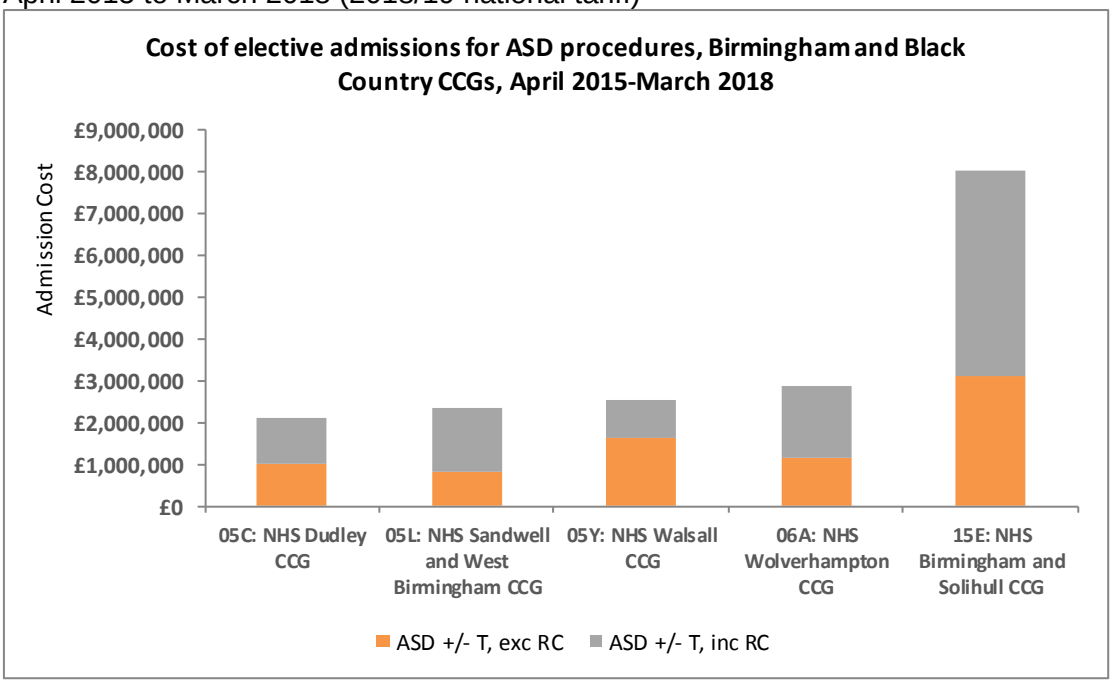
Figure 7 shows that NHS Wolverhampton CCG had the highest elective admission rate for ASD procedures with or without tenotomy, with rotator cuff procedures in all three years. However, the crude elective admission rate was lower in 2017/18 and in 2016/17 than it was in 2015/16.

