Review of MBS items for subacromial decompression

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MSAC application no. 1711

Assessment report

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding through the Medicare Benefits Schedule (MBS) or alternative funding programs/arrangements.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Australian Government

Medical Services Advisory Committee

DCAR Executive Summary

Application No. 1711 – Review of MBS items for subacromial decompression

Applicant:	Medical Services Advisory Committee
Date of MSAC consideration:	MSAC 87th Meeting, 30-31 March 2023

Main issues for MSAC consideration

Clinical issues:

- Populations Current and proposed MBS items for subacromial decompression (SAD) do not define any patient criteria, necessary diagnostic tests or required thresholds (e.g. in terms of pain, function, duration of symptoms, previous therapies or pathological features). During consultation, SESA recommended additional selection criteria.
 - Patients were similar across all trials, being selected on the basis of subacromial pain or impingement and reflecting a relatively younger population of working age, therefore the applicability of the results to an older demographic is uncertain. The duration of symptoms was about 1 year. While all patients were required to have failed conservative therapy, the type or duration of therapy was not described. Patient selection was made using a range of physical and diagnostic tests (X-ray, ultrasound [US], magnetic resonance imaging [MRI]) and other shoulder pathologies were commonly excluded.
- Interventions Current and proposed MBS items for SAD refer to a range of surgical techniques including bursectomy, release of the coraco-acromial ligament, removal of the subacromial bone spur and removal of calcium deposits from the cuff.
 - Interventions were similar across trials and in line with MBS items for SAD. The removal of calcium deposits was not described in any study. Not all trials undertook coraco-acromial ligament release. All patients had standard postoperative rehabilitation, which is a potential confounder to treatment effect, but it would not be possible to design a trial involving joint surgery without postsurgical rehabilitation.
- Comparator Access to best practice conservative therapy (e.g. physiotherapy, exercise therapy) for patients in Australia is uncertain. The MBS provides rebates for up to 5 sessions of allied health services per calendar year for a chronic medical condition (i.e. present for 6 months or more).
 - The most common comparator in the evidence base was exercise therapy. In many cases, the therapy was for 3–6 months, with supervision (1-hour session, 1–3 times per week, where reported) gradually reduced over time as patients became familiar with the exercises.
- Clinical trial evidence 9 randomised controlled trials were included (N = 1,179). The quality and certainty of the evidence varied according to outcome measures, comparators and reporting timelines.
- Safety Little comparative evidence was available; however, few adverse events were associated with SAD, conservative therapy and placebo.
- Compared with conservative therapy, there was no difference in the use of SAD on clinical effectiveness outcomes of pain, health-related quality of life (HRQoL), return to work or total adverse events. The comparative safety and effectiveness of SAD and conservative therapy is mainly limited by the quality of the studies (assessed to be of moderate risk of bias and low or very low GRADE assessment) and the paucity of data for certain measurement timepoints.
 - Incremental effectiveness a statistically and clinically significant improvement was reported for shoulder function at 10 years follow-up comparing SAD with conservative therapy; however, the certainty of evidence was low.
- Compared with placebo (diagnostic arthroplasty), there were no statistically or clinically significant differences in the use of SAD on outcomes such as pain, shoulder function, HRQoL and return to work, with moderate or high GRADE certainty. Studies were

assessed to have a low risk of bias. Aspects of study design, including population, intervention, and outcomes, were similar to all other included trials.

- Applicability of study results to local Australian practice:
 - $\circ~$ It is likely that the trial populations had not tried and failed 6 months of conservative therapy as a prerequisite to surgery, as defined in the PICO set.
 - No trial used a predefined threshold of pain, shoulder function or size of tear as criteria for selection. Study baseline patient demographics were similar between groups, but baseline characteristics of pain and function varied between studies. In one study, a proportion of participants who underwent surgery had no impingement.
 - One trial provided all eligible participants with a 3-month rehabilitation program prior to randomisation to surgery. Subsequently, 39% of patients were excluded from the trial for a range of reasons including reduced symptoms or change of diagnosis and did not receive surgery.
 - Patients who received MBS services for SAD are commonly older (55–74 years) than patients in the RCTs.
 - Recent evidence suggests that patient care and experiences for rotator cuffrelated shoulder pain in Australia are varied. It is uncertain how patients with subacromial impingement are selected for surgery, and if all patients currently receiving these services through the MBS reflect best quality care. However, utilisation information for MBS items 48951 shows that, in line with best practice, US and MRI are most commonly requested by surgeons, and rarely by GPs.
- Due to uncertainty regarding the intended use of SAD in Australia and variability in current practice it is unclear how applicable the evidence base is to local care pathways. For example, a recent high-quality RCT which compared SAD with placebo or ongoing monitoring may be highly representative of clinical practice in the UK, but uncertainty regarding diagnosis and patient selection makes the applicability of these results to Australian clinical practice unclear.

Economic issues:

- A cost comparison analysis was undertaken to compare costs of SAD with those of conservative therapy using an expanded Australian health system perspective, where some of the costs payable by patients and private insurers are also included.
- In the base case the surgical management of subacromial impingement is approximately \$5,235 more expensive than conservative therapy. Although conservative therapy is cheaper for the Australian health system, in the non-surgical pathway some cost burdens are transferred to patients and private health insurers.
- Sensitivity analysis identified that the use of physiotherapy is the main cost driver. This finding reflects the varied and uncertain use of supervised physiotherapy services. Use of various diagnostic imaging services, particularly MRI, is also a small cost driver across both pathways.

Financial issues:

- In the base-case scenario, it is estimated that the full cost of all relevant SAD services in the MBS is over \$6.9 million in 2022, reducing to \$3.7 million in 2027. This is due to the decreasing trend in the number of patients receiving MBS SAD services in the past 5 years. The reason for this trend is uncertain. However, a similar trend is seen with Australian hospital data related to the principal diagnosis of subacromial impingement, therefore this may be associated with more rigorous patient selection prior to referral for surgery.
- Four alternative scenarios investigated potential modifications of the SAD service scope. All scenarios either tightened the patient eligibility for surgery or reduced the scope of the SAD surgical service. All lead to cost savings to the MBS.

• The overall financial impact to the health budget is uncertain with a high probability of cost-savings. The cost associated with alternative treatment due to reduction in SAD surgical services is unclear, and they are not analysed in the current financial implication model. However, the overall costs of alternative therapy and management are unlikely to be more expensive than SAD surgery.

Other relevant information:

- Administrative data for MBS items 48900, 48903 and 48951 for financial year 2020–21 showed differing claiming patterns across the three items. 48951 was claimed most frequently with 4,802 claims in 2020–21 and showed a downward trend in number of claims over the past 5 years (from 7,066 in 2017–18). Twenty percent of all patients who received surgery items 48900, 48903 or 48951 during 2020–21 also claimed physiotherapy services through the MBS in the same financial year. The frequency (number of sessions) and timing of these services (before or after surgery) were uncertain. The timelines between physiotherapy and subsequent surgery is unclear. This data does not account for any non-MBS physiotherapy services provided to private patients. All other non-MBS services paid out-of-pocket by patients (for example shoulder MRI requested by GPs) will not have been identified in this data.
- Based on the claiming pattern, the use of the SAD items is varied. MBS 48900 and 48903 have no claim restrictions with other shoulder procedures. MBS 48900 is likely to be used for image-guided removal of calcium deposits with injection (e.g. lavage) by radiologists or in specialist or GP rooms, while MBS 48903 is commonly used in association with services for other shoulder conditions with a greater use of CT and MRI. MBS 48951 has restrictions to its use and claiming patterns suggest that it most closely represents SAD for subacromial impingement in isolation from other shoulder pathology. However, this item is still co-claimed with other shoulder procedures so is not exclusive to patients with shoulder impingement.
- The evidence for different types of conservative therapies for rotator cuff-related pain is heterogeneous and of limited quality. The most effective protocol has not been identified, and home-based care may be non-inferior to supervised physiotherapy care at the 12 month follow up point. However, symptoms may not resolve completely following conservative therapy, and patients may seek further treatments, including surgery.
- Based on subgroup analyses in a small number of trials, patient outcomes may vary based on factors such as baseline pain, shoulder function and acromial anatomy, although improvements do not reach clinical importance. Several studies report predictive and prognostic factors which may inform surgical outcome, although clinical practice guidelines are not consistent in their advice regarding patient characteristics that can predict a favourable outcome following surgery. Some patients are at risk of ongoing pain despite surgical or conservative therapy.

1. **Purpose of application**

The MSAC Executive requested a full health technology assessment review of current and proposed MBS services for subacromial decompression (SAD) and rotator cuff repair to consider the safety and effectiveness of SAD surgery and ensure government funding of subacromial decompression in Australia is based on strong evidence of clinical and cost effectiveness.

2. Background

SAD surgery and rotator cuff repair are commonly performed in Australia and are currently reimbursed through a number of MBS items, which include a range of procedures available since 1 December 1991 (Appendix F and Appendix G).

The currently subsidised MBS items for SAD (by acromioplasty) are MBS item 48903 and MBS item 48909. Other items related to SAD include 48900 and 48906 (which include excision of the coraco-acromial ligament or removal of calcium deposit) and 48951 and 48960 (which include division of the coraco-acromial ligament, acromioplasty and resection of the acromioclavicular joint).

MSAC has not previously considered items related to SAD.

As part of the Medicare Benefits Schedule (MBS) Review, the final report on the review of Orthopaedic MBS items recommended that for shoulder surgery, existing items for SAD and rotator cuff repair should be consolidated (recommendation 74, 75)¹. The proposed items are shown in Appendix G. Subsequently, an additional item has been proposed for larger rotator cuff tears.

In 2020, MSAC recommended that the MSAC Executive review MBS item 48903 for shoulder SAD surgery². During its deliberations of this item, the MSAC Executive noted the results of 2 recent systematic reviews showed that the clinical benefits of these procedures compared to conservative management was uncertain and advised that a full health technology assessment (HTA) review was required prior to the implementation of recommendations 74 and 75.

Terms of reference for this review with subsequent amendments in strikethrough are:

- Review clinical guidelines on the management of rotator cuff disease, taking account of the clinical characteristics of the population/s recommended for SAD (with/without rotator cuff repair).
- 2. Review the utilisation of SAD services, informed by MBS data and other data that may provide additional insight into clinical use.
- 3. Review evidence on comparative safety and clinical effectiveness of SAD (with/without rotator cuff repair) used in the management of rotator cuff disease. The evidence review will be based on the population, intervention, comparator and outcomes (PICO) confirmation ratified by the PICO Advisory Sub-committee (PASC).
- 4. Subject to the findings of Terms of reference 1, 2 and 3, review and evaluate the cost effectiveness of SAD (with/without rotator cuff repair).

Table 2 summarises the advice and direction from MSAC and PASC and how these have been addressed in the DCAR.

¹ <u>https://www.health.gov.au/resources/publications/taskforce-final-report-orthopaedic-mbs-items</u>

² http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1593-public

Table 1	Summary of advice and	direction from PASC and MSAC	
-			

Component	Matter of concern	How the current assessment report addresses it
The use of subacromial	As advised by PASC and endorsed	Addressed.
decompression as an adjunct to rotator cuff repair.	by the MSAC Executive, the review of rotator cuff repair was not within the scope of this assessment.	The use of subacromial decompression as an adjunct to rotator cuff repair has been removed from the scope of this current review.
The population who may best benefit from SAD is not clearly defined.	PASC requested that the assessment should investigate which prognostic or predictive factors in addition to those defined in the PICO that may further define people who are more likely to benefit from surgery.	Addressed. Sub-group analysis from RCTs and information from observational studies is presented in <u>Section 2</u> and <u>Section</u> <u>6</u> and used to inform scenario modelling for budget impact. The limitation of this evidence is noted.
The requirement of an economic evaluation.	MSAC considered that an economic analysis should be included as a cost comparison.	Addressed. An economic analysis is included as requested by MSAC (Section 4).
Duration of the condition.	MSAC recognised that trials should be included irrespective of duration of condition.	Addressed. Duration of condition and other treatment effect modifiers is investigated in <u>Section 2.2.4</u> , <u>Section</u> <u>6.2</u> and Section 6.3. All trials are included irrespective of the duration of symptoms.
Efficacy of specific exercise or physiotherapy interventions.	MSAC noted the limited evidence on the efficacy of exercise physiotherapy or physiotherapy interventions in the management of rotator cuff disease.	Addressed. Recent systematic reviews of conservative therapies for rotator cuff disease are discussed (<u>Section</u> <u>1.4.10</u>). Comment is provided on the natural history of the condition (<u>Section 1.4.3</u>).

Abbreviations

MSAC = Medical Services Advisory Committee; **PASC** = Protocol advisory sub-committee; **PICO** = population, intervention, comparator, outcomes; **RCT** = randomised controlled trial

As part of this review, PASC considered two PICO sets:

- The use of SAD as a standalone procedure (PICO set 1– patients with subacromial impingement)
- The use of SAD in addition to surgery for rotator cuff repair (PICO set 2 patients for repair of rotator cuff of shoulder).

Following PASC advice and endorsed by the MSAC Executive, the PICO set 2 for the use of SAD as an adjunct to rotator cuff repair was removed from this current assessment. PASC noted that current item numbers (e.g. 48906) are already inclusive of rotator cuff repair with or without SAD. Furthermore, the MBS Review Orthopaedic Clinical Committee Report considered different techniques of SAD including the excision of large bursa, acromioplasty and synovectomy to be inherent components of rotator cuff repair and should not be co-claimed. A review of rotator cuff repair (with/without SAD) may be endorsed when the results of the Australian Rotator Cuff trial are available (ACTRN12620000789965). The final PICO Confirmation is available on the MSAC website³.

3. Prerequisites to implementation of any funding advice

Services for SAD are currently available through the MBS (shown in Appendix F and Appendix G). There are no prerequisites to any funding advice. Current items for SAD as a standalone item are 48900, 48903 and 48951. Item 48951 is restricted with respect to co-claiming with other surgical services (not being a service associated with any other arthroscopic procedure of the shoulder region). The MBS Review Orthopaedic Clinical Committee Report recommended these items to be consolidated (see Table 2).

Services for SAD used in conjunction with rotator cuff repair are not within the scope of this assessment.

4. Proposal for public funding

The Medicare Benefits Schedule (MBS) Review Taskforce Orthopaedics Clinical Committee and the MBS Review Shoulder and Elbow Implementation Liaison Group have proposed the following amended item for SAD performed as any form of open or arthroscopic surgical procedure (MBS 489XX; Table 2).

There is no proposed population. During consultation, SESA recommended that patient selection for acromioplasty should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms
- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion)

The intervention is a mix of procedures, based on patient presentation and shoulder anatomy. As per the ratified PICO confirmation, the use of SAD in conjunction with rotator cuff tear repair is not a part of this assessment of SAD as a standalone procedure. As the fees for the proposed amended MBS item have yet to be determined, the out-of-pocket costs are uncertain.

Table 2 Proposed amended MBS item for SAD

Category 3 – Therapeutic Procedures Group T8 – Surgical Operations Subgroup 15 – Orthopaedic Subheading 8 – Shoulder

MBS 489XX

Open or arthroscopic subacromial decompression of Shoulder

Inclusive of, if performed:

i) coraco-acromial ligament division

- ii) acromioplasty
- iii) excision of outer clavicle and acromioclavicular joint
- iv) removal of calcium deposit
- v) excision of bursa

³ <u>https://www1.health.gov.au/internet/msac/publishing.nsf/Content/1711-public</u>

Not being a service associated with a service to which any open or arthroscopic shoulder region procedure applies. (Anaes.) (Assist.)

Fee: Not provided

Abbreviations

MBS = Medical Benefits Schedule

Source

Page 24 of the Ratified PICO confirmation

5. Population

As identified in the Ratified PICO Confirmation, the population is adult patients with symptomatic subacromial shoulder impingement (PICO set 1) and symptoms unresolved despite conservative therapy for 6 months. The summary of the PICO criteria and clinical management algorithm for patients with subacromial impingement is summarised in Appendix A, Table 49.

Subacromial shoulder impingement is diagnosed with a range of physical tests, and also with the use of imaging, such as X-ray, to exclude other pathologies of the shoulder (as per PICO).

SAD is considered for patients who have ongoing pain and/or shoulder dysfunction following a course of conservative therapy.

6. Comparator

The comparator as identified in the Ratified PICO Confirmation is continued conservative therapy, including physiotherapy, exercise therapy, movement therapy, medications for pain and inflammation, as well as subacromial injections of corticosteroid or local anaesthetic. The assessment has also included placebo⁴ (diagnostic arthroscopy) as an additional comparator, as reflected in a small number of published trials.

Although all clinical guidelines recommend conservative therapy for all rotator cuff-related pain, there is no defined protocol. In practice, it is likely that patients receive care tailored to their own experience and their ability to access different services and advice, which may include GPs, physiotherapists, rheumatologists, radiologists, and surgeons.

A musculoskeletal condition that has been present or is likely to be present for 6 months or longer is termed a chronic medical condition, and patients are eligible to have a chronic disease management (CDM) plan, formerly enhanced primary care (EPC), through the MBS and prepared by their general practitioner (GP). CDM will enable the GP to plan and coordinate a multidisciplinary team, which may include physiotherapy. Under the CDM, the patient is allocated up to 5 sessions with a Medicare rebate for allied health services in a calendar year, which includes physiotherapy (MBS 10960 or 10953). The patient is required to pay any gap fee for these 5 sessions⁵. Without the CDM plan, the full physiotherapy cost is paid by the patient. Private health insurance can cover a portion of the cost of any continued or additional services

⁴ Standard medical management (reflected in studies as no treatment, placebo or sham treatment) may include the use of medicines, medical services, best supportive care or conservative management; <u>Guidelines for preparing assessments for MSAC, p36</u>

⁵ Australian Government - Department of Health. 2021. *MBS Online Medicare Benefits Schedule - Item* 10960 [Online]. Available:

http://www9.health.gov.au/mbs/fullDisplay.cfm?q=10960&qt=ItemID&type=item [Accessed 3 February 2022]

subject to yearly cost limits and level of coverage. Patients can only claim one source of payment for each service (that is either MBS or private health insurance).

For ultrasound (US)-guided subacromial injections, there are two MBS items available (55848, 55850). An additional MBS item is available for US-guided injections in combination with a diagnostic musculoskeletal US service (55850).

7. Summary of public consultation input

Consultation feedback previously provided on this assessment is summarised in full in the <u>PICO</u> <u>Consultation</u> and <u>Clinical Guidelines Review</u>, available on the MSAC website. Consultation feedback for application 1711 was received from one professional organisation and two individuals, both health professionals. The Shoulder and Elbow Society of Australia (SESA), and one health professional provided two responses each.

Feedback was incorporated to the PICO Confirmation following the PASC meeting. A brief summary of the feedback follows.

The SESA noted that standalone subacromial decompression may be warranted for extrinsic causes of compression where there is no loss of rotator cuff function. Arthroscopic acromioplasty can reduce the risk of rotator cuff disease in the future. However, acromioplasty should not be used for shoulder pain alone. SESA recommended to retain acromioplasty as a treatment for established impingement that has not responded to appropriate conservative management.

SESA commented that investigations such as X-ray, magnetic resonance imaging (MRI) or US are valuable as they provide information for surgical preparation and can inform surgical prognosis. SESA noted that the choice of imaging modality is made based on patient history and clinical presentation, and that MRI is considered to be the gold standard investigation.

For patient selection SESA noted that for "chronic impingement/tendonitis that has failed a long course (4-6 months) of nonoperative treatment and is associated with extrinsic impingement, an arthroscopic acromioplasty is an excellent form of management". Specifically, SESA recommended that patient selection for acromioplasty should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms
- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion)

SESA noted that a shorter review period and an earlier intervention may be necessary dependent on patient factors and the severity of the presentation. SESA advised that patients older than 70 years with a low functional demand can be managed nonoperatively. The President also noted that arthroscopic intervention for repair can minimise the need for more expensive interventions at a later time, such as shoulder arthroplasty.