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

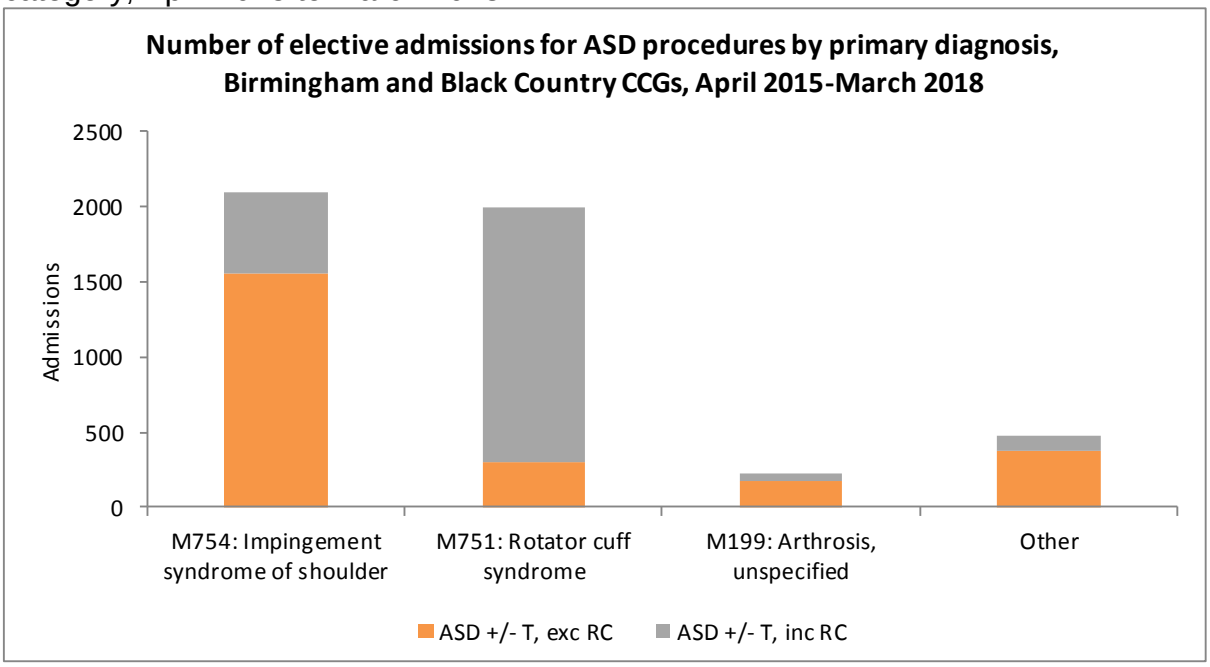
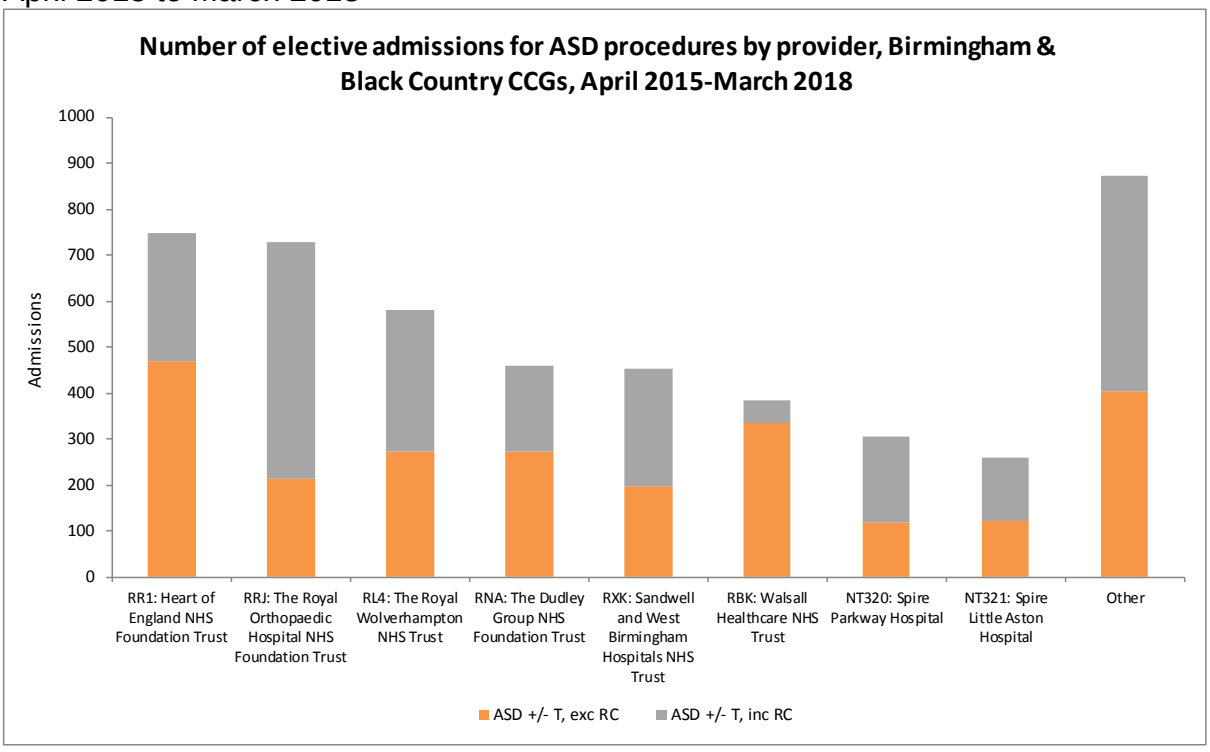