SESA agreed that the evidence for subacromial decompression has evolved but disagree that the service should be removed entirely. Comment was provided on a recent RCT, which was considered to be poorly designed and not in line with current practice. The study was underpowered and a number of participants crossed over to the surgery group; patients were included for shoulder pain and could have had a different diagnosis, and it was unclear if patients had acromial spurs. Many patients had only 12 weeks of nonoperative treatment, and as such many of the participants were likely to have improved with ongoing conservative therapy.

SESA was also critical of the Cochrane reviews which included studies on shoulder pain not impingement, and as such the arithmetic conclusions of the studies should not be taken on face value. SESA noted that studies with longer-term follow-up can show additional benefits to surgical decompression.

SESA noted issues with the wording of MBS items. These included issues regarding the separate pathologies of acromioclavicular arthritis and biceps tendinopathy. These issues will not be investigated as part of this current assessment process. SESA also provided comment on the appropriateness of the exclusions applied to the proposed MBS items, and the impact on services for other pathologies of the shoulder.

SESA advised that arthroscopic debridement was provided by a separate MBS item (48948).

One health professional provided a recent Australian article discussing a lack of benefit of number of surgical interventions compared to placebo surgery, including arthroscopy for shoulder pain⁶.

8. Characteristics of the evidence base

Broadly speaking the evidence base and this report aligns with the final PICO. Any variations, uncertainties, and applicability to the Australian context, particularly regarding the population, is described.

The evidence base presented is similar to that used in a recent Cochrane review⁷. Any differences are noted, with comments provided.

Overall quality of studies

A total of 24 studies (9 randomised controlled trials [RCTs] reported in 9 publications and 5 case series studies) met the inclusion criteria for assessing the safety and effectiveness of SAD compared to conservative therapy. The RCTs had a total number of 1,179 randomised participants. Two follow-up publications of the FIMPACT (Paavola) trial and one new RCT are available in addition to those in the Cochrane review⁸. Due to the lack of reporting of safety data

⁶ Ferreira G, Harris I, Zadro J and O'Keefe M. 2022. 3 orthopaedic surgeries that might be doing patients (and their pockets) more harm than good [Online]. the conversation. Available: <u>https://theconversation.com/3-orthopaedic-surgeries-that-might-be-doing-patients-and-their-pockets-more-</u>

https://theconversation.com/3-orthopaedic-surgeries-that-might-be-doing-patients-and-their-pockets-moreharm-than-good-179370 [Accessed 19 April 2022]

⁷ Karjalainen TV, Jain NB, Page CM, Lahdeoja TA, Johnston RV, Salamh P, Kavaja L, Ardern CL, Agarwal A, Vandvik PO and Buchbinder R 2019b. Subacromial decompression surgery for rotator cuff disease. Cochrane Database of Systematic Reviews, 1, CD005619.

⁸ Bäck M, Paavola M, Aronen P, Järvinen TLN and Taimela S 2021. Return to work after subacromial decompression, diagnostic arthroscopy, or exercise therapy for shoulder impingement: a randomised, placebo-surgery controlled FIMPACT clinical trial with five-year follow-up. BMC musculoskeletal disorders, 22, 889.

Cederqvist S, Flinkkila T, Sormaala M, Ylinen J, Kautiainen H, Irmola T, Lehtokangas H, Liukkonen J, Pamilo K, Ridanpaa T et al. 2021. Non-surgical and surgical treatments for rotator cuff disease: A pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation. Annals of the Rheumatic Diseases, 80, 796-802.

Paavola M, Kanto K, Ranstam J, Malmivaara A, Inkinen J, Kalske J, Savolainen V, Sinisaari I, Taimela S and Järvinen TL 2021. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: a 5-year follow-up of a randomised, placebo surgery controlled clinical trial. British journal of sports medicine, 55, 99-107.

in the RCTs, 5 case series with populations greater than 1,000 were used for safety outcomes but not for effectiveness.

Due to multiple publications, each trial is referred to by the surname of the first author (e.g. Beard) (see also Table 3).

Two trials at low risk of bias included the use of sham surgery as a placebo (Beard, Paavola).

Other trials were at higher risk of bias, commonly due to a lack of protocol, a lack of information regarding randomisation, an inability to blind across treatment populations, and imbalances across reported populations at follow-up. The GRADE certainty of evidence was moderate to high for comparisons to placebo, and low or very low for comparisons with conservative therapy.

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
SAD vs conservative treatment			-			
Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy only; 104 no treatment)	Multicentre, randomised, pragmatic, parallel group, placebo- controlled, 3- group trial	Low	Patient with subacromial pain for at least 3 months with intact rotator cuff tendons	Pain Shoulder function	No*
		1-year follow-up				
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise)	Randomised clinical trial 2.5-year follow-up	High	Rotator cuff disease (stage II impingement syndrome)	Pain Shoulder function	No*
Cederqvist (Cederqvist et al., 2021)	417 (190 surgical; 190 non-surgical)	Pragmatic randomised clinical trial 2-year follow-up	Some concerns	Patients with long-term (>3 months) subacromial pain	Pain Shoulder function	No*
Farfaras (Farfaras et al., 2016, Farfaras et al., 2018)		Prospective randomised study 2 to 3 years after the intervention	High	SAIS	Shoulder function Quality of life	No*
Haahr (Haahr and Andersen, 2006, Haahr et al., 2005)	84 (41 arthroscopic surgery; 43 physiotherapy)	Randomised controlled study	Some concerns	Subacromial impingement	Pain and dysfunction score Shoulder	No*
		1-year follow-up			function	

 Table 3
 Key features of the included evidence comparing SAD with conservative therapy or placebo

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Ketola (Ketola et al., 2009, Ketola et al., 2016, Ketola et al., 2015, Ketola et al., 2017)	140 (70 exercise; 70 acromioplasty with exercise)	Randomised controlled trial 1-year follow-up	Some concerns	Stage II SAIS	Pain	No*
Paavola (Bäck et al., 2021, Paavola et al., 2021, Paavola et al., 2018, Paavola et al., 2017)		Multicentre, 3- group, randomised, double-blind, sham-controlled trial.	Low	Patients with symptoms associated with shoulder impingement syndrome	Effectiveness: Pain Shoulder function	No*
		2-year follow-up			Return to work Safety: Complication and adverse events	
Peters (Peters and Kohn, 1997)	72 (32 surgery; 40 nonoperative treatment)	Prospective randomised study 4-year follow-up	High	SAIS	Pain Mobility Instability Activity Overhead	No*
Rahme (Rahme et al., 1998)	42 (number per group not specified at baseline)	Randomised prospective study 1-year follow-up	High	SAIS	work Pain	No*
SAD versus placebo						
Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy only; 104 no treatment)	Multicentre, randomised, pragmatic, parallel group, placebo- controlled, 3- group trial	Low	Patient with subacromial pain for at least 3 months with intact rotator cuff tendons	Pain Shoulder function	No*
		1-year follow-up Placebo is arthroscopy				
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30	Randomised clinical trial	High	Rotator cuff disease (stage II	Pain Shoulder function	No*

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
	placebo laser; 50 supervised exercise)	2.5-year follow-up		impingement syndrome)		
		Placebo is detuned laser				
Paavola (Bäck et al., 2021, Paavola et al., 2021, Paavola et al., 2018, Paavola et al., 2017)		Multicentre, 3- group, randomised, double-blind, sham-controlled trial.	Low	Patients with symptoms associated with shoulder impingement syndrome	Effectiveness: Pain Shoulder function	No*
		2-year follow-up			Return to work	
					Safety:	
		Placebo is arthroscopy			Complication and adverse events	
Shoulder arthroscopic surgery						
Shields (Shields et al., 2015)	10,570	Prognostic case series	Moderate	Shoulder arthroscopy	Complications	No*
		30 days		cases from the adult American College of Surgeons NSQIP database from 2005 and 2011	30-day mortality 30-day morbidity (major and minor complications)	
Heyer (Heyer et al., 2020)	134,822	Case series 30 days	Moderate	Shoulder and knee arthroscopy, including shoulder arthroscopy with SAD from the adult American College of Surgeons NSQIP database from 2010 and 2016		No*
Hill (Hill et al., 2017)	15,385	Prognostic case series	Moderate	Shoulder arthroscopy	30-day readmission	No*
		30 days		cases from the adult		

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
				American College of Surgeons NSQIP database from	Complications (major and minor complications)	
				2011 and 2013		
Rees (Rees et al., 2022)	261,248	Case series 90 days	Moderate	Shoulder arthroscopy cases from the Hospital Episode Statistics for NHS England database from 1 April 2009 to 31 March 2017		No*
Yeranosian (Yeranosian et al., 2014)	165,820 (consecutive, from a database)	Case series 30 days	Very high	Shoulder arthroscopy Cases from a United States insurance database between 2004 and 2009.	Infections and reoperations within 30 days	No*

Abbreviations

N = number, NSQIP = National Surgical Quality Improvement Program, SAD = subacromial decompression, SAIS = subacromial impingement syndrome.

Note

* = a modelled economic evaluation was not undertaken for this assessment.

Where reported, patients within studies appeared well matched at baseline between study groups.

Across the duration of the trials, relatively large proportions of patients had interventions other than that to which they were randomised or did not receive the intervention per protocol. Of the patients who were allocated to conservative therapy, between 10% (Farfaras) and 57% (Rahme) converted to surgery. Where permitted, these changes in intervention would suggest a lack of subjective patient satisfaction.

Relevant outcomes, in line with the ratified PICO confirmation, were reported by all studies. Where reported, there were no differences in results between intention-to-treat (ITT) and perprotocol analyses (Beard, Ketola, Paavola).

Population characteristics

Broadly, patients in all trials were similar, and selected on the basis of subacromial pain or impingement, with similar mean ages of between 44 and 59 years representing a relatively young population of working age. Patients in the RCTs had symptoms for at least 3 months, with durations of about 1 year (where reported). Other shoulder pathologies commonly included were full-thickness rotator cuff tears (FTT), osteoarthritis (of the glenohumeral or acromioclavicular joint), rheumatoid arthritis, instability, adhesive capsulitis, calcific tendinitis and trauma.

Cederqvist included treatment for tenotomy of the long head of the biceps as part of the intervention, although the use of this procedure is not reported. Cederqvist and Rahme did not exclude FTT.

In one trial, the diagnosis was left to local protocols (Beard). The results may therefore be reflective of patient selection in the UK, but the applicability to Australian clinical practice is uncertain. Physical tests were used in all trials. Imaging, such as X-ray, were commonly used to exclude other shoulder pathologies, and a positive impingement test (injection of local anaesthetic to the subacromial space) was also used. In two studies the use of imaging was unclear, or imaging was not used (Beard, Brox). The use of imaging to confirm the cause of impingement, or the pathology of the identified impingement was not commonly described.

In Cederqvist, all patients underwent a 3-month formal rehabilitation program (with a recommended 15 physiotherapy sessions) prior to randomisation to surgery, or continuation of rehabilitation. 39 per cent (161/417) of participants were subsequently excluded from further participation due to a combination of improved symptoms and change of diagnosis. This study is therefore likely to reflect best practice most closely, in line with the PASC-approved PICO, although outcome data were not available solely for patients treated with SAD.

One trial reported the presence of impingement in between 61% and 75% of patients who underwent surgery (Beard). This may reflect a lack of precision in patient selection, either for this study or in clinical practice as a whole.

In all trials, patients were required to have failed conservative therapies although the duration and type of therapy is rarely reported. Therefore, it is unlikely that all patients underwent a formal rehabilitation program for 6 months and may not align with the population described in the PICO Confirmation.

Baseline characteristics of pain and function varied between studies from better to worse scores. Better scores for pain did not always coincide with better scores for function. This may indicate variability across trials in terms of the severity of the shoulder pathology. The impact on outcomes is unclear.

No trial used a predefined threshold of pain, shoulder function or size of tear as criteria for selection. As a result, patients are likely to be included regardless of whether their presentation had been determined to reach a certain level of clinical severity.

Intervention and comparator

Interventions are similar across trials, commonly including use of bursectomy, release of the coraco-acromial ligament and removal of a subacromial bone spur. Removal of calcium deposits or resection of the lateral end of the clavicle are not mentioned as part of the surgical interventions. Studies do not report any variation in the procedures, or if there were changes to the intervention based on the shoulder anatomy, although Ketola describes the releasing of the coraco-acromial ligament only if it felt tight or thick.

All patients included standard postoperative rehabilitation, which commonly involved one or more physiotherapy visits and guidance for home exercises.

Ongoing or additional conservative co-interventions such as pain medications, antiinflammatories and subacromial injections of corticosteroids were not described in all trials, and therefore their use is uncertain.

Across all trials, 4 distinct comparators were reported.

The most common comparator was exercise therapy. In many cases, the therapy was for 3–6 months, with supervision (1-hour session, 1–3 times per week where reported) gradually reduced over time as patients became familiar with the exercises (Brox, Farfaras, Paavola). Physiotherapy by the method of Bohmer was mentioned by 2 trials (Farfaras, Rahme).

A sham surgery placebo was reported in 2 trials (Beard, Paavola). Placebo was arthroscopy only, with exactly the same approach as SAD but with no surgical removal or excision (Beard). In Paavola, bursal tissue could be stretched or resected, keeping resection to a minimum. In both trials, postoperative rehabilitation was the same as for the SAD group.

One trial used active monitoring with specialist reassessment (Beard). Patients attended a reassessment appointment 3 months after entering the study.

One trial used a placebo therapy of a detuned laser given in 12 sessions, with no additional physiotherapy or exercise therapy (Brox). However, after a preliminary analysis of outcomes showed inferior results, the laser therapy was discontinued after 6 months. Most patients originally randomised to laser therapy received SAD (15 received SAD and 2 had a different treatment from a total cohort of 30).

9. Comparative safety

Adverse events and complications

Across all included studies, reported adverse events were in line with the outcomes provided in the PICO Confirmation, noting that there was no reported incidence of wasting or avulsion of the deltoid muscle.

Adverse events are rarely reported in the RCTs. Table 4 presents the reported adverse events and complications based on 2 RCTs (Beard, Paavola) and 5 large case series studies from the US and UK (Shields, Heyer, Hill, Rees, Yeranosian). Case series reported outcomes at 30 days (Heyer, Hill, Shields, Yeranosian) or 90 days and 1 year (Rees).

Due to the low event rate reported in the 2 RCTs (Beard, Paavola), the reported adverse events were pooled for placebo and conservative management interventions and compared to SAD. An adverse event was reported in 1.9% to 5.1% of the patients who had SAD and 1.4% to 2.8% of patients with conservative therapy or placebo. Frozen shoulder was the most commonly-reported event; studies do not describe how this was resolved.

The included case series reported 30-day major and minor complications, or reoperations for infections (open or closed surgical drainage) associated with shoulder arthroscopy (Hill, Shields, Yeranosian). However, the population was from a database not restricted to shoulder decompression surgery and included procedures such as rotator cuff repair, superior labrum anterior and posterior (SLAP) lesion repair, capsulorrhaphy, distal claviculectomy, extensive debridement, limited debridement, lysis and resection of adhesions with or without manipulation, biceps tenodesis, complete synovectomy, foreign-body removal and partial synovectomy. These interventions represent a broader range of arthroscopic procedures and may reflect a slightly more invasive set of operations. The reported rates for mortality and major and minor complications were 1.00% to 1.17% of the patients who had shoulder arthroscopy. Heyer reported safety outcomes from the same database for SAD, with an overall complication rate (including death) of 0.65%.

Table 4 Safety outcomes

Study types and outcomes	Intervention	Comparator
Randomised controlled trials		·
Frozen shoulder	 1.9% (2/106) Beard 5.1% (3/59) Paavola 	Conservative therapy • 1.9% (2/104) Beard • 2.8% (2/71) Paavola Placebo • 1.9% (2/103) Beard • 1.6% (1/63) Paavola
Low back pain		Conservative therapy • 1.4% (1/71) Paavola
Temporary swelling postoperative		Placebo • 1.6% (1/63) Paavola
Overall adverse event rate (p = 0.86)	• 3.0% (5/165) Beard, Paavola	• 3.7% (9/241) Beard, Paavola
Case series		
Overall adverse event rate: Arthroscopic shoulder surgery	 1.17% (175/15,015) Hill 1.0% (103/10,255) Shields 0.27% (450/165,820) Yeranosian (reoperations for surgical drainage) 	
Overall adverse event rate: Subacromial decompression	 0.65% (210/32,228) Heyer 1.15% (1,186/103,211) Rees 	

From a prospective insurance database of 165,820 patients in the United States, there was an overall infection rate (represented by reoperations within 30 days for surgical drainage) of 0.27% (450/165,820) following shoulder arthroscopy (Yeranosian).

A recently published dataset from the UK of 103,211 patients showed an overall rate of adverse events or reoperation within 90 days following SAD of 1.15% (95% confidence interval 1.09 to 1.22) (Rees).

Evidence from published systematic review state that conservative therapies are safe, with reported adverse events transient and mild.

10. Comparative effectiveness

All clinical effectiveness outcomes requested in the PICO Confirmation were available.

The assessment for effectiveness is limited by the low quality of evidence based on the GRADE quality appraisal on outcomes such as pain, shoulder function, HRQoL and return to work in comparing SAD with conservative therapy.

Pain

Based on the available data from the included RCTs, pain scores at different timepoints were generally lower for patients who had SAD compared to conservative therapy or placebo (Table 5).

When compared to conservative therapy, the mean difference in pain score was not statistically significant except at the 3-month timepoint. However, the difference in pain level was not

clinically relevant based on a minimum clinically important difference (MCID) of 1.5 points. There was no difference in pain for SAD compared with placebo.

Table 5Pooled data from RCTs, mean difference between groups (SAD and conservative therapy/placebo) atfollow-up for pain

Timepoints	SAD vs conservative therapy (mean [95% confidence interval])	SAD vs placebo (mean [95% confidence interval])
3 months	-0.68 (-1.32 to -0.03) (p = 0.04)	0.50 (-0.41 to 1.41)
6 months	-0.48 (-1.00 to 0.04)	-1.01 (-3.24 to 1.21)
1 year	-0.77 (-1.59 to 0.04)	-0.27 (-0.85 to 0.31)
2 years	-0.35 (-1.34 to 0.64)	-0.90 (-1.80 to 0.00)
5 years	-0.12 (-0.57 to 0.33)	-0.80 (-1.71 to 0.11)
10 years	1.0 (-0.24 to 2.24)	NR

Abbreviations

NR = not reported, SAD = subacromial decompression.

<u>Notes</u>

Pain (0-10); lower scores mean less pain. Minimal clinically important difference = 1.5 points

p > 0.05 unless otherwise shown

Bold text indicates statistically significant results

Source

Figure 6, Figure 10

Shoulder function

Table 6Pooled data from RCTs, mean difference between groups (SAD and conservative therapy/placebo) atfollow-up for shoulder function

Timepoints	SAD vs conservative therapy (mean [95% confidence interval])	SAD vs placebo
3 months	6.21 (-7.34 to 19.76)	NR
6 months	2.71 (-4.67 to 10.09)	-0.70 (-6.33 to 4.93)
1 year	3.60 (-9.16 to 16.37)	1.30 (-4.53 to 7.13)
2 years	5.91 (2.08 to 9.74)	4.20 (-1.72 to 10.12)
5 years	4.41 (-1.71 to 10.53)	7 (0.75 to 13.25) (p = 0.03)
10 years	9.59 (1.98 to 17.19) (p = 0.01)	NR

Abbreviations

NR = not reported, SAD = subacromial decompression.

Notes

Function (0–100); higher scores mean better function: MCID = 8.3 points

p values are greater than 0.05 unless otherwise shown

Bold text indicated statistically significant results

Source

Figure 7, Figure 11

Table 6 shows the mean difference in shoulder function scores at different timepoints between SAD and conservative therapy/placebo. For surgery versus conservative therapy, while a higher shoulder function score was evident at all timepoints, this difference was not statistically significant) except at the 10-year follow-up timepoint. The mean difference between SAD and conservative therapy at the 10-year follow-up timepoint was statistically significant and clinically

important based on the MCID for shoulder function of 8.3 points. Based on GRADE, there is a very low certainty of evidence regarding SAD's impact on shoulder function.

SAD showed a higher shoulder function score compared to placebo, although the results were not statistically significant for most reported timepoints and were not clinically important. The result comparing surgery and placebo was of high certainty.

Health-related quality of life (HRQoL)

The HRQoL was not significantly different at all timepoints when comparing SAD with conservative therapy (3 RCTs) or placebo (2 RCTs). Therefore, SAD has little to no effect on HRQoL. The result may be influenced by the low number of studies included in the review and the low certainty on the quality of evidence for SAD vs conservative therapy and high certainty for SAD vs placebo.

Return to work

The number of patients who were able to return to work at different timepoints is presented in Table 7. Compared to conservative therapy, the percentage of patients who returned to work after surgery is not statistically different. However, the evidence on the effect of SAD vs conservative therapy on patients' return-to-work status or ability is uncertain due to the very low level of certainty on the quality of the studies included in the review. Only one RCT was available to compare SAD with placebo, with moderate level of evidence certainty based on GRADE.

Timepoints	SAD vs conservative therapy (% [n/N])	SAD vs placebo (% [n/N])
3 months	SAD: 66% (39/59) CT:69% (47/68)	NR
6 months	SAD: 77% (67/87) CT: 73% (73/100)	NR
1 year	SAD: 86% (48/56) CT: 87% (55/63)	NR
2 years	SAD: 74% (65/88) CT: 78% (79/101)	SAD: 82% (47/57) P: 80% (47/59)
5 years	SAD: 66% (110/153) CT: 67% (107/160)	SAD: 67% (38/57) P: 69% (41/59)
10 years	SAD: 98% (43/44) CT: 91% (42/46)	NR

 Table 7
 Pooled data from RCTs, percentage of patients who returned to work at different timepoints

Abbreviations

CT = conservative therapy, NR = not reported, P = placebo, SAD = subacromial decompression surgery.

Source

Figure 9, Section 2.2.3

Failure of surgery and reoperations

Compared with conservative therapy, the presence of full-thickness tears as identified with MRI was similar at 5 years (1 study) and improved for patients following SAD at 13 years (1 study).

Additional surgery or reoperation was not commonly reported. One trial reported a total of 4 reoperations (1/59 for SAD, 3/15 for patients who converted to SAD from conservative therapy)

including additional SAD, distal clavicle resection, and long head of biceps repair (Paavola). There were no other reported reoperations, and none in patients treated with diagnostic arthroscopy.

GRADE quality assessment

The summary of findings for the GRADE quality assessment is shown in Table 8 and Table 9.

Depending on the reported outcome, the number of RCTs available for the comparison with conservative therapy varied. Accordingly, the certainty of evidence varied from moderate to very low based on the number and risk of bias of the RCTs. At 12 months there were no statistically significant differences reported for pain (low certainty evidence), HRQoL (low certainty evidence) and return to work (very low certainty evidence). The main reason the evidence was downgraded was due to the risk of detection and performance bias, as participants were not blinded to their treatment allocations. Moderate-certainty evidence shows no statistically significant difference reported on the total adverse events. However, the certainty of evidence was downgraded due to imprecision and the low event rates reported.

Outcome (units) Follow-up	Participants (studies)	Quality of evidence	Risk of bias	Range of effect
Pain (12 months)	316 participants (k=3)	⊕⊕⊖⊖ Low	Serious	0.77 points lower to 1 point higher
Shoulder function (12 months)	259 participants (k=3)	⊕⊖⊖⊖ Very low	Serious	2.71 to 9.59 points higher
HRQoL (12 months)	116 participants (k=1)	⊕⊕⊖⊖ Low	Serious	Not estimable
Return to work (5 years)	313 participants (k=3)	⊕⊖⊖⊖ Very low	Serious	27 fewer to 167 more people
Total adverse events (12–24 months)	406 participants (k=2)	⊕⊕⊕⊖ Moderate	Serious	26 fewer to 62 more people

Table 8 Clinical benefit and harm using SAD versus conservative therapy

Abbreviations

HRQoL = health-related quality of life, SAD = subacromial decompression surgery.

Source

Table 63

Table 9 Clinical benefit and harm of using SAD versus placebo

Outcome (units) Follow-up	Participants (studies)	Quality of evidence	Risk of bias	Range of effect
Pain	281 participants (k=2)	⊕⊕⊕⊕ High	Not serious	0.85 points lower to 0.31 points higher
Shoulder function	157 participants (k=1)	⊕⊕⊕⊕ High	Not serious	4.57 points lower to 7.13 points higher
HRQoL	285 participants (k=2)	⊕⊕⊕⊕ High	Not serious	0.28 points lower to 0.18 points higher
Return to work	116 participants (k=1)	⊕⊕⊕⊖ Moderate	Serious	100 fewer to 183 more people

Abbreviations

HRQoL = health-related quality of life, SAD = subacromial decompression surgery.

Source

High-certainty evidence indicates that SAD compared to placebo provides no improvement in pain, shoulder function or HRQoL. There is no statistically significant difference reported in the return-to-work outcome between SAD and placebo based on moderate-certainty evidence.

The certainty of evidence was moderate to high due to the inclusion of 2 RCTs at low risk of bias.

Overall clinical claim

This review is not based on a formal application with a defined clinical claim. However, based on the benefits and harms reported in the evidence base, data synthesis showed that there was no difference in the use of SAD versus conservative therapy on clinical effectiveness outcomes such as pain, shoulder function, HRQoL and return to work, and on clinical safety outcome (total adverse events). For shoulder function, compared with conservative therapy, surgery reaches clinical significance at the 10-year timepoint, with a mean difference in shoulder function scores of 9.59 (95% confidence interval [CI] 1.98 to 17.19). However, this is based on results from 2 trials of very low certainty and so should be treated with caution.

SAD does not show statistically and clinically significant difference on outcomes such as pain, shoulder function, HRQoL and return to work compared to placebo based on moderate to high certainty of evidence.

Reported adverse events associated with SAD, conservative therapy and placebo were rare. Case series evidence shows that serious adverse events associated with subacromial decompression are not common. Systematic reviews have found that adverse events associated with conservative therapies are mild and transient.

The trial populations likely reflect a broader population of patients who were not selected based on defined criteria of pain or function, and previous conservative therapies varied. Due to the lack of defined populations in the current and proposed MBS items the applicability of this evidence to Australian practice is uncertain.

11. Economic evaluation

Based on MSAC advice, a cost comparison analysis was undertaken to compare SAD with conservative therapy. The cost comparison was based on the framework of a cost-minimisation analysis (CMA). However, as clinical non-inferiority was not established this analysis should not be considered a CMA study. The cost comparison takes an expanded Australian health system perspective, where some of the costs payable by patients and private insurers are also included. The inclusion of these service costs ensured the completeness of the service delivery.

Various costs and levels of service utilisations were incorporated in the cost analysis. The information was sourced from MBS statistics, published literature and available clinical practice guidelines. This information was also used to inform assumptions regarding plausible clinical situations. Due to the high levels of uncertainty for service use in the evidence base and in Australian clinical practice, the result of the cost comparison is likely to be highly uncertain. Oneway deterministic sensitivity analyses and scenario analyses were performed to investigate the cost drivers of the uncertainties. A summary of the assumptions used in each scenario is shown in Table 10. Key analysis results are summarised in Table 11.

Service item	Base-case Uncertainty ranges value ^a		Usage of the assumption in scenarios	Assumption references	
MBS 10960 (Physiotherapy)	20%	12.6%, 80.5%	Scenario 1, 2	Literature ^b	
MBS 10953 (Exercise physiology)	20%	12.6%, 80.5%	Scenario 1, 2	Literature ^b	
MBS 721 (GP management plan)	20%	12.6%, 80.5%	Scenario 1, 2	Literature ^b	
MBS 723 (GP coordinate team care arrangements)	20%	12.6%, 80.5%	Scenario 1, 2	Literature ^b	
MBS 63325 (MRI of shoulder)	43.3%	0.5%, 72%, 0%	Scenario 1, 2, 3	Literature ^b , clinical guidelines	
MBS 56627 (CT of shoulder)	4.4%	0.2%, 0%	Scenario 1, 3	Literature ^c , clinical guidelines	
MBS 55864 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature ^b	
MBS 55865 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature ^b	
MBS 55866 (US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature ^b	
MBS 55867(US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Literature ^b	
MBS 57700 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Literature ^b	
MBS 57703 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Literature ^b	
Specialist physiotherapy ^f	6	2, 12	Scenario 1, 2	Literature ^d , clinical guidelines	
Post-surgery rehabilitation	2	1, 4	Scenario 1, 2	Literature •	

Table 10 Assumptions and parametric uncertainties involved in cost comparison calculations

Abbreviations

MBS = Medicare Benefit Schedule.

Note

Scenario 1 assumptions were based on an overall lower rate of physiotherapy and diagnostic imaging as identified in the literature Scenario 2 assumptions were based on an overall higher rate of physiotherapy and diagnostic imaging services as identified in the literature literature

Scenario 3 involves the exclusion of MRI and CT from conservative therapy in line with guidelines that do not recommend these services to be available in primary care

a = The base-case assumptions were taken from utilisation data for item 48951, other than for specialist physiotherapy and post-surgery rehabilitation

b = Naunton, J., Harrison, C., Britt, H., Haines, T. & Malliaras, P. 2020. General practice management of rotator cuff related shoulder pain: A reliance on ultrasound and injection guided care. PLoS One, 15, e0227688-e0227688.

Smythe, A., Rathi, S., Pavlova, N., Littlewood, C., Connell, D., Haines, T. & Malliaras, P. 2021. Self-reported management among people with rotator cuff related shoulder pain: An observational study. Musculoskelet Sci Pract, 51, 102305.

c = Naunton, J., Harrison, C., Britt, H., Haines, T. & Malliaras, P. 2020. General practice management of rotator cuff related shoulder pain: A reliance on ultrasound and injection guided care. PLoS One, 15, e0227688-e0227688.

d = Hopewell, S., Keene, D. J., Marian, I. R., Dritsaki, M., Heine, P., Cureton, L., Dutton, S. J., Dakin, H., Carr, A., Hamilton, W., Hansen, Z., Jaggi, A., Littlewood, C., Barker, K. L., Gray, A. & Lamb, S. E. 2021. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. Lancet, 398, 416-428.

e = Beard, D. J., Rees, J. L., Cook, J. A., Rombach, I., Cooper, C., Merritt, N., Shirkey, B. A., Donovan, J. L., Gwilym, S., Savulescu, J. & Et Al. 2018. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet (london, england), 391, 329 - 338.

Cederqvist, S., Flinkkila, T., Sormaala, M., Ylinen, J., Kautiainen, H., Irmola, T., Lehtokangas, H., Liukkonen, J., Pamilo, K., Ridanpaa, T. & Et Al. 2021. Non-surgical and surgical treatments for rotator cuff disease: A pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation. Annals of the Rheumatic Diseases, 80, 796 - 802.

f = Specialist physiotherapy is provided by an experienced physiotherapist as the alternative to surgery after the patient has exhausted the physiotherapy sessions available through the MBS chronic disease management plan

Table 11	Cost comparison results between SAD with and without surgery

Scenario	Key driver in the scenario analysis	Intervention with SAD surgery	Intervention without SAD surgery	Cost difference
Base-case		\$6,474	\$1,239	-\$5,235
Scenario 1: low service usage	Reduced usage in allied health services and diagnostic imaging services	\$6,131	\$587	-\$5,544
Scenario 2: high service usage	Increased usage in allied health service and diagnostic imaging services	\$7,191	\$2,368	-\$4,823
Scenario 3: diagnostic imaging	Reduced usage in diagnostic imaging service in non-surgical patients	\$6,474	\$1,051	-\$5,422

Abbreviations:

SAD = subacromial decompression

Notes:

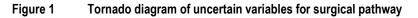
The base-case assumptions were taken from utilisation data for item 48951

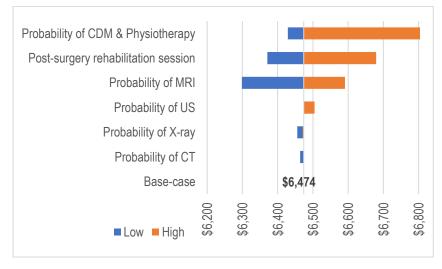
Scenario 1 assumptions were based on an overall lower rate of physiotherapy and diagnostic imaging as identified in the literature Scenario 2 assumptions were based on an overall higher rate of physiotherapy and diagnostic imaging services as identified in the literature literature

Scenario 3 involves the exclusion of MRI and CT from conservative therapy in line with guidelines that do not recommend these services to be available in primary care

The cost comparison shows that the management of subacromial impingement is more expensive when SAD is involved in all scenarios. The cost saving is approximately \$5,000 when using conservative therapy alone (i.e. intervention without SAD surgery). The greatest contributing factors to this cost difference are hospitalisation costs, and fees and charges directly associated with the surgery. While additional physiotherapy will increase costs in the conservative-only pathway, the cost increments are still not comparable to the cost of surgical intervention. Thus, the use of conservative therapy is cheaper for the Australian health system. However, it should be noted that in the non-surgical pathway, some cost burdens are transferred to patients and private health insurers. Therefore, conservative therapy may not be cost-saving from the perspectives of patients and private health insurers. Due the subjective variability in service usage, as well as how much patients and private health insurers are charged in different settings, this burden of cost transfer is highly uncertain.

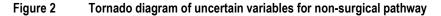
In addition to the scenario analyses, one-way deterministic sensitivity analyses were undertaken for the 2 SAD treatment pathways. Tornado diagrams were produced to illustrate different cost drivers of the uncertainties in both arms (Figure 1 and Figure 2). For the purposes of the economic analyses, it was assumed that initial physiotherapy (used by all patients) was accessed through the MBS Chronic Disease Management plan (CDM), and physiotherapy used by patients as an alternative to surgery was subsequently provided independently of the MBS by a senior or specialist physiotherapist. The intent was to differentiate between services available through, and outside of the MBS, and to recognise that many clinics advertise different seniority of physiotherapists at different costs. It is acknowledged that access to, use of and payment for physiotherapy services by patients with shoulder impingement pain will vary.

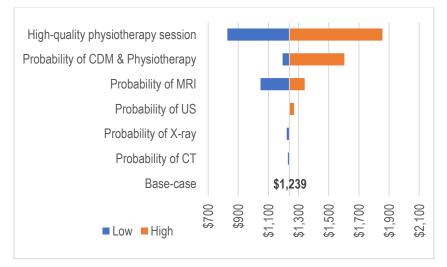




Abbreviations:

CDM = chronic disease management plan; CT = computed tomography; MRI = magnetic resonance imaging; US = ultrasound.





Abbreviations:

CDM = chronic disease management plan; CT = computed tomography; MRI = magnetic resonance imaging; US = ultrasound.

From the sensitivity analysis, we observe that the use of physiotherapy in both the surgical and non-surgical pathways is the main cost driver. This is particularly the case for the non-surgical pathway. This finding reflects the varied and uncertain clinical practice in management of subacromial impingement, as well as the preference of patients to undertake exercise therapy at home. Use of various diagnostic imaging services is also a small cost driver across both pathways. MRI usage is the most impactful, particularly in the surgical pathway.

12. Financial/budgetary impacts

Financial impacts

The financial implication for MBS SAD surgical services was projected over 6 financial years from 2022 to 2027. A market-share approach was used to predict the number of patients potentially

eligible for SAD surgical interventions under the current and proposed SAD service scope. MBS historical claim data as well as AIHW hospital data were used as the basis of this estimate.

Several categories of medical and surgical services relevant to SAD are identified in the MBS. The utilisation of each relevant MBS item was derived via current clinical practice, MBS co-claim patterns (via the data request) and reasonable assumptions. The categorical subtotal costs to the MBS were then aggregated by the cost of surgery, the cost of all relevant perioperative services, and other associated medical services before and after surgery. The financial implication of MBS SAD services was then calculated over the projected 6 financial years. The key results of the base case, plus 4 different plausible scenarios, are presented in Table 12.

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Base-case scenario	\$6,922,388	\$6,272,417	\$5,622,489	\$4,974,547	\$4,322,653	\$3,672,731
Scenario 1: new SAD item	-\$957,233	-\$860,252	-\$763,270	-\$666,288	-\$569,307	-\$472,325
Scenario 2: full physiotherapy	-\$729,081	-\$656,293	-\$583,504	-\$510,716	-\$437,928	-\$365,592
Scenario 3: restriction for surgery	-\$415,452	-\$372,511	-\$329,569	-\$286,628	-\$243,686	-\$200,745
Scenario 4: full disinvestment	-\$2,578,265	-\$2,336,198	-\$2,094,131	-\$1,852,064	-\$1,609,997	-\$1,367,930

 Table 12
 Financial implication for MBS SAD services under the base case and all scenarios

Abbreviations

MBS = Medical Benefit Scheme, **SAD** = subacromial decompression.

<u>Notes</u>

Base-case scenario: Informed by the MBS data utilisation and co-claiming for item 48951

Scenario 1: Based on a single consolidated item with a weighted average fee

Scenario 2: Based on scenario 1, but with all patients receiving 3 months rehabilitation and 39% patients not receiving surgery as informed from the literature

Scenario 3: Based on scenario 1, but with services restricted to 55% of patients with radiological signs of impingement, having failed conservative therapy, as informed from the literature and consultation feedback

Scenario 4: Complete removal of SAD services from the MBS

In the base-case scenario, it is estimated that the full cost of all relevant SAD services in the MBS is over \$6.9 million in 2022, reducing to \$3.7 million in 2027. This is due to the decreasing trend in the number of patients receiving MBS SAD surgical services in the past 5 years. Four alternative scenarios are produced to capture potential modifications of the SAD service scope. All 4 scenarios are aimed to either tighten the patient eligibility for surgery or reduce the scope of the SAD surgical services and direct patients to receive conservative management, including physiotherapy. Consequently, these scenarios all lead to cost savings to the MBS and are presented as negative values in Table 12 to quantify their net impact to the MBS.

13. Other relevant information

Review of MBS item utilisation data

A review of the utilisation of SAD services (MBS items 48900, 48903 and 48951) provided insights into patterns of use relative to other services and to provide information on relevant scenarios for budget impact analysis. The output includes information on the utilisation of MBS item use for referrals, diagnostic imaging and treatment.

Two AIHW datasets include information on hospital procedures and healthcare interventions for SAD and arthroscopic SAD, and the hospitals' principal diagnosis for impingement syndrome of the shoulder.

While the AIHW data provide valuable information on hospitalised patients diagnosed with subacromial impingement, the true number of patients with the condition can be underrepresented. Patient diagnosis often occurs in the primary care setting.

Various datasets for MBS services included information on MBS services data for items 48900, 48903 and 48951; MBS co-claiming data for the top 10 claim combinations and the top 10 coclaimed services; MBS diagnostic imaging services and referral information; and MBS patients who received exercise physiology or physiotherapy.

While these MBS data provide useful information on the medical services used, there are a number of limitations. For example, there is no information on co-claiming beyond the top 10 combinations, no detail regarding the number of physiotherapy or exercise physiology services accessed by the patient, and no certainty on the exact timing of physiotherapy and/or exercise physiology services (e.g. whether this is accessed before or after surgery). The data was restricted to one financial year as adding multiple years would increase the number of services co-claimed by the patient for other indications and reduce the usefulness of the dataset. However, co-claimed services related to SAD surgery accessed before this time period would not have been counted and it is therefore likely that the number of services provided to patients for physiotherapy and diagnostic imaging were under-represented in this analysis. This analysis has not included any non-MBS-funded services (e.g. additional physiotherapy services, out-of-pocket diagnostic imaging).