Table 7 and Figure 10 give the number of elective admissions for ASD procedures by provider. This shows that 750 procedures (16%) were carried out at the Heart of England NHS Foundation Trust; 728 procedures (15%) at the Royal Orthopaedic Hospital NHS Foundation Trust; and 581 (12%) at the Royal Wolverhampton 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

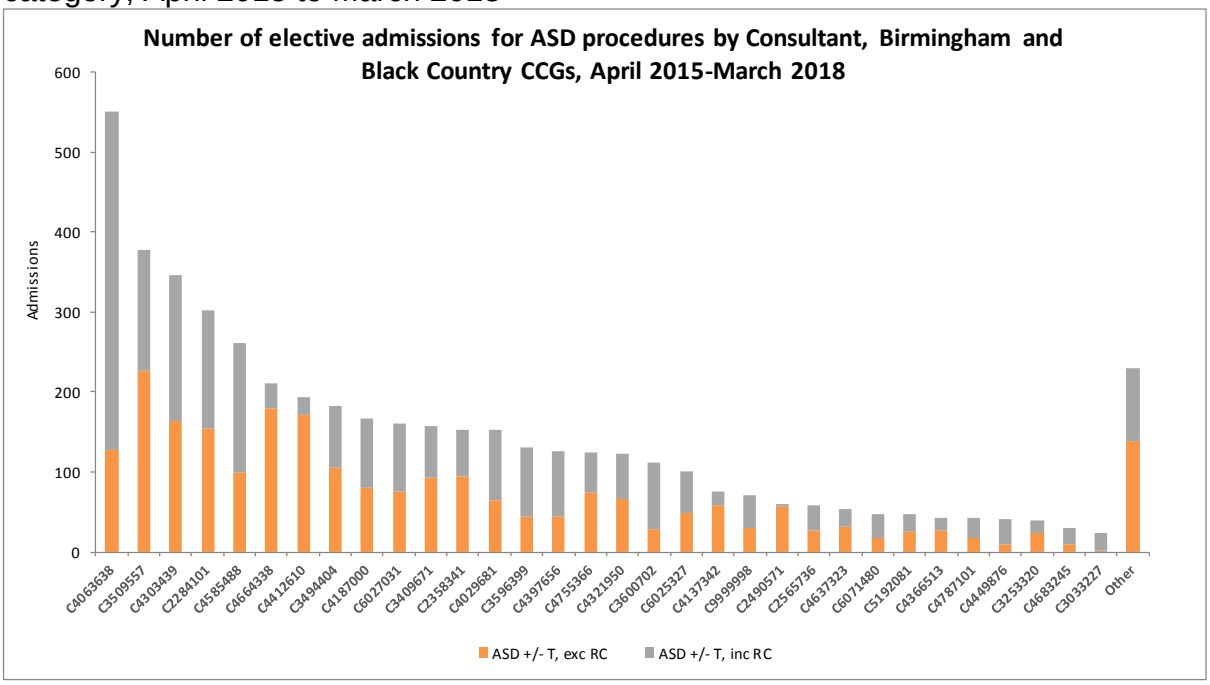


ASD is not a highly specialised shoulder procedure; the operations performed over the three-year period were undertaken by at least 32 different Consultants (Figure 11). The Consultants carrying out the largest number of ASD procedures are identified through the codes listed in Table 8 below. 51% of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