Analysis of MBS utilisation data for MBS items 48900, 48903 and 48951 show the following for financial year 2020–21:

- Co-claiming. The differing claiming patterns of the three SAD items with other surgical services indicated that these items are used differently to one another. MBS 48900 is coclaimed with US or echography in conjunction with a surgical procedure using interventional techniques (55848, 5850 or 55850), which likely indicates the use of this item for image-guided removal of calcium deposits with injection (e.g. lavage) by radiologists or in specialist or GP rooms.
- A range of other shoulder services were commonly claimed with MBS item 48903, such as excision of ganglion cysts, synovectomy of the shoulder and total shoulder replacement. This use of item 48903 in association with services for other shoulder pathologies is likely related to a lack of restriction in the item descriptor.
- MBS 48951 was claimed as a standalone procedure in half of the total top 10 episodes on co-claiming data. Its use is therefore most likely to represent SAD for subacromial impingement in isolation from other shoulder pathology. Shoulder services such as removal of ganglion or cyst, tendon and ligament transfer, and rotator cuff repair were also used in combination with MBS 48951.
- Demographic data. There is variability in population characteristics across MBS items. The proportion of female patients is higher in MBS 48900, while males are more commonly represented in 48951. For item 49803 there is a similar distribution of males and females. The proportion of younger patients (0–54 years) is higher in MBS 48900, whereas for 49803 and 49851 patients age 55–74 are more common.
- Surgical services. For financial year 2020–21, MBS 48951 had the highest number of claims, consistent with historical claims from previous years. There has been a downward trend in the number of claims over the past 5 years. There is a similar downward trend in the rates of diagnosis of subacromial decompression in Australian hospitals.
- Diagnostic imaging. X-ray and US were the most commonly requested diagnostic imaging procedures for MBS 48900 and 48903, while X-ray and MRI were more common for MBS 48951. CT was rarely used but was most commonly claimed for 48903. Across all 3

surgical items, the average patient received 1.46 services for diagnostic imaging per surgical service.

- Referral patterns. There is variability in the referral patterns for diagnostic imaging across MBS SAD items. A higher proportion of requests came from GPs for MBS 48900, from specialist orthopaedic surgeons for MBS 48903, and from GP or specialist for MBS 48951. A higher proportion of the requests from GPs were for X-ray and US, while all MRI requests were made by specialists. For 48951, all MRI requests and most US services (96.7%) came from specialists, while 56.1% of X-ray requests came from GPs. This is in line with recommendations of clinical practice guidelines that US and MRI should not be provided in primary care for suspected rotator cuff disease or subacromial impingement. Any non-MBS-funded diagnostic services (e.g. shoulder MRI referred from a GP, paid for out-of-pocket by a patient) has not been identified in this analysis.
- Allied health. Uptake of allied health services (physiotherapy and/or exercise physiology) was generally low, with approximately 20% of all patients accessing these services through the MBS. This may be attributed to the patient's eligibility for a CDM plan, which gives them access to 5 allied health sessions with a Medicare rebate, and likely underrepresents the total number of claims as this analysis was restricted to data from one financial year. Patients who accessed additional physiotherapy privately or outside the CDM were not included in the dataset. Female patients and those age 55–74 were more likely to access these services.

Supplementary clinical evidence

Long-term follow-up of 10 years or more was reported in 7 case series. The rate of repeat surgeries was similar to that reported in RCTs, varying from 3% to 26% across studies. Where reported (2 case series), there was no difference in outcome between short-term (1 or 8 years) or long-term (13 and/or 25 years) follow-up.

Seventeen studies (clinical guidelines, RCTs, non-randomised comparative studies, case series) reported a range of factors considered to be predictive or prognostic of improved outcomes following SAD and for recovery from rotator cuff disorders. This evidence should be treated with caution as none of the identified clinical studies reported being suitably powered to examine subgroups and it is unclear which, if any, improvements reached clinically important differences. Commonly reported factors that led to improved outcomes included older age and a worse clinical score at baseline. No RCT showed clinically significant differences on pre-planned subgroup analyses.

Seven case series were identified which reported the impact of radiological evidence of abnormal morphology, impingement or abrasion. Of these, 2 studies reported that radiological signs of impingement were consistently associated with a good outcome (p < 0.001) or were seen in all patients meeting the set criteria for an improved outcome.

There were few ongoing studies. The FIMPACT trial is continuing to 10-year results (Paavola). One trial is currently recruiting to compare SAD with placebo in 160 randomised patients who must have completed at least 3 months of supervised shoulder training (NCT04644042, expected year of completion 2026).

14. Questions for consultation

1. In the trials and in usual practice, X-ray, US and MRI are used to exclude other shoulder pathologies or determine the state of rotator cuff tendons, rather than to identify the source of the impingement. A small number of publications use X-ray to identify radiologic causes of impingement. Is this useful in clinical practice and patient selection?

- 2. Are there any other patient characteristics or selection criteria which are relevant for patient selection, or for identifying patients who may best benefit from surgery?
- 3. At baseline, patients in the trials have unclear or varied access to previous conservative therapies including physiotherapy or exercise therapy. Publications suggest that patient experiences of conservative therapies in Australia also varied, although it is unclear if this applies to patients who have surgery. In Australia, do patients with subacromial impingement have appropriate access to best practice conservative therapy and advice prior to being considered for surgery?

Acronyms and abbreviations

AA	arthroscopic acromioplasty
AIHW	Australian Institute of Health and Welfare
ARTG	Australian Register of Therapeutic Goods
ASAD	arthroscopic subacromial decompression
BMI	body mass index
CAL	coraco-acromial ligament
CDM	chronic disease management
CI	confidence interval
CPR	cardiopulmonary resuscitation
CPT	current procedural terminology
CSAW	Can shoulder arthroscopy work?
DA	diagnostic arthroscopy
DCAR	department contracted assessment report
EPC	enhanced primary care
ESC	evaluation sub-committee of MSAC
FIMPACT	Finnish shoulder impingement arthroscopy controlled trial
FTT	full-thickness rotator cuff tears
GP	general practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluations
HRQoL	health-related quality of life
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
ITT	intention-to-treat
MBS	Medicare Benefits Schedule
MCID	minimum clinically important difference
MD	mean difference
N410	
MIC	minimum important change
MIC	minimum important change minimal important difference
MID	minimal important difference

NR	not reported
NRS	numeric rating scale
NSQIP	National Surgical Quality Improvement Program
OAA	open anterior acromioplasty
OSS	Oxford shoulder Score
PASC	PICO Advisory Sub-committee of MSAC
PICO	population, intervention, comparator, outcome
PTT	partial-thickness rotator cuff tear
RCT	randomised controlled trial
RoB 2	risk of bias 2 tool
QALY	quality-adjusted life year
SAD	subacromial decompression
SD	standard deviation
SDQ	shoulder disability questionnaire
SLAP	superior labrum anterior and posterior
SSI	surgical site infection
SSRS	subjective shoulder rating score
TBD	to be determined
TGA	Therapeutic Goods Administration
VAS	visual analogue scale

1.1 Purpose of application

This department contracted assessment report (DCAR) of subacromial decompression (SAD) for the treatment of patients with symptomatic subacromial shoulder impingement is intended for the Medical Services Advisory Committee (MSAC).

MSAC appraises medical services, health technologies and health programs for public funding through an assessment of their comparative safety, clinical effectiveness, cost-effectiveness and total cost, using the best available evidence. This includes, but is not limited to, amendments and reviews of existing services funded on the Medicare Benefits Schedule (MBS) or other non-MBS-funded programs (e.g. blood products, screening programs or prostheses referred to the Prostheses List Advisory Committee).

The Royal Australasian College of Surgeons (RACS) has been commissioned by the Australian Government Department of Health to conduct a systematic literature review and economic evaluation of SAD. This assessment has been undertaken to inform MSAC's decision-making regarding whether the proposed health technology should be publicly funded. The purpose of this assessment report is to synthesise the information most likely to be useful for committee members. Technical appendices provide assurance of the rigour behind the systematic review and construction of the economic and financial analyses.

The proposed use of SAD in Australian clinical practice was outlined in a PICO confirmation that was presented to, and accepted by, the PICO Confirmation Advisory Sub-Committee (PASC). The PICO confirmation was released for public comment on 11 March 2022.

1.2 Background

SAD surgery and rotator cuff repair are commonly performed in Australia and are currently reimbursed through a number of MBS items, which include a range of procedures available since 1 December 1991 (Appendix G).

The currently subsidised MBS items for SAD (by acromioplasty) are MBS item 48903 and MBS item 48909. Other items related to SAD include 48900 and 48906 (which include excision of the coraco-acromial ligament or removal of calcium deposit) and 48951 and 48960 (which include division of the coraco-acromial ligament, acromioplasty and resection of the acromioclavicular joint).

MSAC has not previously considered items related to SAD.

As part of the Medicare Benefits Schedule (MBS) Review (Medical Benefits Review Taskforce, 2020), the final report on the review of Orthopaedic MBS items recommended that for shoulder surgery, existing items for SAD and rotator cuff repair should be consolidated (recommendation 74, 75) (MBS Review, 2019). The proposed items are shown in Appendix G.

In 2020, MSAC recommended that the MSAC Executive review MBS item 48903 for shoulder SAD surgery (MSAC, 2020). During its deliberations of this item, the MSAC Executive noted the results of 2 recent systematic reviews showed that the clinical benefits of these procedures compared to conservative management was uncertain and advised that a full health technology

assessment (HTA) review was required prior to the implementation of recommendations 74 and 75 (Australian Government Department of Health, 2021, Karjalainen et al., 2019a, Karjalainen et al., 2019b).

Terms of reference for this review with subsequent amendments in strikethrough:

- Review clinical guidelines on the management of rotator cuff disease, taking account of the clinical characteristics of the population/s recommended for SAD (with/without rotator cuff repair).
- 2. Review the utilisation of SAD services, informed by MBS data and other data that may provide additional insight into clinical use.
- 3. Review evidence on comparative safety and clinical effectiveness of SAD (with/without rotator cuff repair) used in the management of rotator cuff disease. The evidence review will be based on the population, intervention, comparator and outcomes (PICO) confirmation ratified by the PICO Advisory Sub-committee (PASC).
- 4. Subject to the findings of Terms of reference 1, 2 and 3, review and evaluate the cost effectiveness of SAD (with/without rotator cuff repair).

As part of this review, PASC considered two PICO sets:

- The use of SAD as a standalone procedure (PICO set 1– patients with subacromial impingement)
- The use of SAD in addition to surgery for rotator cuff repair (PICO set 2 patients for repair of rotator cuff of shoulder).

Following PASC advice and endorsed by the MSAC Executive, the PICO set 2 for the use of SAD as an adjunct to rotator cuff repair was removed from this current assessment. PASC noted that current item numbers (e.g. 48906) are already inclusive of rotator cuff repair with or without SAD. Furthermore, the MBS Review Orthopaedic Clinical Committee Report considered different techniques of SAD including the excision of large bursa, acromioplasty and synovectomy to be inherent components of rotator cuff repair and should not be co-claimed. A review of rotator cuff repair (with/without SAD) may be endorsed when the results of the Australian Rotator Cuff trial (ACTRN12620000789965) are available (ANZCTR, 2022).

The final PICO Confirmation is available on the MSAC website⁹.

The application history is described in Table 13.

Committee	Date(s)
Consultation (Draft PICO confirmation, Draft clinical guidelines review)	11 March 2022
PASC	13-14 April 2022
MSAC (advice for economic evaluation for further development of DCAR)	28-29 July 2022
Consultation (Draft assessment report)	9 November 2022

Table 13 MSAC application history

Table 14 summarises the advice and direction from MSAC and PASC and how these have been addressed in the DCAR.

⁹ <u>https://www1.health.gov.au/internet/msac/publishing.nsf/Content/1711-public</u>

Component	Matter of concern	How the current assessment report addresses it
The use of subacromial decompression as an adjunct to rotator cuff repair.	As advised by PASC and endorsed by the MSAC Executive, the review of rotator cuff repair was not within the scope of this assessment.	Addressed. The use of subacromial decompression as an adjunct to rotator cuff repair has been removed from the scope of this current review.
The population who may best benefit from SAD is not clearly defined.	PASC requested that the assessment should investigate which prognostic or predictive factors in addition to those defined in the PICO that may further define people who are more likely to benefit from surgery.	Addressed. Sub-group analysis from RCTs and information from observational studies is presented in <u>Section 2</u> and <u>Section</u> <u>6</u> and used to inform scenario modelling for budget impact. The limitation of this evidence is noted.
The requirement of an economic evaluation.	MSAC considered that an economic analysis should be included as a cost comparison.	Addressed. An economic analysis is included as requested by MSAC (Section 4).
Duration of the condition.	MSAC recognised that trials should be included irrespective of duration of condition.	Addressed. Duration of condition and other treatment effect modifiers is investigated in <u>Section 2.2.4</u> , <u>Section</u> <u>6.2</u> and Section 6.3. All trials are included irrespective of the duration of symptoms.
Efficacy of specific exercise or physiotherapy interventions.	MSAC noted the limited evidence on the efficacy of exercise physiotherapy or physiotherapy interventions in the management of rotator cuff disease.	Addressed. Recent systematic reviews of conservative therapies for rotator cuff disease are discussed (<u>Section</u> <u>1.4.10</u>). Comment is provided on the natural history of the condition (<u>Section 1.4.3</u>).

Table 14 Summary of advice and direction from PASC and MSAC

Abbreviations

MSAC = Medical Services Advisory Committee; **PASC** = Protocol advisory sub-committee; **PICO** = population, intervention, comparator, outcomes; **RCT** = randomised controlled trial

1.3 Prerequisites to implementation of any funding advice

Services for SAD are currently available through the MBS (shown in Appendix F and Appendix G). There are no prerequisites to any funding advice. Current items for SAD as a standalone item are 48900, 48903 and 48951. These items are not restricted with respect to co-claiming with other surgical services. The MBS Review Orthopaedic Clinical Committee Report recommended these items to be consolidated (Table 16).

Services for SAD used in conjunction with rotator cuff repair are not within the scope of this assessment.

1.4 Population

The population relevant to this assessment is adult patients with symptomatic subacromial shoulder impingement AND:

• Symptoms unresolved despite conservative therapy for 6 months;

AND excluding:

- Patients who require rotator cuff repair AND
- patients with other pathologies of the shoulder e.g. glenohumeral joint osteoarthritis, acromioclavicular arthritis, labral tear including superior labral anterior-posterior (SLAP) tears, adhesive capsulitis/frozen shoulder, tendinopathy of the long head of the biceps, calcific tendinopathy, bicipital tendon disorders, neuropathy, shoulder fractures, shoulder instability/dislocation, malignancy, infection

1.4.1 Subacromial impingement

The rotator cuff is comprised of 4 muscles and tendons which envelop the shoulder joint that assist in movement and stabilisation (Whittle and Buchbinder, 2015) (Figure 3). Rotator cuff disease is an umbrella term used to encapsulate all symptomatic disorders of the rotator cuff that can result in pain, weakness, instability and dysfunction in the shoulder joint regardless of pathology or anatomical location (Whittle and Buchbinder, 2015, Migliorini et al., 2021). These include tendinopathy/tendinitis, partial- and full-thickness tears of the tendon (PTT or FTT), rotator cuff tear arthropathy, calcific tendinitis, subacromial bursitis and subacromial impingement syndrome (Coghlan et al., 2008, Karjalainen et al., 2019a).

Rotator cuff disease is thought to be the result of biological and mechanical influences including acute injury, chronic degeneration (impingement of acromial bone spurs and friction leading to oedema, inflammation and rupture), or biological factors and tendon degeneration (Karjalainen et al., 2019a, Hamid and Sazlina, 2021, Ketola et al., 2013, Whittle and Buchbinder, 2015).

Figure 3 Anatomy of the shoulder (reproduced with permission) (Wikimedia Commons, 2022)

Shoulder impingement or subacromial impingement syndrome is a common cause of shoulder pain, where a rotator cuff tendon rubs or catches on nearby tissue and bone as the arm is lifted (NHS, 2020), which presents as a set of clinical and radiological findings that pertains to tendinitis and bursitis of the rotator cuff and adjacent tissues (Nazari et al., 2019). These pathological changes to the subacromial space can be extrinsic or intrinsic.

Shoulder impingement was originally described as a mechanical problem from an anatomical cause whereby the subacromial space is narrowed leading to contact between the acromion and soft tissues causing irritation of the subacromial tissue with consequent degeneration (Beard et al., 2018, Neer, 1983). It is often considered to be caused by bony 'spurs' forming on the acromion leading to inflammation in the surrounding bursa and tendons (Jones et al., 2019, Longo et al., 2021). This physical contact or impingement causes pain when the arm is in certain positions. Accordingly, a hook-shaped acromion may be associated with increased risk for rotator cuff disease, and acromial spurs can be associated with FTT (Song et al., 2016).

However, others have reported that the development of the acromial bony spur is a secondary degenerative change, implying that the majority of rotator cuff tears are initiated not by impingement but by an intrinsic degenerative tendinopathy (Shin et al., 2012).

Shoulder impingement syndrome may be associated with acromioclavicular joint arthritis and both PTT and FTT, as well as adhesive capsulitis (New York Workers Compensation Board, 2021).

Calcium deposits have been reported in up to 42.5% of patients with subacromial pain (Loew et al., 2021, Simpson et al., 2020). The calcium deposits can in some cases resorb spontaneously, can be treated through a range of non-surgical approaches, or be removed as part of subacromial decompression (Loew et al., 2021, Surace et al., 2020).

1.4.2 Clinical presentation and diagnosis

Patients present with functional loss and disability. Shoulder pain is reported particularly with overhead activities (a painful arc between 60° and 120° abduction) and is often worse when the patient is lying in bed (Karjalainen et al., 2019b). Rotator cuff disorders can cause chronic shoulder pain which may affect the patient's quality of life (Burbank et al., 2008).

In Australia, the management of shoulder pain by general practitioners is highly variable (Buchbinder et al., 2013). Clinical practice guidelines recommend that patient history combined with clinical and physical examination, including for muscle wasting and tenderness, are used for the initial diagnosis (Whittle and Buchbinder, 2015, Hopman et al., 2013, ACC, 2003). A combination of physical tests and manoeuvres are recommended, for example, for subacromial impingement, a combination of the Hawkins-Kennedy test, the painful arc test (with pain occurring between 60° and 120°) and the infraspinatus muscle strength test should be used (Diercks et al., 2014, Colorado Department of Labor and Employment, 2015, Hopman et al., 2013). Multiple tests are commonly used in practice, and the reliability of these tests vary with experience of the examiner (Whittle and Buchbinder, 2015). In diagnosing pathology related to the rotator cuff tendons, clinicians determine if the symptoms are related to another source such as referred pain, frozen shoulder, osteoarthritis, osteosarcoma or shoulder instability (Lewis, 2016).

The use of diagnostic imaging is variously described in published guidelines (AAOS, 2019, ACR, 2018, Hopman et al., 2013, Lafrance et al., 2022a). However, imaging tests are generally not recommended unless there is trauma or suspected serious pathology (Whittle and Buchbinder, 2015) or where the person is not responding to initial conservative management and the imaging result is expected to change clinical management decisions, for example clinical suspicion of full-thickness rotator cuff tear (Lafrance et al., 2022a, Whittle and Buchbinder, 2015). According to the American College of Radiology, X-ray is usually appropriate for initial imaging of patients with shoulder pain (ACR, 2018). X-rays can detect osteoarthritis, bone pathology or calcium deposits and may not be indicated in the initial few weeks in the absence of red flags (Hopman et al., 2013). Imaging with US or MRI (without contrast) can be considered where there is a suspected rotator cuff tear (ACR, 2018). Imaging with MRI or US is not recommended in primary care unless

surgery is being considered as this can help to identify the size and location of tears (Whittle and Buchbinder, 2015, BOA, 2014, Colorado Department of Labor and Employment, 2015). US and MRI are accurate for detection of FTT in patients for whom surgery is being considered, but they are less sensitive for detecting PTT (Lenza et al., 2013).

There are concerns that imaging findings in primary care, particularly the use of US, may be misleading and result in inappropriate management or a delay in correct diagnosis (Buchbinder et al., 2013). There is a poor association between symptoms related to rotator cuff tendinopathy and structural failure observed on imaging (Lewis, 2016, Lewis et al., 2015). US in the primary care setting may identify structural abnormalities that are not the cause of shoulder pain (Naunton et al., 2020).

Subacromial injection of a local anaesthetic or steroid can reduce the pain either directly or by reducing inflammation (Zadro et al., 2021b, New York Workers Compensation Board, 2021, Hohmann et al., 2020, Washington State Department of Labor and Industries, 2018). Some guidelines recommend the use of these injections to help diagnosis of shoulder impingement (Washington State Department of Labor and Industries, 2018, New York Workers Compensation Board, 2021, Hohmann et al., 2020), although there is a paucity of high-quality studies for this method (Whittle and Buchbinder, 2015).

There are existing MBS items for US of the shoulder or upper arm (55864, 55865, 55866, 55867), diagnostic radiology using X-ray of the shoulder or scapula (57700, 57703), CT scan of upper limb (56627, 56628) and MRI scan of the shoulder or its supporting structures (63325) (MBS, 2022a).

An analysis of the current MBS items is shown in Section 3.

1.4.3 Prevalence in Australia

Musculoskeletal disorders have a high burden of disease across the Australian population, accounting for 653,000 disability-adjusted life years in 2019 (AIHW 2018)(AIHW, 2018, Karjalainen et al., 2019b). Shoulder pain is the third most common musculoskeletal complaint and affects almost a quarter of people in the Australian community, with a significant impact on quality of life and physical functioning (Karjalainen et al., 2019b, Hill et al., 2010). Internationally, there is a lifetime prevalence of up to 66.7% (Brindisino et al., 2021, Jones et al., 2019, Karjalainen et al., 2019b, Thorpe et al., 2016) and an annual prevalence of seeking care for shoulder pain of 2.4% (Buchbinder et al., 2013). Shoulder pain becomes more common with increasing age (Thorpe et al., 2016).

Rotator cuff disorders, specifically rotator cuff tears or subacromial pain, is responsible for up to 65% to 85% of shoulder pain (Whittle and Buchbinder, 2015, Brindisino et al., 2021, Jones et al., 2019, Thorpe et al., 2016, Karjalainen et al., 2019b) with increasing incidence with age (Sakha et al., 2021). The most common disorder among shoulder complaints is subacromial shoulder pain which accounts for 89% of total shoulder complaints referred to GPs and physiotherapists (Virta et al., 2012).

In Australian hospitals there was a total number of 29,190 separations for symptoms related to the rotator cuff (M75.1 Rotator cuff syndrome, M75.4 Impingement syndrome of shoulder, S46.0 Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder) in 2020–21 (AIHW, 2022a). There were 5,429 separations for impingement syndrome. The number of these diagnoses has increased over time, although the rate has plateaued in recent years.

The natural course of shoulder pain remains unclear and poorly described (Koester et al., 2005, Tangrood et al., 2018). The clinical course and recovery of patients with subacromial pain may be

influenced by the stage of the disorder (acute or chronic), personal (age), shoulder pain disease characteristics (duration and amount of disability), psychological factors, central sensitisation and the experience of pain, and the type of primary care treatment (Reilingh et al., 2008, Lewis et al., 2015). Patient belief and expectations may also impact decision-making and perceptions on outcomes (Maxwell et al., 2022).

In some patients, shoulder pain can be a benign and self-limiting problem (Whittle and Buchbinder, 2015). However, some patients may have more prolonged symptoms such as those with chronic pain (Reilingh et al., 2008, Schwerla et al., 2020). Among patients with subacute shoulder pain, 50% may improve after 6 months, and 40% after 1 year (van der Heijden, 1999). Among patients with chronic subacromial pain, 50% recover after 10 to 18 months of onset of symptoms (Kuijpers et al., 2004, Croft et al., 1996). Between 65% to 85% of patients with rotator cuff related shoulder pain even with rotator cuff tear recover with exercise (Naunton et al., 2020).

1.4.4 Treatments in primary care

While nearly half of all patients with new-onset shoulder pain consult their general practitioner only once, and most never require referral for specialist care, some patients need targeted care (Whittle and Buchbinder, 2015). The primary aim of any therapy is to relieve pain and restore shoulder function (Schmucker et al., 2020) (Lewis, 2016). Conservative therapy is recommended by guidelines as the first line of treatment for rotator cuff disorder (Green et al., 2003, Verbel et al., 2020). Initial treatments include modification of lifting activities, simple analgesia or non-steroid anti-inflammatories (Whittle and Buchbinder, 2015). Movement, exercise and physiotherapy improve strength and stability, and are recommended in all clinical practice guidelines (AAOS, 2019, Hopman et al., 2013, Vandvik et al., 2019).

A summary of clinical guidelines recommendations (best practice) for diagnostic imaging and therapy in primary care is shown in Table 65 (Appendix E). This provides a summary of information provided in the clinical guidelines review¹⁰ as well as information regarding the conservative therapies provided in RCTs.

Inconsistencies have been identified in the translation of evidence-based treatment recommendations for musculoskeletal shoulder pain into healthcare services, with little known about factors influencing decision-making (Maxwell et al., 2022).

The therapeutic benefit of various primary care or conservative interventions for patients with shoulder pain has been reported in various guidelines as summarised in Table 65. Few examples of defined and explicit published protocols for best practice conservative care are available (Lewis, 2016). It is likely that in clinical practice treatments are patient-focused, and may vary according to the availability of services and patient choice. Common initial treatment options available to patients with suspected subacromial impingement are summarised below.

1.4.5 Rest or no treatment

In certain cases, patients may be offered a wait-and see approach, or non-structured exercise (Washington State Department of Labor and Industries, 2018). Active rest of the shoulder may assist to relieve pain and to lessen the strain on the affected area. Movements that might provoke the symptoms of shoulder injury, such as lifting of heavy objects or repetitive overhead movements, should be avoided (Simons and Michael Roberts, 2021).

¹⁰ <u>https://www1.health.gov.au/internet/msac/publishing.nsf/Content/1711-public</u>

1.4.6 Medication for pain and inflammation

Anti-inflammatory pain relievers such as aspirin, ibuprofen and naproxen are beneficial in easing mild to moderate shoulder pain and inflammation (Eubank et al., 2021, Genootschap, 2019, Industrial Insurance Chiropractic Advisory Committee, 2014, Washington State Department of Labor and Industries, 2018, Juel et al., 2019, Kassolik et al., 2018, Kauta et al., 2021). For severe pain nonsteroidal anti-inflammatory medications (NSAIDs) may be helpful but must be taken with caution, particularly by patients who are vulnerable to gastrointestinal and renal complications (Tytherleigh-Strong et al., 2001).

The use of opioids is not recommended as a first-line pharmacological treatment due to the risks of adverse events such as vomiting, nausea, constipation, dizziness, drowsiness, pruritus or dry mouth and have an increased risk of dependency, overdose or death (Lafrance et al., 2022a).

1.4.7 Physiotherapy

Physiotherapy is often the first line of treatment for shoulder disorders (Cheshire and Wirral Partnerships, 2013, Eubank et al., 2021, Green et al., 2003, Kassolik et al., 2018, Yu et al., 2021). If treatment with analgesics or NSAIDs is not effective, patients with persistent symptoms are often referred for physiotherapy (Eubank et al., 2021). Physiotherapeutic interventions include information/advice, exercise therapy, massage, manual joint mobilisation or manipulation, trigger point therapy, taping/bracing and posture correction or physiotherapeutic modalities such as extracorporeal shockwave therapy and transcutaneous electrical nerve stimulation (Yu et al., 2021). Physiotherapy including exercise therapy is initially recommended for 5 to 12 weeks (Eubank et al., 2021, Yu et al., 2021). However, the most effective exercise type and dose remains uncertain (Colorado Department of Labor and Employment, 2015, Eubank et al., 2021, Lafrance et al., 2022a). There were conflicting recommendations on the use of manual therapy may provide benefit as an adjunct therapy with exercise (Yu et al., 2021, Lafrance et al., 2022).

Although a range of exercises and adjunctive therapies are available there is a lack of consensus in the literature and little data to guide the physiotherapist on the ideal care (Klintberg et al., 2015, Smythe et al., 2020, Lewis, 2016). In addition, patient experience in exercise is variable and may reflect variability in the quality of physiotherapy (Smythe et al., 2021).

Australian physiotherapy clinics commonly don't mention the number of physiotherapy sessions required for shoulder pain on their websites, although a small number comment that the time taken for improvement can range from 6 to 12 weeks, or that treatment duration is discussed with the patient on a case-by-case basis (Table 65, Appendix E). Many physiotherapy clinics advertise services by senior or specialised physiotherapists at a higher cost which may reflect that the patient will be treated by a physiotherapist with greater experience in shoulder pathologies (Australian Physiotherapy Association, 2022).

Patients who have low expectations regarding the effectiveness of physiotherapy are more likely to fail non-operative treatment (Thorpe et al., 2017).

1.4.8 Exercise and movement therapy

Movement therapy and exercise are usually administered with physiotherapy (Page et al., 2016a). This includes a shoulder muscle strengthening program, motor control and functional rehabilitation, mobility/flexibility interventions and stability exercises (Dubé et al., 2020, Industries, 2014, Juel et al., 2019, Kassolik et al., 2018, Simons and Michael Roberts, 2021,

Washington State Department of Labor and Industries, 2018, Yu et al., 2021). Patients can also undertake exercises at home.

Where described, guidelines commonly recommend 12 weeks of home or supervised exercise therapy with the goal of alleviating pain and improving range of motion (BOA, 2014, Colorado Department of Labor and Employment, 2015, Eubank et al., 2021, Juel et al., 2019, Lafrance et al., 2022b, New York Workers Compensation Board, 2021, Rees et al., 2021). As with physiotherapy, medical therapy or injection can be given to the patient if improvement in range of motion and pain reduction are not achieved.

1.4.9 Subacromial injection

Subacromial injection of local anaesthetic or steroid may be considered if there is deterioration or no improvement of the patient's condition after the initial course of treatment (Cheshire and Wirral Partnerships, 2013, Genootschap, 2019, Industrial Insurance Chiropractic Advisory Committee, 2014, Juel et al., 2019, Kassolik et al., 2018, Kauta et al., 2021, Washington State Department of Labor and Industries, 2018, Whittle and Buchbinder, 2015), or to help with pain management to assist with physiotherapy or exercises. The main objective of the injection is to reduce the inflammation, thus causing alleviation of pain and continuation of the physiotherapy intervention. Subacromial injections may be image- or landmark-guided (Bloom et al., 2012). Recommendations from the Australian Rheumatology Association state that ultrasound (US) guidance provides no additional benefit to landmark techniques for injections to the subacromial space (Australian Rheumatology Association, 2018, Morrisroe et al., 2018). Most image-guided procedures are provided by radiologists in a radiology practice (Zadro et al., 2021b). Previous MBS items for landmark-guided injections were removed in November 2009 (Morrisroe et al., 2018, Naunton et al., 2020). Current MBS items for GP and specialist consultations can be used for the purposes of specialist landmark-guided injections.

As recommended by published guidelines, it is a common practice to limit corticosteroid injections to a maximum of 2-3 times a year to prevent further damage to the tendons and bone (Hohmann et al., 2020). If there is no significant reduction in pain and disability after a second corticosteroid injection, additional injections are not recommended (Lafrance et al., 2022a, New York Workers Compensation Board, 2021). A maximum of 2-4 injections to the same site is recommended (Juel et al., 2019, Rees et al., 2021, New York Workers Compensation Board, 2021, Washington State Department of Labor and Industries, 2018).

The use of corticosteroid injections in a patient with rotator cuff disease ranges from 15.8 to 62% (van Doorn et al., 2022, Naunton et al., 2020, Smythe et al., 2021).

In Australia, US-guided and landmark-guided corticosteroid injections are available at radiology or sports clinics (St. George SportsMed, 2022, Pioneer Health Albany, 2022, Melbourne Radiology Clinic, 2022, Dr Jones & Partners, 2022). These services can also be provided by GPs or orthopaedic surgeons as part of a consultation (Morrisroe et al., 2018).

1.4.10 Safety and effectiveness of conservative therapies for rotator cuff disease and subacromial impingement

A formal investigation of the safety and effectiveness of all treatments for subacromial impingement is beyond the scope of this current review. However, a number of recent systematic reviews and RCTs provide evidence on the safety and effectiveness of conservative therapies for rotator cuff disease and subacromial impingement (Table 68).

Babatunde 2021 is a recent systematic review and network meta-analysis of all treatment options for subacromial shoulder conditions (Babatunde et al., 2021). (A similar network metaanalysis by Lavoie-Gagne 2022 is not discussed here as it was considered to be of low quality using the AMSTAR tool (data not shown) (Lavoie-Gagne et al., 2022).) Of 99 RCTs included in Babatunde 2021, 54 trials were included in the network meta-analysis, which investigated nonsurgical (corticosteroid injections, therapeutic exercise, shockwave therapy) and surgical treatment compared with each other, with placebo, usual care or no treatment.

For exercise therapy there was an improvement compared with placebo at 3 months, with direct evidence provided by a single trial (standardised mean difference 0.39, 95% confidence interval [CI] 0.18 to 0.59) (Babatunde et al., 2021). However, a Cochrane review determined that there were no clinically important differences between groups for any outcome for manual therapy and exercise reflective of common current practice compared to placebo (Page et al., 2016a). The single RCT for this evidence was based in Australia and involved 10 supervised sessions (Bennell et al., 2010).

Two recent RCTs provide evidence for supervised physiotherapy (6 sessions) compared with either best practice advice for home exercise (one session with a physiotherapist and an advice booklet) or advice and an exercise leaflet (Hopewell et al., 2021, Roddy et al., 2021). Compared with the exercise leaflet, physiotherapist-led exercise improved Shoulder Pain and Disability Index (SPADI) scores at 6 months but not at 12 months (Roddy et al., 2021). Compared to best practice advice there was no difference in outcomes at any time to 12 months. SPADI scores improved from above 50 to approximately 20–25 in all groups at 12 months, with a slight deterioration over 12 months (Hopewell et al., 2021). As noted by the authors, participants' shoulder pain and function improved over time irrespective of allocated interventions, although SPADI scores at 12 months showed that the condition did not resolve completely. The impact of trial conditions on patient attitude and compliance during these studies is uncertain and may have improved patient participation compared to usual care.

Scapula-focused approaches may provide short-term benefit compared to generalised approaches for up to 6 weeks, but these benefits may not be apparent at 6 months (Bury et al., 2016, Saito et al., 2018). There was inconsistent evidence to support the use or effectiveness of specific resistive exercise strategies.

While there is a large body of evidence regarding exercise therapy, there is a lack of certainty regarding exercise type, dose and duration (Pieters et al., 2020, Desmeules et al., 2016).

There was no evidence to support the superiority of multimodal care (defined as a conservative program of care involving at least 2 distinct therapeutic modalities provided by 1 or more healthcare disciplines) compared with individual interventions (Goldgrub et al., 2016).

Corticosteroid injections may have a short-term benefit (up to 8 weeks) over local anaesthetic injections alone in the management of rotator cuff-related shoulder pain (Cook et al., 2018). Systematic reviews show no benefit to US-guided injections compared to landscape-guided injections (Zadro et al., 2021b). Recent RCTs confirm a short-term benefit to corticosteroid injections at 8 weeks, but not at later timepoints, and no difference between US- and landscape-guided injections in terms of the overall effect (Hopewell et al., 2021, Roddy et al., 2021). A separate recent small RCT showed that a physiotherapy program provided improvements compared with corticosteroid injection for shoulder function, but not for pain (Daghiani et al., 2022).

The evidence for kinesiotaping is uncertain and seems to demonstrate little or no benefit (Saracoglu et al., 2018, Gianola et al., 2021). Other interventions such as therapeutic US, low-

level laser therapy and pulsed electromagnetic field are no better than placebo treatment (Haik et al., 2016, Page et al., 2016b).

In summary, the evidence base for conservative therapies is heterogeneous and limited in terms of quality and design. While some treatments provide short-term benefits, no single defined protocol is identified as a preferred treatment. In addition, while many therapies provide an overall improvement compared to baseline scores for pain and function across the entire study population, some residual symptoms are likely to remain and may be more severe in certain individuals. Depending on the options and advice available to them, some patients may thus seek additional therapies, including surgery.

1.4.11 Australian practices for shoulder pain, rotator cuff disease and subacromial impingement

Various publications have suggested that the care of patients with shoulder pain including rotator cuff disease and subacromial impingement in Australia is variable.

The perspective of Australian patients with rotator cuff-related shoulder pain showed heterogeneity in practice and experience (Smythe et al., 2021). Of a cohort of 120 patients recruited from a radiology centre specialising in musculoskeletal imaging, 77 had atraumatic pain. This population included patients with rotator cuff tears. Across the entire population, 34% had no activity modification advice. While 80.5% of atraumatic patients had undertaken exercise, 20.4% found it helpful while 12.3% reported it made symptoms worse. One third of patients stopped exercises at a median of 11 weeks; 38.1% of people with atraumatic pain had surgery prior to any exercise care. Medical imaging was common for patients with atraumatic rotator cuff-related shoulder pain (X-ray 46.8%, US 74%, MRI 72%); 66.2% of patients had corticosteroid injections. A wide variation in symptom duration and care costs is reported for patients referred for shoulder surgery in an Australian public hospital (Marks et al., 2018).

Published patient information about the effectiveness of shoulder surgery may not reflect best practice, as a recent review of Australian websites showed that online information about the effectiveness of shoulder surgery is not based on best available evidence (Robertson et al., 2021).

GP care is not always aligned with best practice as defined by systematic reviews and published guidelines (Buchbinder et al., 2013). Based on a hypothetical presentation of a patient with rotator cuff tendinopathy, GPs were more likely to order X-ray and US ($p \le 0.004$) and less likely to provide advice for home exercise (p < 0.002) compared with a rheumatologist. GPs and rheumatologists commonly provided corticosteroid injection for rotator cuff tendinopathy (28% and 61%, respectively) or referral for an image-guided injection (24% and 33%, respectively).

A recent review of a database on GP management of rotator cuff-related shoulder pain over 5 years showed that GP care relied on US (41.2% of all patients), which is not in line with best practice care as recommended by recent clinical guidelines from a range of countries (Naunton et al., 2020). 19.5% of all patients were given a corticosteroid injection and 11.6% of patients received an X-ray. There was a reported doubling in US imaging and corticosteroid injections and a reduction in NSAID use from 2000–2004 to 2012–16. However, in line with best practice only a small proportion of patients (4.5%) were referred to a surgeon.

Earlier studies were also critical of the overuse of imaging in primary care. In 2004, imaging was recorded at the first visit for 58 patients (69%) and in 2008 it was identified that 95% of patients had received either X-ray or US prior to referral to a surgeon, even though a diagnosis was only suggested in 31% of cases (Broadhurst et al., 2004, Johal et al., 2008). It is unclear if these older studies reflect current practice.

In terms of physiotherapy practice, in a study of 278 public orthopaedic shoulder patients with shoulder pain in a Queensland hospital, there was found to be near perfect agreement between an experienced senior physiotherapist and an orthopaedic surgeon regarding the use of corticosteroid injections and the decision for surgical or non-surgical care (Marks et al., 2016). In a NSW public hospital shoulder physiotherapy service the diagnosis of subacromial impingement found in 29.5% of patients attending the service, and while treatments were highly varied and multimodal, patients improved after a median of 6.1 treatment sessions (Roberts and Li, 2014).