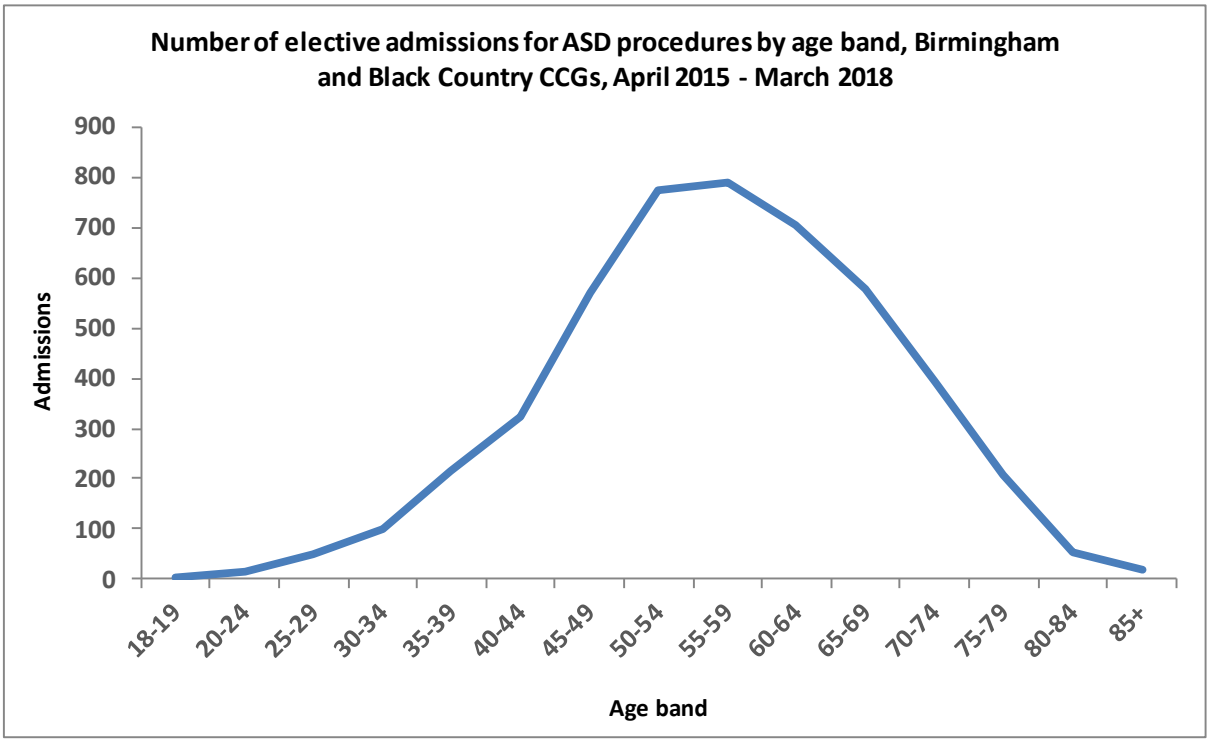


The number of elective admissions for ASD procedures by age band is given in Table 9 and Figure 12. These show that 47% of admissions are for patients aged 50 to 64, with a further 24% of admissions occurring in those aged 45 to 49 or 65 to 69.

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.

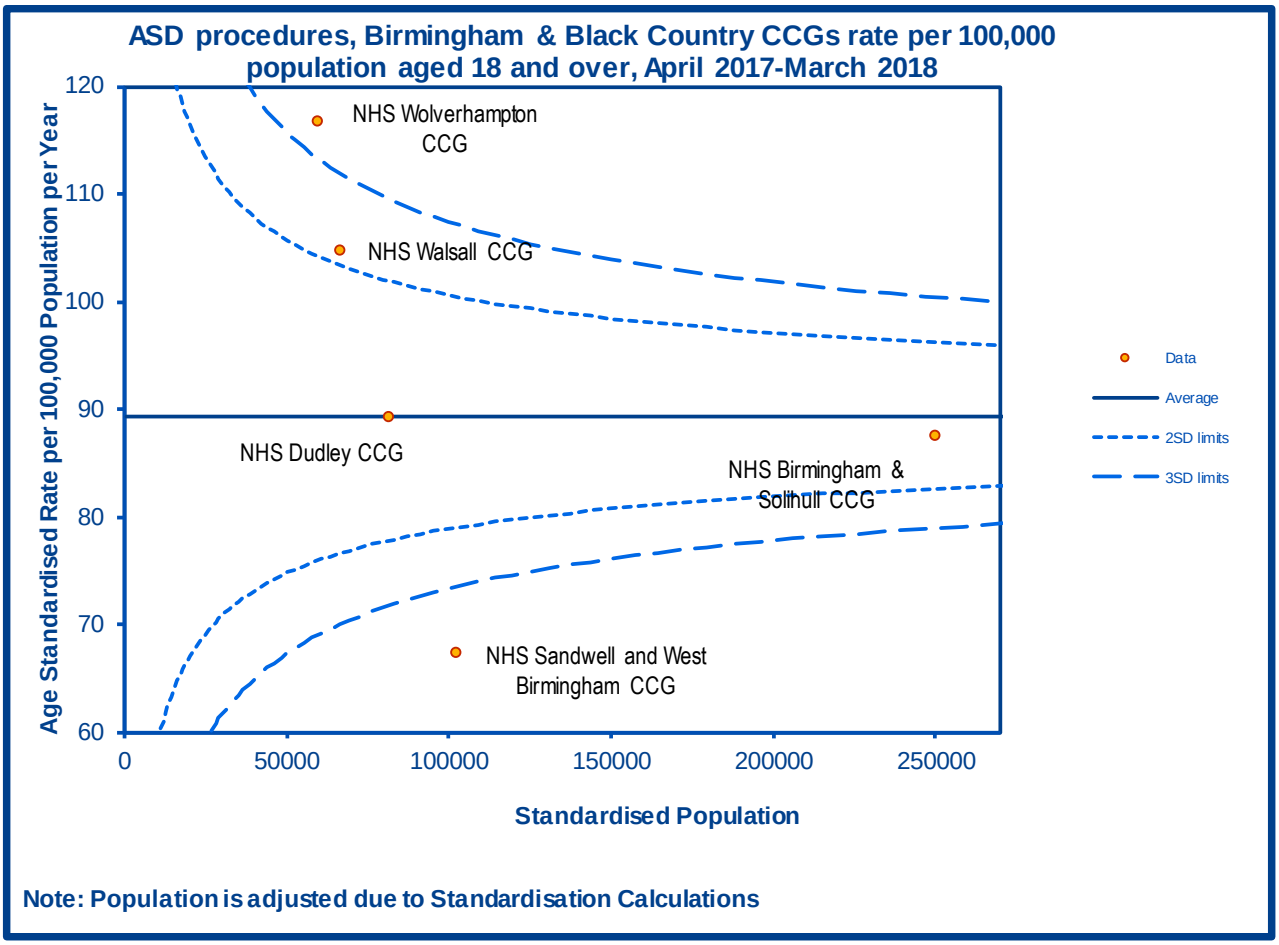
Table 10: Crude elective admission rates per 10,000 population by CCG and financial year, 2015/16 to 2017/18