Physiotherapy care in Australia has been shown to be broadly consistent with recommended practice for rotator cuff tendinopathy (Smythe et al., 2020). Across a series of vignettes including rotator cuff tendinopathy/subacromial impingement, physiotherapist responses were generally in line with clinical guidelines including for the restricted use of imaging and corticosteroid injections, limited referrals to orthopaedic surgeons, and the use of exercise and patient advice. However, the type of exercise therapy and adjunctive therapy varied, likely due to a lack of consensus in the literature. The timeframe for physiotherapy care ranged from 6–8 weeks to 12 weeks or more, largely depending on patient needs. A study of rheumatologists recognised that there was no standard treatment for shoulder pain, including subacromial impingement (Pribicevic et al., 2009).

Little data are available in Australia for surgery for rotator cuff disorders, although surgery rates increased 108.7% from 2001–2013 in Western Australian public and private hospitals (Thorpe et al., 2016). The authors suggest that patient demand may be driving up rates of surgery.

The practice of Australian orthopaedic surgeons also varies in relation to the treatment of rotator cuff tears. Responses to a number of hypothetical patient examples related to shoulder pain associated with rotator cuff tears showed variability in decision-making, and in many cases these did not align with clinical guidelines, including decisions regarding the use of physiotherapy, corticosteroid injection or surgery (Thorpe et al., 2017). The study described that patients with full-thickness rotator-cuff tears are more influenced in their decision to have surgery by low expectations regarding the effectiveness of physiotherapy than patient symptoms or anatomic features of the rotator cuff tear (Dunn et al., 2016). Therefore, surgeons should not only consider promoting physiotherapy management as a first choice, but also reinforce positive expectations regarding the outcome of a conservative approach. The study authors considered that the survey respondents were likely to represent almost all of the 24 shoulder and elbow surgeons listed on the website of the Australian Orthopaedic Association; however, the anonymous nature of the survey precluded a definitive conclusion (Thorpe et al., 2017). The applicability of these results to subacromial impingement pain is uncertain.

In a study of patients on an orthopaedic waiting list for shoulder surgery at a public hospital in Queensland, only 22% of patients across a 2-year period received surgery, suggesting a low conversion rate (Marks et al., 2018). The authors noted an inefficient referral of patients to orthopaedic care, reflecting a lack of treatment options and suboptimal care in primary practice (Marks et al., 2018, Buchbinder et al., 2013).

As shown in Section 3, although there are some administrative data available for patients who use existing MBS items for SAD, due to limitations of the available data and the co-claiming practices of the available items, specific details regarding patients who have surgery for shoulder impingement are unavailable. The range of previous therapies provided to these patients is uncertain, including whether all patients have tried best quality conservative therapy. Therefore, while recent studies have identified variability in local practice and patient experiences, the impact of this on current clinical practices and the decision to undertake SAD for subacromial impingement is uncertain.

1.5 Intervention

The intervention for this assessment is any form of open or arthroscopic SAD, with no concomitant rotator cuff tear repair. This includes coraco-acromial ligament division, acromioplasty, coplaning of the clavicle and excision of the acromioclavicular joint, removal of calcium deposit and excision of bursa.

The primary aim of any therapy is to relieve pain and restore shoulder function (Schmucker et al., 2020). Surgical practice is varied (Lapner et al., 2021).

1.5.1 Subacromial decompression

SAD describes a procedure that removes bone or soft tissue that cause the narrowing of the subacromial space. There are a range of surgical options, and often a combination of procedures is used (Coghlan et al., 2008). The purpose of this surgery is to address the mechanical impingement of the shoulder and decompress the subacromial space by removing bone spurs and soft tissue and releasing the coraco-acromial ligament (AMRC, 2018b, Haahr and Andersen, 2006, Jones et al., 2019). The widening of the subacromial space to allow more room for tendons is believed to relieve symptoms and halt the pathological processes (Karjalainen et al., 2019b, Paavola et al., 2017, Sun et al., 2018). SAD can be performed with an open, mini open procedure or arthroscopically, which can reduce healing time (Coghlan et al., 2008). There is reportedly no difference between open and arthroscopic surgery (Husby et al., 2003). Arthroscopy is undertaken under general anaesthesia, with posterior and lateral portals, and a 4 mm arthroscope (Paavola et al., 2018).

Some guidelines include the option of SAD or acromioplasty as a standalone procedure for certain patients (AMRC, 2018b, BOA, 2014, New York Workers Compensation Board, 2021, Diercks et al., 2014, Washington State Department of Labor and Industries, 2018, NICE, 2018, Oliva et al., 2015). Other guidelines state that SAD is not medically necessary (AIM, 2021, Vandvik et al., 2019). Where recommended, all guidelines suggest that patients should have attempted and failed various strategies of conservative therapy, and received specific physical and radiology or imaging tests as clinically indicated.

In general, the clinical practice guidelines are not explicit on individual procedures, although some mention the use of bursectomy, acromioplasty and coraco-acromial ligament release (Colorado Department of Labor and Employment, 2015). SAD can include:

- Acromioplasty: The underside of the acromion is smoothed to decompress the passage of the rotator cuff tendon through the subacromial space (Paavola et al., 2018). Acromioplasty is included in MBS items 48903, 48951, 489XX, (see Appendix G).
- Bursectomy or excision of bursa: Debridement of the subacromial bursa using electrocautery (Paavola et al., 2018). Bursectomy is included in MBS item 489XX.
- Coraco-acromial ligament release: The division of the coraco-acromial ligament with a shaver releases tension to decompress the subacromial space (Moshi et al., 2021). Coraco-acromial ligament release is included in 48900, 48903, 48951, 489XX.
- Coplaning: Coplaning removes or smooths spurs or portions of the projecting surface of the acromion and/or the distal section of the clavicle to decrease injury to the rotator cuff (Barber, 2001, Paavola et al., 2018). For MBS items, this technique includes excision of the clavicle and acromioclavicular joint. Coplaning is included in MBS items 48903, 489XX.

• Removal of calcium deposits: Removal of calcium deposits is included in MBS items 48900, 489XX. For this review, the focus is on the removal of calcium deposits as part of open or arthroscopic subacromial decompression and not as an isolated intervention.

1.5.2 Utilisation of services for SAD

The reported rates of subacromial decompression range from 52 per 100,000 (England), to 115 per 100,000 in Western Australia and 131 per 100,000 in Finland (Jones et al., 2019).

Based on a Western Australian review of administrative data, there has been an increase in all surgical procedures for rotator cuff disease of 55.1% from 2001 to 2013 (Thorpe et al., 2016). The greatest increases were for arthroscopic subacromial decompression and arthroscopic rotator cuff repair (102% and 68% respectively) (Thorpe et al., 2016). For arthroscopic subacromial decompression there was a significantly higher growth in the public hospital system (8.1% versus private 3.2%, p < 0.001). In England there has been a 91% increase in the number of subacromial decompression services in 10 years from 2007-17 with a large variability in the use of this service across the country (Jones et al., 2019).

In 2020-21, the number of services of the current MBS items related to subacromial decompression (48900, 48903, 48951) was 8,356; the most commonly used item was 48951 (MBS, 2022b, MBS, 2022a).

In 2020–21, there were 11,894 procedures for decompression of the subacromial space in Australian hospitals (procedure codes, 48903-00, 48951-00) (AIHW, 2022b). The majority of these were provided arthroscopically (11,098). While the numbers of procedures for arthroscopic subacromial decompression have increased since their introduction, the numbers have plateaued over the past 5 years.

An analysis of Australian administrative data is provided in Section 3.

1.6 Comparator

The comparator is ongoing conservative therapy, including physiotherapy, exercise therapy, movement therapy, medications for pain and inflammation, as well as subacromial injections of corticosteroid or local anaesthetic.

Trials which compare surgery to conservative therapy for subacromial impingement commonly provide little detail on the conservative programs provided (Table 65, Appendix E). Where reported, supervised physiotherapy sessions ranged from 7 to 19, with NSAIDS allowed as necessary and corticosteroid injections permitted if pain interfered with the execution of the training program (Cederqvist et al., 2021, Haahr et al., 2005, Ketola et al., 2009, Paavola et al., 2018). This is further described in Section 2. Recent RCTs which compared supervised physiotherapy with informed home exercises reported from up to 6 to a maximum of 12 sessions per patient (Hopewell et al., 2021, Roddy et al., 2021, Daghiani et al., 2022).

1.6.1 Comparator therapies available on the MBS

Certain comparator services are available on the MBS. A musculoskeletal condition that has been present or is likely to be present for 6 months or longer is termed a chronic medical condition, and patients are eligible to have the chronic disease management (CDM) plan, formerly enhanced primary care (EPC), through the MBS and prepared by their general practitioner (GP). CDM enables the GP to plan and coordinate a multidisciplinary team, which may include physiotherapy. Under the CDM, the patient is allocated 5 sessions with a Medicare rebate for allied health services in a calendar year, which includes physiotherapy (MBS item 10960 or 10953). The patient is required to pay any gap fee for these 5 sessions and cannot claim private health insurance in combination with the MBS fee for each service. Private health insurance can cover a portion of the cost of any additional physiotherapy services, subject to yearly cost limits and level of coverage. Alternatively, patients without a CDM may receive physiotherapy services independently of the MBS, either through private health insurance or paid in full by the patient.

For US-guided subacromial injections, there are two MBS items available (55848, 55850). The number of services for US-guided injections in Australia has risen significantly since 2000 (Buchbinder et al., 2013). The service for US-guided injection is provided by MBS items 55850, 55848 and 55054. The combined number of these services has increased from 416,036 in 2010–2011 to 907,066 in 2019–2020 (MBS, 2022b). However, the items are not specific to body area therefore the number of injections to the shoulder is unknown.

1.7 Summary of PICO criteria

The summary of the PICO criteria is shown in Table 15. The complete PICO criteria for this assessment is provided in Appendix A, Table 49.

Component	Description					
Population	 Adult patients with symptomatic subacromial shoulder impingement AND: Symptoms unresolved despite conservative therapy for 6 months; AND excluding: Patients who require rotator cuff repair AND; Patients with other pathologies of the shoulder e.g. glenohumeral joint osteoarthritis, acromioclavicular arthritis, labral tear including superior labral anterior-posterior (SLAP) tears, adhesive capsulitis/frozen shoulder, tendinopathy of the long head of the biceps, calcific tendinopathy, bicipital tendon disorders, neuropathy, shoulder fractures, shoulder instability/dislocation, malignancy, infection 					
Intervention	Any form of open or arthroscopic subacromial decompression of shoulder (i.e. standalone)					
Comparator	Continued conservative therapy (including pain relief, physiotherapy or other type of allied health or primary care)					
Outcomes	Safety: • All adverse events Effectiveness: • Shoulder function • Pain • Health-related quality of life • Failure of surgery or need for revision surgery • Return to work or normal function Health care system outcomes: • Consultations in primary care, specialist or surgery • Pain management medication • Diagnostic tests • Physiotherapy costs • Consumables and implants for surgery					

 Table 15
 PICO criteria for assessing SAD for symptomatic subacromial impingement

	Indirect costs (work days lost)
Systematic review quest	ions:
What is the safety, effective symptomatic subacromial	veness and cost-effectiveness of SAD compared to conservative therapy in patients with impingement?
From MBS data modelling	, what is the budgetary impact of a range of scenarios?
Abbreviations	
SAD = subacromial decompres	ssion.

1.8 Alignment with the PICO confirmation

This assessment was able to align with all aspects of the PICO criteria, although it is likely that the populations in the trials did not meet the stringent requirement of symptoms unresolved despite conservative therapy for 6 months. All differences or uncertainty in the population, intervention and comparator are described.

1.9 Clinical management algorithm

The clinical management algorithm for patients with subacromial impingement is summarised in Table 49. As this service has been available on the MBS since 1991 and there are no material changes in the proposed new MBS item, the algorithm is based on best practice as represented by clinical practice guidelines.

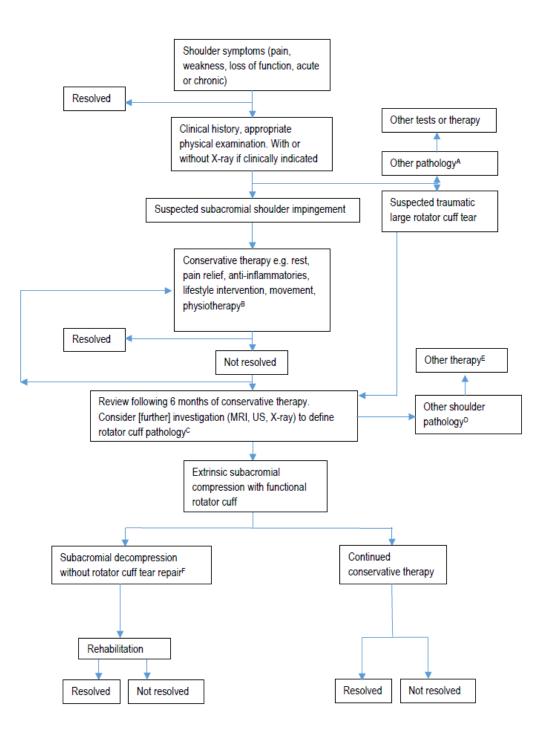


Figure 4 Current clinical management algorithm for treatment of patients with rotator cuff disease

Abbreviations

MRI = magnetic resonance imaging, US = ultrasound.

Notes

A = Other pathologies may include cardiac conditions, pain in other locations, fracture, dislocation, instability, infection, inflammatory arthropathy, suspected malignancy.

B = May include subacromial injections (1–3) e.g. corticosteroid or local anaesthetic for short-term pain relief, if clinically indicated. **C** = Rotator cuff pathology would include bursitis, tendinopathy, tear.

D = Other pathologies may include rotator cuff arthropathy, SLAP lesions, bicipital tendinitis, adhesive capsulitis, glenohumeral osteoarthritis, isolated calcific tendinitis, symptomatic rotator cuff tear.

E = Other therapies may include reverse shoulder arthroplasty.

F = Subacromial decompression may include coraco-acromial ligament division, acromioplasty, coplaning of the clavicle, excision of the acromioclavicular joint, removal of calcium deposit and excision of bursa.

1.10 Proposal for public funding

The Medicare Benefits Schedule (MBS) Review Taskforce Orthopaedics Clinical Committee and the MBS Review Shoulder and Elbow Implementation Liaison Group have proposed the following amended item for SAD performed as any form of open or arthroscopic surgical procedure (MBS 489XX; Table 16). This consolidates the three current items 48900, 48903 and 48951.

Table 16 Proposed amended MBS item for SAD

Category 3 – Therapeutic Procedures Group T8 – Surgical Operations Subgroup 15 – – Shoulder	Orthopaedic Subheading 8
MBS 489XX	
Open or arthroscopic subacromial decompression of Shoulder	
Inclusive of, if performed:	
i) coraco-acromial ligament division ii) acromioplasty iii) excision of outer clavicle and acromioclavicular joint iv) removal of calcium deposit v) excision of bursa	
Not being a service associated with a service to which any open or arthroscopic shoulder reg (Anaes.) (Assist.)	gion procedure applies.
Fee: Not provided	

MBS = Medical Benefits Schedule.

There is no proposed population. During consultation, SESA recommended that patient selection for acromioplasty should be:

- A failure of nonoperative measures over 4–6 months
- Examination consistent with impingement and with the exclusion of other common causes of shoulder pain such as adhesive capsulitis, long head of biceps tendonitis, osteoarthritis etc.
- Ongoing untenable symptoms
- The demonstration of a mechanical cause for the cuff impingement (e.g. radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion)

In line with other service changes recommended by the Shoulder and Elbow Working Group, there is no distinction between open and arthroscopic surgery. The proposed item contains all procedures available in the existing items based on shoulder anatomy, and specifies that the proposed item cannot be co-claimed with any other arthroscopic surgery of the shoulder.

The MBS Review Taskforce on Orthopaedics expected that all surgeries previously claimed under items 48900, 48903 and 48951 will be billed under consolidated item 489XX. It was suggested that a weighted average could be applied to the adjusted schedule fee to account for this change. The Taskforce did not provide a suggested fee. As the fees for the proposed amended MBS item have yet to be determined, the out-of-pocket costs are uncertain.

Section 2 Clinical evaluation of therapeutic technologies

2.1 Methods for undertaking the assessment

2.1.1 Literature sources and search strategies

A systematic search, based on the search strategy from two recent Cochrane reviews, was undertaken on 26 April 2022 (Karjalainen et al., 2019b, Karjalainen et al., 2019a). Searches were in Medline, Embase, PubMed and Cochrane. No limits were placed on the searches.

Studies were arranged in an EndNote database according to population (subacromial decompression with and without concomitant rotator cuff repair, and for shoulder pathologies other than impingement).

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Figure 28) and list of excluded studies are shown in Appendix B and Appendix C respectively.

2.1.2 Appraisal of the evidence

Nine randomised controlled trials (RCTs) were identified, consisting of a total of 19 publications. The included studies were supplemented by 5 case series reporting safety outcomes in large populations.

Risk of bias for RCTs was appraised using the Risk of Bias 2 (RoB 2) tool (Sterne et al., 2019), and for case series using the Institute of Health Economics case series tool (Guo et al., 2016).

Data were extracted to standardised and predefined tables.

The risk of bias was incorporated into the Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessment for study quality (Guyatt et al., 2013). Risk of bias, alongside imprecision, inconsistency of results, indirectness of evidence and the likelihood of publication bias, provides the foundation for GRADE, which provides an overall quality rating of the evidence per outcome across all studies. The GRADE tables provide an indication of the confidence in the available results (Appendix D).

The included studies are supplemented by additional studies (Other relevant information, Section 6). These studies do not add to the primary evidence for effectiveness and safety, but provide additional context in terms of predictive and prognostic factors for surgical outcomes, and information related to other populations that may benefit from subacromial decompression that are not represented in the primary analyses. These studies include clinical practice guidelines, RCTs (of other populations and/or other comparators or interventions), non-randomised comparative studies, and case series.

2.1.3 Methods for data analysis

The methods of the data analysis are shown in Appendix A.

2.2 Characteristics of the evidence base

2.2.1 Results of literature search

A total of 24 studies (19 RCTs and 5 case series studies) met the inclusion criteria for assessing the safety and effectiveness of SAD. Nine trials compared to conservative therapy, and 3 compared to placebo (either sham surgery/diagnostic arthroscopy, or detuned laser). Full study profiles are presented in Appendix B, Table 53. Nineteen studies were publications from 9 RCTs. Due to the lack of reporting of safety data in the RCTs, 5 case series of populations greater than 1,000 patients were used for safety outcomes.

The evidence base presented in these draft results is similar to that used in a recent Cochrane review. Any differences are noted, with comments provided.

Two non-randomised comparative studies were identified. These studies were not included in the primary analysis due to the presence of higher-level evidence and concerns regarding study design, including patient selection and randomisation. These two studies are described in Other relevant information, Section 6.

A summary of the key features of the studies for comparative safety and effectiveness is provided in Table 17.

Due to multiple publications, each trial is referred to by the surname of the first author (e.g. Beard, Brox etc) (see also Table 17).

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
SAD vs conservative treatment						
Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy only; 104 no treatment)	Multicentre, randomised, pragmatic, parallel group, placebo- controlled, 3- group trial	Low	Patient with subacromial pain for at least 3 months with intact rotator cuff tendons	Pain Shoulder function	No*
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise)	Randomised clinical trial 2.5-year follow-up	High	Rotator cuff disease (stage II impingement syndrome)	Pain Shoulder function	No*
Cederqvist (Cederqvist et al., 2021)	417 (190 surgical; 190 non-surgical)	Pragmatic randomised clinical trial 2-year follow-up	Some concerns	Patients with long-term (>3 months) subacromial pain	Pain Shoulder function	No*

 Table 17
 Key features of the included evidence comparing SAD with conservative therapy or placebo

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation	
Farfaras (Farfaras et al., 2016, Farfaras et al., 2018)	surgery; 29 arthroscopic	Prospective randomised study	High	SAIS	Shoulder function Quality of life	No*	
	surgery; 34 nonoperative treatment)	2 to 3 years after the intervention					
Haahr (Haahr and Andersen, 2006, Haahr et al., 2005)	84 (41 arthroscopic surgery; 43	Randomised controlled study	Some concerns	Subacromial impingement	Pain and dysfunction score	No*	
	physiotherapy)	1-year follow-up			Shoulder function		
Ketola (Ketola et al., 2009, Ketola et al., 2016, Ketola et al., 2015, Ketola et al., 2017)	140 (70 exercise; 70 acromioplasty with exercise)	Randomised controlled trial 1-year follow-up	Some concerns	Stage II SAIS	Pain	No*	
Paavola (Bäck et al.,	210 (139	Multicentre, 3-	Low	Patients with	Effectiveness:	No*	
2021, Paavola et al., 2021, Paavola et al.,	surgery [SAD or diagnostic	group, randomised,		symptoms associated with shoulder impingement syndrome	Pain		
2018, Paavola et al., 2017)	arthroscopy]; 71 exercise therapy)				Shoulder function		
		2-year follow-up			Return to work		
					Safety:		
					Complication and adverse events		
Peters (Peters and	72 (32 surgery;	Prospective	High	SAIS	Pain	No*	
Kohn, 1997)	40 nonoperative treatment)	randomised study			Mobility Instability		
		4-year follow-up			Activity		
					Overhead work		
Rahme (Rahme et al., 1998)	42 (number per group not specified at baseline)	Randomised prospective study	High	SAIS	Pain	No*	
		1-year follow-up		<u> </u>	1	1	
SAD vs placebo Beard (Beard et al., 2015, Beard et al., 2018)	313 (106 decompression surgery; 103 arthroscopy	Multicentre, randomised, pragmatic, parallel group, placebo-	Low	Patient with subacromial pain for at least 3 months with intact	Pain Shoulder function	No*	

Trials	N Design/duration		Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation	
	only; 104 no treatment)	controlled, 3- group trial		rotator cuff tendons			
		1-year follow-up					
		Placebo is arthroscopy					
Brox (Brox et al., 1999, Brox et al., 1993)	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise)	Randomised clinical trial 2.5-year follow-up	High	Rotator cuff disease (stage II impingement syndrome)	Pain Shoulder function	No*	
		Placebo is detuned laser					
	surgery [SAD or diagnostic	Multicentre, 3- group, randomised, double-blind, sham-controlled	Low	Patients with symptoms associated with shoulder impingement syndrome	Effectiveness: Pain Shoulder function	No*	
		trial. 2-year follow-up			Return to work		
		Placebo is arthroscopy			Safety: Complication and adverse events		
Shoulder arthroscopic surgery							
Shields (Shields et al., 2015)	10,570	Prognostic case series	Moderate	Shoulder arthroscopy	Complications	No*	
				cases from the adult American College of Surgeons NSQIP database from 2005 and	30-day mortality 30-day morbidity (major and minor complications)		
				2005 and 2011			
Heyer (Heyer et al., 2020)	134,822	Case series 30 day	Moderate	Shoulder and knee arthroscopy, including shoulder arthroscopy with SAD from	30-day complications and mortality	No*	

Trials	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
				the adult American College of Surgeons NSQIP database from		
				2010 and 2016		
Hill (Hill et al., 2017)	15,385	Prognostic case series	Moderate	Shoulder arthroscopy	30-day readmission	No*
				cases from the adult American College of Surgeons NSQIP database from	Complications (major and minor complications)	
				2011 and 2013		
Rees (Rees et al., 2022)	261,248	Case series 90 days	Moderate	Shoulder arthroscopy cases from the Hospital Episode Statistics for NHS England database from 1 April 2009 to 31 March 2017	Death, reoperation or adverse event within 90 days Reoperation within 1 year	No*
Yeranosian (Yeranosian et al., 2014)	165,820 (consecutive, from a database)	Case series 30 days	Very high	Shoulder arthroscopy Cases from a United States insurance database between 2004 and 2009.	Infections and reoperations within 30 days	No*

Abbreviations

N = number, NSQIP = National Surgical Quality Improvement Program, SAIS = subacromial impingement syndrome. Note

* = a modelled economic evaluation was not undertaken for this assessment.

2.2.2 Randomised controlled trials

Nine randomised trials are included, including a total of 19 publications (Beard et al., 2015, Beard et al., 2018, Brox et al., 1999, Brox et al., 1993, Cederqvist et al., 2021, Farfaras et al., 2016, Farfaras et al., 2018, Haahr and Andersen, 2006, Haahr et al., 2005, Ketola et al., 2009, Ketola et al., 2016, Ketola et al., 2015, Ketola et al., 2017, Bäck et al., 2021, Paavola et al., 2021, Paavola et al., 2018, Paavola et al., 2017, Peters and Kohn, 1997, Rahme et al., 1998). Two follow-up publications and one new RCT are available in addition to those in the Cochrane review (Cederqvist et al., 2021, Bäck et al., 2021, Paavola et al., 2021).

Five trials were single site or suspected single sites with 1 or 2 surgeons (Brox, Farfaras, Haaha, Peters, Rahme). Three were conducted on 2–3 sites (Cederqvist, Ketola, Paavola), and one was a large multicentre study incorporating 30 hospitals and 38 surgeons (Beard). All trials were from northern or central Europe, or the United Kingdom.

Trials compared with placebo (sham surgery) with arthroscopy only (Beard, Paavola), active monitoring (Beard), supervised exercises or rehabilitation (Brox, Cederqvist, Ketola, Paavola, Peters, Rahme, Farfaras, Haahr), or a placebo of a detuned laser (Brox). All studies allowed patient cross-over from exercise therapy to surgery. The number of patients receiving interventions other than that which they were randomised for is shown in Table 55.

Where reported, trial funding was from research funding or grant awarding bodies. Where declared, competing interests were not considered to influence the published work (Table 53).

Study design

Most studies utilised an intention-to-treat design and also analysed outcomes according to perprotocol approach (Beard, Brox, Cederqvist, Ketola, Paavola, Rahme).

Haahr was an intention-to-treat design, with no per-protocol analysis (Haahr).

Farfaras and Peters were a per-protocol design (Farfaras, Peters).

Number of patients randomised

Across all included trials there were a total number of 1,179 randomised participants.

Where reported, the power calculations to estimate the required number of participants were to detect a difference of a defined change in at least one primary outcome, usually stated to be a minimal clinically important difference (Beard, Cederqvist, Farfaras, Haahr, Ketola, Paavola).

Three studies did not meet the planned number of participants (Cederqvist, Farfaras, Paavola). All other studies met or exceeded the planned number of participants.

No power calculations were reported in 3 trials (Brox, Peters, Rahme).

In Cederqvist, all eligible patients underwent a formal 3-month rehabilitation program (including physiotherapist support, exercise therapy, cold-hot pack treatment and manual therapy) prior to randomisation of patients with ongoing symptoms to surgery or ongoing rehabilitation. In total, 230 of 417 patients were excluded following the rehabilitation program (including for 102 patients with healed or mild symptoms, 59 with lack of cooperation or change of diagnosis, 50 who had decided to have surgery and 19 with an irreparable tendon tear) (Table 55).

Follow-up, changes in intervention and patient losses over time

The total follow-up across included trials ranged from 1 year (Beard, Rahme) to 10 years (mean 13.7 and 12.3 years respectively, Farfaras, Ketola) (Table 55).

Patient losses over time, and deviations from the randomised intervention, is shown in Table 55.

Across the duration of the trials, relatively large proportions of patients had interventions other than that to which they were randomised (Table 55). Of the patients who were allocated to conservative therapy, between 10% (Farfaras) to 57% (Rahme) converted to surgery.

Where reported, there were no differences in results between ITT and per-protocol analyses (Beard, Ketola, Paavola).

RCT risk of bias

Using the RoB 2 tool, 2 trials were at low risk of bias (Beard, Paavola) (Table 61). The remaining trials were of increased risk of bias, based on factors including the inappropriate blinding of patients or assessors, and the lack of a published protocol. Patients who received sham surgery placebo were blinded, whereas patients receiving other comparator procedures (e.g. physiotherapy) were not blinded to the intervention (Beard, Paavola).

Randomisation process

Trials reported a predefined target number of patients in each group, other than Brox, Peters and Rahme. The randomisation method was not reported in one study (Peters). In all other studies the randomisation process was appropriate (Beard, Brox, Cederqvist, Haahr). Patient baseline characteristics were not reported in Peters and Rahme.

In Cederqvist, patients were randomised into two groups (surgery or rehabilitation), with the surgery group reported according to FTT (treated with rotator cuff repair with bone anchors) and without FTT (treated with subacromial decompression alone). For the purposes of this assessment, the focus is on patients treated with subacromial decompression alone.

In Farfaras the randomisation process is not described although patients appear well matched at baseline. In this trial, the randomisation was stopped before reaching the target number of patients due to longer than expected times for recruitment.

In Peters and Rahme, no information is provided regarding the concealment of the allocation of the intervention, and baseline population characteristics are poorly reported. There is therefore some concern regarding the randomisation process.

Deviations from intended interventions

In Beard and Paavola, the use of sham surgery as a placebo allowed these patients to be blinded to the intervention. In all other studies and for other comparators, patients were not able to be blinded to the intervention, so were at risk of bias.

There were some deviations from the intended interventions in all trials, with patients varying from the allocated intervention due to a range of reasons including a change in diagnosis, improvement in condition, lack of improvement or lack of motivation (Table 55).

In Brox, recruitment to the placebo group (detuned laser) was terminated after 6 months after an unintended interim analysis indicated no benefit.

Farfaras is considered to be at high risk of deviations from intended interventions due to a perprotocol design combined with a high rate of attrition, as a large proportion of patients were lost to follow-up.

Peters and Rahme were considered to be at high risk of deviation from the intended intervention. Peters was a per-protocol design and a reasonable number of patients did not respond to the follow-up questionnaire, with an imbalance across intervention groups. In Rahme, trial design meant that many people chose surgery after 6 months of physiotherapy, leading to a significant imbalance across the treatment groups. This change is likely to have biased the overall result in that poor outcomes of physiotherapy were not recorded.

Missing outcome data

Data were available for most patients in 5 trials, with similar losses in all groups (Beard, Brox, Cederqvist, Haahr, Paavola) (Table 55).

A high proportion of patients were missing to follow-up in Farfaras although a greater number of patients were available at the longer follow-up.

The Cochrane systematic review reports a large number of missing patients, unequal across intervention groups at 3 and 6 months in Ketola (Karjalainen et al., 2019b). This could not be verified in the published data. However, at 12 months, the number of missing patients was low and numbers were similar across both groups.

In the study by Peters, patient outcome data were collected via a questionnaire, and the response rate varied across each follow-up period, leading to some concerns regarding missing data (Peters). In Rahme, the cross-over of patients to the surgery group leads to a high risk for missing outcomes data.

Measurement of outcome

In all studies, the outcomes were measured using a range of appropriate tools for pain, shoulder function and (where used) HRQoL.

Outcome assessors were blinded to intervention in most studies (Beard, Brox, Farfaras, Ketola, Paavola, Rahme). In Cederqvist and Haahr, the authors report assessors (physiotherapists) were not blinded to the treatment allocation and recognise this as being a weakness in their study design. We believe that this was not likely to influence the outcomes, and therefore these studies are considered to be of some concerns of bias for this domain.

There is a high risk of bias regarding the measurement of outcomes by Peters, as outcome data were collected with a self-reported patient questionnaire.

Selection of reported results

A protocol was published as a separate publication or as part of trial registration by 3 trials (Beard, Paavola, Cederqvist).

The remaining trials are at risk of bias as there was no pre-specified analysis plan or protocol (Brox, Farfaras, Haahr, Peters, Rahme), and trials were not registered. However, these studies reported and analysed all outcomes comprehensively and therefore were not considered to be at a high risk of bias for this domain.

Haahr is considered to be at some risk of bias, as there is no protocol, and different outcomes are reported at the various timepoints. However, complete outcomes appear to be reported with no missing data.

2.2.3 Reported outcomes

The effectiveness outcomes were reported as described in the PASC-approved PICO Confirmation. Study outcomes are shown in Table 53.

Pain

Pain was most commonly reported on a 0-10 scale (Visual Analogue Scale [VAS] or Numeric Rating Scale [NRS]), with 0 indicating no pain. In some studies, pain was reported according to different scales: VAS score 0-15 (Haahr), 15 being no pain; pain score 1-9 (Brox), 1 being no

pain; and PainDETECT score for neuropathic pain, -1 to 38 (Beard), a lower score indicating less pain.

Where needed for comparison and synthesis, scores were transformed to comparable scales of 0 -10 (Appendix A).

Shoulder function

For shoulder function, most reported scales ranged from 0–100. The Constant or Constant-Murley scale was most commonly reported and was utilised in the meta-analysis. Other scores reporting using the range 0–100 were the Shoulder Disability Questionnaire (Ketola), the Subjective Shoulder Rating Score (SSRS) (Peters), and the Neer score (Brox). Beard also reported the Oxford Shoulder Score (OSS), with a range of 0–48 (Beard). There is no reported difference between effect-size estimates between OSS and the Constant score (Christiansen et al., 2015).

Radiologic evaluation (10 points) is part of the Neer shoulder score. All radiographs in the Brox study were assessed as normal, which is equivalent to 10 points. For comparability with the other studies that used the Constant score (which does not include radiographic evaluation in the scoring), the shoulder function score in the Brox study assessed using Neer score scale from 10 to 100 was converted to 0 to 100 using the formula in Appendix A.

Health-related quality of life

For HRQoL, most scales used a range of 0-1 (or 0-100) scale, with higher scores indicating a better score. Scores included 15D (Paavola), SF-36 (0-100) (Farfaras, Paavola) and RACD 36-item (Cederqvist). The EQ-5D-3L (range -0.59 to 1) was also reported (Beard).

For all outcomes, the minimum clinically important differences are shown in Appendix A.

2.2.4 Population characteristics

Inclusion and exclusion criteria

Patient selection criteria were broadly similar across all trials (Table 53). In most studies, patients had subacromial impingement (Farfaras, Haahr, Ketola, Paavola, Peters)

In 3 studies, patients were described more broadly with subacromial pain or rotator cuff disease (Beard, Brox, Cederqvist). In Rahme, an explicit diagnosis was not provided.

In most studies, patients had symptoms for at least 3 months (Beard, Brox, Cederqvist, Haahr, Ketola, Paavola). Patients in Farfaras had symptoms of at least 6 months, and in Rahme at least 12 months. The duration of symptoms is not described in Peters.

Most studies excluded FTT (Beard, Brox, Farfaras, Haahr, Ketola, Paavola, Peters). In one study, FTT and non-FTT were reported separately (Cederqvist), and in Rahme, FTT were not excluded (5 were repaired).

Other commonly excluded shoulder pathologies were osteoarthritis (of the glenohumeral or acromioclavicular joint) (Cederqvist, Farfaras, Haahr, Ketola, Paavola, Rahme), rheumatoid arthritis (Beard, Brox, Cederqvist, Farfaras), instability (Brox, Cederqvist, Ketola, Paavola), adhesive capsulitis (Cederqvist, Haahr, Ketola), calcific tendinitis (Beard, Haahr, Paavola), trauma (Cederqvist, Haahr) and diabetes (Farfaras). A broad exclusion of 'other shoulder pathologies' was reported by Beard.

Peters did not exclude any specified shoulder pathology other than FTT, and therefore patient selection was based on signs of clinical impingement alone. Biceps pathology was not mentioned in any trial.

Patient diagnosis

The methods of patient diagnosis used in the trials are shown in Table 54. Diagnostic imaging was used to exclude other shoulder pathologies such as FTT, osteoarthritis and calcification of the tendon and was not used to identify physical impingement in any study. Where reported, a specialist (e.g. orthopaedic surgeon or rehabilitation specialist) conducted the tests.

MRI, X-ray or US was used in most studies as part of the diagnostic criteria. MRI or MRI arthroscopy was used in 3 studies (Cederqvist, Ketola, Paavola); US was used in 2 studies (Farfaras, Haahr); X-ray was used in 6 studies (Farfaras, Haahr, Ketola, Paavola, Peters, Rahme). A combination of either US, MRI and/or X-ray was used in 4 studies (Farfaras, Haahr, Ketola, Paavola). One study used no US, MRI or X-ray (Brox).

The (positive) impingement test (injection of local anaesthetic in the subacromial space as a means to identify the location of the pain), was used in 4 studies (Brox, Farfaras, Haahr, Ketola)

A clinical examination with physical tests was used in all RCTs, where reported, although this was unclear in one study (Beard). In this trial, local pathways were used for diagnosis. Therefore, the use of X-ray, MRI, US and physical tests is uncertain and may have varied between participants (Beard).

Previous therapies

All patients were required to have completed and/or failed a previous program of conservative therapy. However, the details of any program varied (Table 54). Where reported, these therapies included physiotherapy or exercise therapy, often with subacromial corticosteroid injection.

In Cederqvist, many patients had previously attempted guided or home-based exercises (mean range 46–63%). However, all randomised patients underwent a formal 3-month rehabilitation using a defined protocol with up to 15 physiotherapy sessions. Only patients who remained symptomatic after this time were randomised to the intervention (Cederqvist).

Details of any previous program, including the type of therapy, definition of failure and any timelines (e.g. mean or minimum required) were not provided in 5 trials (Beard, Brox, Farfaras, Ketola, Paavola). In Peters, patients were required to have previous conservative therapy of about 6 months. In Rahme, the requirement for previous therapies was not reported.

Haahr provided detail of previous therapies: included patients had received passive (58–67%) and active (34-39%) physiotherapy and subacromial injections (49–64%).

Duration of symptoms and previous therapies

The reported duration of symptoms is shown in Table 54. In 3 studies, most patients had symptoms for more than 1 year (Brox, Farfaras and Haahr). The mean duration was 2.5 months in one study (Ketola), 1 year in two studies (Cedeqvist, Paavola) and 4 years in Rahme.

Two studies did not describe the mean duration of symptoms (Beard, Peters).

Patient baseline demographics

Population ages were broadly similar across all trials, ranging from a mean of approximately 42–44 years (Rahme, Haahr) to 56–59 years (Cederqvist, Peters) (Table 54). There was commonly an equal or higher proportion of female patients in most trials, apart from Peters and Cederqvist.

One trial reported patient body mass index (BMI) as a mean of 27.4 kg/m² in each group (Ketola). No other comorbidities (e.g. diabetes, hypertension, cholesterol or smoking status) were reported in the trials, noting that diabetic patients were excluded in Farfaras.

Baseline patient characteristics

Baseline pain was reported by all studies apart from two (Farfaras, Rahme). Based on a scale of 0-10 (0 being no pain), baseline pain varied from a low score (less pain) of approximately 3-4 (Beard, Brox, Cederqvist, Peters, Paavola), to a high score (more pain) of approximately 6-7 (Haahr, Ketola, Paavola).

For function (based on the Constant scale or similar, with a range of 0-100, 100 is best), scores ranged from a worse score of approximately 30-40 (Beard, Haahr, Paavola) to a better score of approximately 65-80 (Brox, Neer).

Better scores for pain did not always coincide with better scores for function.

Rahme did not provide patient baseline characteristics of pain or function. Otherwise, where reported, all patients appeared well matched at baseline.