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

		• Therapeutic arthroscopy of the shoulder W8603 • Resurfacing arthroplasty of shoulder W5060] Exclude : stabilisation procedures including labral(SLAP) tear/tendon repair)			

Inclusion Criteria Peer reviewed publications, English language

Exclusion Criteria Abstracts, Letters, Commentaries, Conference papers, Case reports, Papers published more than 10 years ago

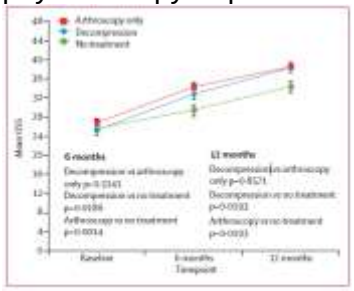
9 References

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 tendinpathy. 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 Digitalhttps://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	Thank you for the opportunity to contribute my thoughts. 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. In this cohort of cases, patients with prolonged symptoms are usually keen to try surgical decompression as conservative measures have	Thank you for these helpful comments. 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. 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. 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

		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.  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*

		patients. 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 conjuction with the British Orthopaedic Asssociation: http://www.bess.org.uk/media/Research%20Committee/National%20Guidelines/Subacromial%20Shoulder%20Pain.pdf It is easily accessible and useful for the framework of managing shoulder pain.	*symptoms fail to resolve with conservative treatment, subacromial decompression surgery (acromioplasty) is recommended."* 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]. The guideline then explains that *"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."* If increasing the subacromial space is effective, this does not explain why there was no clinically significant different 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.

04 Dec. 2018	Mr. Samir Massoud, Consultant Trauma & Orthopaedics, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust	Thanks, 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. 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. 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. I am not sure whether you have enough data to	Thank you for these helpful comments. We agree that the Kukkonen et al study focused on the hypothesis that *“rotator cuff repair yields superior results compared with the other treatment modalities”[10].* 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. The long term outcomes for these patients with a symptomatic but untreated supraspinatus tears<75% was out of scope of this review. 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. The data is available for further analysis should that be agreed. 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.

		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)	Mr Kalogrinanitis - considered low clinical value and not offered to patients. Mr Cooper - had already been issued by CCG to Shoulder surgeons but recirculating again for comments 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	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

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.