The surgical presence of impingement was reported in one study (Beard). In patients who underwent arthroscopic subacromial decompression (ASAD) or diagnostic arthroscopy, there was identified impingement in 75% (67/89) patients who received SAD, 61% (46/80) patients with arthroscopy, and 75% of patients in the control (no therapy) group.

2.2.5 Interventions and comparators

Surgical intervention

For arthroscopic SAD, most studies reported the use of bursectomy, release of the coracoacromial ligament, and removal of the subacromial bone spur (Beard, Brox, Haahr) (Table 56).

In Farfaras and Paavola, there is no reported release of the coraco-acromial ligament. Peters provides no description of the procedures used for SAD (open or arthroscopic). Farfaras describes coplaning of the undersurface of the acromion. Bursectomy is not described in Ketola.

Ketola describes SAD as involving debridement and decompression. It is assumed that debridement refers to the action of acromioplasty. Debridement of the rotator cuff tendons is not described.

Open surgery including acromioplasty, coraco-acromial ligament release and coplaning (no acromioclavicular joint resections) is reported as a separate subgroup in Farfaras, and is performed according to Neer in Rahme, or as an alternative to the arthroscopic approach in Peters.

Cederqvist reports two interventions for rotator cuff disease: surgery for patients with no FTT (acromioplasty, acromioclavicular joint resection [for acromioclavicular arthritis] or tenotomy of the long head of the biceps) and surgery for patients with FTT (tear repair; when necessary,

patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps). Biceps tenotomy is not mentioned in other studies.

The outcome data provided by Cederqvist at the 2-year follow-up are for all patients with rotator cuff disease, patients with non-full thickness rupture and patients with full thickness rupture regardless of the intervention given. Outcomes were not provided separately for patients treated with only SAD, therefore the results from this trial were not able to be included in meta-analyses.

Removal of calcium deposits or resection of the lateral end of the clavicle are not mentioned as part of the surgical interventions. In Beard, Haahr and Paavola, patients with calcifications (Haahr exceeding 2 cm in the rotator cuff tendons) were excluded. Studies do not report any variation in the procedures or mention whether there were changes to the intervention based on the shoulder anatomy although Ketola describes the releasing of the coraco-acromial ligament if it felt tight or thick.

Postoperative rehabilitation

All trials included standard postoperative rehabilitation (Table 56). Rehabilitation commonly involved one or more physiotherapy visits and guidance for home exercises.

In two studies, postoperative rehabilitation involved physiotherapy and training, the same as in the comparator (exercise therapy) group (Farfaras, Ketola).

Time to intervention

In 5 studies, the mean time from randomisation to surgical intervention was not reported (Beard, Cederqvist, Farfaras, Peters and Rahme) (Table 56). In Haahr and Paavola, surgery was provided within 4 and 12 weeks of enrolment or randomisation, respectively. In Brox, the average time between randomisation and first day of treatment was 2 months, and in Ketola following randomisation there was a mean delay of 1.2 months (0.2 to 4.6) to the commencement of treatment in the exercise group and 8.3 months (1.4 to 11.8) for the patients who underwent arthroscopy.

For Beard, the mean time to intervention was not reported. However, at 12 months, patients who had not received their intervention per protocol were 25% (SAD, of whom a total of 5% had received rotator cuff surgery), 34% (diagnostic arthroscopy, of whom a total of 10% had received surgery including SAD), 25% (no treatment/active surveillance, of whom a total of 24% had surgery including SAD).

Co-interventions

Ongoing or additional conservative co-interventions such as pain medications, antiinflammatories and subacromial injections of corticosteroids, were not described in 6 trials (Beard, Farfaras, Haahr, Paavola, Peters, Rahme) (Table 56). Therefore, their use in conjunction with surgery is uncertain.

In Brox, analgesics, including anti-inflammatory drugs but not cortisone injections, were allowed for all patients, and in Ketola, nonsteroidal anti-inflammatory drugs (NSAIDs) were allowed as necessary and subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program.

In Cederqvist, the use of additional non-surgical therapy (including physiotherapy, home-based exercises or corticosteroid injections) during 2-year follow-up was allowed. The use differed

between non-surgical and surgical groups with more physiotherapy reported in the surgery group (p < 0.001) and more corticosteroid injections in non-surgery group (p = 0.015).

Comparator

Across all trials, 4 distinct comparators were reported (Table 56).

The most common comparator was exercise therapy. In many cases, the therapy was for 3–6 months, with supervision (where reported at 1–3 times per week over 1-hour sessions) gradually reduced over time as patients became familiar with the exercises (Brox, Farfaras, Paavola). Physiotherapy by the method of Bohmer was mentioned by 2 trials (Farfaras, Rahme).

Where reported, daily home exercises were also used (Haahr, Paavola).

In Ketola, training sessions were performed at least 4 times a week with a minimum of 7 controlled visits to the therapist until patient was able to perform independently and undertake the exercises at home. In Cederqvist, the exercise therapy was a continuation of the rehabilitation therapy provided to all participants prior to the final randomisation (duration not provided, although patients were advised to undergo up to 15 sessions). In Peters, intense physical therapy was provided while patients were hospitalised.

The total number of supervised sessions was 15–19 in two trials (Haahr, Paavola). The duration of the therapy was not described in 2 trials (Peters, Rahme).

A sham surgery placebo was reported in two trials (Beard, Paavola). Placebo was arthroscopy only, with exactly the same approach as SAD but with no surgical removal or excision (Beard). In Paavola, bursal tissue could be stretched or resected, keeping resection to a minimum. Additional pathology identified or treated meant that patient was excluded. In both trials, postoperative rehabilitation was the same as for the SAD group.

One trial used active monitoring with specialist reassessment (Beard). Patients attended a reassessment appointment 3 months after entering the study.

One trial used a placebo therapy of a detuned laser given in 12 sessions, with no additional physiotherapy or exercise therapy. However, after a preliminary analysis of outcomes showed inferior results, the laser therapy was discontinued after 6 months. Most patients in this group received SAD (17 of 30 had different treatment including 15 receiving SAD).

2.2.6 Case series

Five case series with populations greater than 1,000 were included for safety (Heyer et al., 2020, Hill et al., 2017, Shields et al., 2015, Yeranosian et al., 2014, Rees et al., 2022). These are described in Table 17 and Table 58, with quality appraisal shown in Table 62.

Each publication provided an analysis of causes of patient readmission following shoulder arthroscopy including SAD from a population of between 10,255, and 261 248 patients (Shields et al., 2015, Heyer et al., 2020, Hill et al., 2017 and Yeranosian et al., 2014 respectively). Four of the case series were assessed as being at moderate risk of bias (see Appendix D). For all studies the evidence was identified from large datasets of hospital statistics.

2.3 Results

2.3.1 Safety

Across all included studies, reported adverse events were in line with the outcomes provided in the PICO Confirmation, noting that there was no reported incidence of wasting or avulsion of the deltoid muscle.

Evidence on comparative safety from RCTs

Two RCTs were included in the analysis of safety outcomes comparing SAD and nonoperative conservative treatment or SAD and placebo/sham surgery (Table 17) (Beard, Paavola). Safety outcomes are summarised in Table 57 (Appendix B). There were no reported serious adverse events in Cederqvist, although the authors provide no definition for this outcome. The study by Ketola reported no major complications for the arthroscopic acromioplasty with exercise program group but did not clearly report the presence or absence of any adverse events in the exercise therapy group.

According to the study by Beard, 2.8% (2/106) patients in the ASD group, 3.1% (2/103) in the placebo group and 3.1% (2/104) patients in the conservative treatment group reported having frozen shoulder. The study by Paavola showed that 5.1% (3/59) in the SAD group, 1.6% (1/63) participants in the placebo group and 2.8% (2/71) in the exercise group had frozen shoulder. Temporary swelling was also reported by one participant in the placebo group and one participant reported low back pain in the exercise group.

	Subacromial decompr	ession	placebo and conserv	vative		Risk Ratio		Risk Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl		M-H, Random, 95% Cl		
Beard 2018	2	106	4	107	41.0%	0.50 [0.09, 2.70]				
Paavola 2018	3	59	5	134	59.0%	1.36 [0.34, 5.52]				
Total (95% CI)		165		241	100.0%	0.91 [0.31, 2.65]		-		
Total events	5		9							
Heterogeneity: Tau² = Test for overall effect:	0.00; Chi² = 0.80, df = 1 Z = 0.18 (P = 0.86)	(P = 0.37)	; I² = 0%				0.01	0.1 1 1 Favours (ASD) Favours (ci	 10 ontrol]	100

Figure 5 Forest plot indicating the risk ratio for total adverse events in SAD compared to placebo/nonoperative management

Figure 5 shows the forest plot for the total adverse events for SAD versus placebo and conservative management. The risk ratio for the adverse events was 0.91 (95% Cl 0.31 to 2.65). Due to the low event rate, the association between SAD and increased risk of adverse events compared to the placebo and conservative management group is uncertain.

Removing diagnostic arthroscopy from the analysis has no effect on the overall outcome (risk ratio 1.11 [95% Cl 0.33 to 3.75], p = 0.87).

Evidence on safety from observational studies (case series)

Safety data and adverse events reported by large (>1,000 patients) case series are shown in Table 4 and Table 59.

The safety data for the 2 case series studies are derived from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database of patients who underwent shoulder arthroscopy from 2005 to 2011 (Shields) and from 2011 to 2013 (Hill) (Table 58). The

study population included cases of shoulder arthroscopy surveyed using the current procedural terminology (CPT) billing codes and not specific to the shoulder decompression surgery.

The study of Shields et al reported 119 complications in 103 cases within 30 days of surgery in a total cohort of 10,255 patients. One per cent (103/10,255) of the cohort developed at least 1 complication (death or major or minor morbidity); 0.57% (58/10,255) had at least 1 major complication while 0.53% (54/10,255) developed at least 1 minor complication. Return to the operating room was the most common among the 119 complications reported (29%). Death was included as a major complication with a mortality rate of 0.4% (4/10,255).

The study of Hill et al reported a 30-day readmission rate in a total population of 15,015 of 0.98% with pulmonary embolism as the most common cause of readmission (Hill 2016). The complication rate is 1.17% (0.58% for major complications and 0.57% for minor complications). Two patients died during the 30-day postoperative period (mortality rate of 0.01%). Among patients who are older than 65, the complication rate is higher at 1.95% (59/3,024).

30-day complications following SAD in a population of 32,228 from the prospective NSQIP database (2010-2016) were reported by Heyer. There was an overall complication rate (cardiac, renal, sepsis, clotting, pulmonary adverse events, or mortality) of 0.65% (210/32,228), and a 30-day mortality of 0.04% (12/32,228). There was an increase rate of overall complications for smokers (odds ratio 1.462 p = 0.033).

A recent large cohort study, published after the formal literature searches, was added for safety outcomes (Rees). Outcomes for 103,211 patients who had received SAD were identified from the Hospital Episode Statistics for NHS England database (2009-2017) were identified. The overall rates of adverse events or reoperation within 90 days was 1.15% (95% confidence interval 1.09 to 1.22). There was no association between death and surgery.

From a prospective insurance database of 165,820 patients in the United States, there was an overall infection rate (represented by reoperations within 30 days for surgical drainage) of 0.27% (450/165,820) (Yeranosian).

Safety for conservative therapies

A small number of systematic reviews comment on the safety of conservative therapies.

Adverse events associated with manual therapy and exercise are relatively more frequent than placebo but mild in nature. Reported events included short-term pain during or after treatment in the clinic, short-term pain after home exercises, or mild irritation with taping (Page et al., 2016a).

For corticosteroid injections, no serious adverse events were reported in any trial although this was rarely reported (5 of 19 trials reported this outcome) (Zadro et al., 2021b). The reported adverse events included transient post injection pain, facial redness, warmth (Page et al., 2016a, Zadro et al., 2021a).

A recent systematic review of any conservative therapy for shoulder impingement of 177 studies noted that across all conservative therapies there was insufficient reporting of adverse events (Steuri et al., 2017).

Safety claim conclusion

Based on 3 RCTs (Beard, Paavola, Cederqvist) and 5 case series (Heyer 2020, Hill 2017, Shields 2015, Rees 2022, Yeranosian 2014), the comparative safety of SAD surgery versus conservative therapy and placebo is uncertain with an overall low risk of having adverse or serious adverse events. The GRADE certainty of evidence for safety is moderate (Table 63).

2.3.2 Effectiveness: SAD versus conservative therapy

All the clinical effectiveness outcomes requested in the PICO Confirmation were reported in the literature.

Shoulder pain

Four RCTs were included in analysing the effect of SAD versus conservative therapy on shoulder pain (Figure 6) (Brox, Haahr, Ketola, Paavola). The meta-analysis used a pain scale of 0 to 10. Included in the analysis were four RCTs at 3- and 6-month timepoints, three RCTs at 1- and 2-year timepoints and three RCTs at a 5-year timepoint. Missing standard deviations (SD) were imputed as described in Appendix A.

Pain outcome was reported using the VAS by the studies of Ketola et al and Paavola et al. The study by Brox et al assessed pain outcome using the 0 to 9 pain scale while the pain scale used in the study by Haahr et al (0 as worst possible pain and 15 as best outcome) was converted to 0-10 scale to be consistent with other included studies (Appendix A).

There was no statistically significant difference on shoulder pain between conservative treatment and SAD at 6 months (MD = -0.48; 95% CI: -1.00 to 0.04, p = 0.09), 1 year (MD = -0.77; 95% CI: -1.59 to 0.04; p = 0.06), 2 years (MD = -0.35; 95% CI: -1.34 to 0.64; p = 0.48) and 5 years (MD = -0.12; 95% CI: -0.57 to 0.33; p = 0.59). Heterogeneity and inconsistency were moderate to considerable at 6 months (χ^2 = 5.04, I² = 40%), 1 year (χ^2 = 4.24, I² = 53%) and 2 years (χ^2 = 8.07, I² = 75%), and low at 5 years (χ^2 = 0.99, I² = 0%).

The outcome of the 10-year timepoint should be interpreted with caution since only one RCT was available for analysis, considered to be of some concern of risk of bias (Ketola). At a follow-up of 1, 2 and 5 years, the GRADE certainty of the evidence was low due to two of the three trials having some concerns for risk of bias (Table 63).

There was a statistically significant difference in favour of SAD over conservative treatment at 3 months (MD = -0.68, 95% CI: -1.32 to -0.03, p = 0.04), but this was not clinically important (for pain, a change in 1.5 points on a 0–10 scale was considered to be the minimal clinically important difference). The heterogeneity and inconsistency were moderate at 3 months ($\chi^2 = 6.31$, $I^2 = 52\%$).

	Subacromial			Conserva				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.1.1 3 months									
Brox 1993	3.6	1.42	31	4.76	1.6	42	30.7%	-1.16 [-1.86, -0.46]	_
Haahr 2005	8.1	2.5	41	7.9	2.4	43	21.1%	0.20 [-0.85, 1.25]	
Ketola 2009	3.2	2.4	43	4.4	2.2	57	24.3%	-1.20 [-2.12, -0.28]	_
Paavola 2018	4.2	2.6	54	4.5	2.5	62	23.9%	-0.30 [-1.23, 0.63]	
Subtotal (95% CI)			169			204	100.0%	-0.68 [-1.32, -0.03]	-
Heterogeneity: Tau² = Fest for overall effect:			= 0.10); l ^a	= 52%					
1.1.2 6 months									
3rox 1993	3.4	1.4	41	3.5	1.3	49	36.0%	-0.10 [-0.66, 0.46]	-
Haahr 2005	7.4	2.4	41	7.5	2.3	43	18.7%	-0.10 [-1.11, 0.91]	
<etola 2009<="" td=""><td>2.5</td><td>2.1</td><td>44</td><td>3.7</td><td>2.4</td><td>56</td><td>22.3%</td><td>-1.20 [-2.08, -0.32]</td><td>_ </td></etola>	2.5	2.1	44	3.7	2.4	56	22.3%	-1.20 [-2.08, -0.32]	_
Paavola 2018	3.8	2.5	59	4.5	2.4	67	23.1%	-0.70 [-1.56, 0.16]	_
Subtotal (95% CI)			185		2	215	100.0%	-0.48 [-1.00, 0.04]	◆
Heterogeneity: Tau ² =	0.11: Chi ² = 5.0)4. df = 3 (P	= 0.17); P	= 40%					-
Fest for overall effect:			,						
I.1.3 1 year									
Haahr 2005	7.6	2.9	41	7.5	2.1	43	29.8%	0.10 [-0.99, 1.19]	_
Ketola 2009	2.3	2.4	51	3.7	2.7	62	34.4%	-1.40 [-2.34, -0.46]	_
Paavola 2018	2.4	2.5	55	3.3	2.5	64	35.8%	-0.90 [-1.80, 0.00]	
Subtotal (95% CI)			147			169	100.0%	-0.77 [-1.59, 0.04]	
Heterogeneity: Tau ² = Fest for overall effect:			= 0.12); lª	= 53%					
1.1.4 2 years									
3rox 1993	2.8	2.1	39	2.3	1.5	45	34.5%	0.50 [-0.29, 1.29]	
(etola 2009	2.5	2.6	68	2.9	2.7	66	32.5%	-0.40 [-1.30, 0.50]	
Paavola 2018	1.6	2.5	59	2.8	2.5	68	33.0%	-1.20 [-2.07, -0.33]	
Subtotal (95% CI)			166			179	100.0%	-0.35 [-1.34, 0.64]	
Heterogeneity: Tau ² = Fest for overall effect:			= 0.02); l ^a	= 75%					
.1.5 5 years									
laahr 2005	8.1	1.1	39	8	1.7	40	50.7%	0.10 [-0.53, 0.73]	— —
<etola 2009<="" td=""><td>1.9</td><td>2.5</td><td>57</td><td>2.2</td><td>2.3</td><td>52</td><td>24.8%</td><td>-0.30 [-1.20, 0.60]</td><td></td></etola>	1.9	2.5	57	2.2	2.3	52	24.8%	-0.30 [-1.20, 0.60]	
°aavola 2018	1.3	2.5	59	1.7	2.7	68	24.6%	-0.40 [-1.30, 0.50]	
Subtotal (95% CI)			155			160	100.0%	-0.12 [-0.57, 0.33]	-
leterogeneity: Tau ² = est for overall effect:			= 0.61); P	= 0%					
.1.6 10 years									
<etola 2009<br="">Subtotal (95% CI)</etola>	2.8	3	44 44	1.8	3	46 <mark>46</mark>	100.0% 100.0%	1.00 [-0.24, 2.24] 1.00 [-0.24, 2.24]	
Heterogeneity: Not ap Fest for overall effect:		11)							
								_	-2 -1 0 1 2
									Favours Surgery Favours CT

Figure 6 Forest plot indicating the mean difference in pain for SAD versus conservative therapy

Shoulder function

Six RCTs were included in analysing the effect of SAD versus conservative therapy on shoulder function (Figure 7) (Brox, Haahr, Ketola, Paavola, Farfaras, Peters). Three RCTs were included in the meta-analysis at 3 months, four at 6 months, three studies at 1 year, five studies at 2 years, two studies at 5 years and two studies at the 10-year timepoint.

There was no statistically significant difference for shoulder function between conservative treatment and SAD at 3-months (MD = 6.21, 95% CI: -7.34 to 19.76, p = 0.37), 6-month (MD = 2.71, 95% CI: -4.67 to 10.09, p = 0.47), 1-year (MD = -3.60, 95% CI: -9.16 to 16.37, p = 0.58) and 5-year (MD = -4.41, 95% CI: -1.71 to 10.53, p = 0.16) timepoints. Heterogeneity and inconsistencies were low at 5 years (χ^2 = 0.05, I² = 0%) and 10 years (χ^2 = 0.98, I² = 0%), moderate at 6 months (χ^2 = 8.30, I² = 64% and substantial at 3 months (χ^2 = 10.49, I² = 81%) and 1 year (χ^2 = 8.07, I² = 75%).

There were statistically significant differences observed at the 2-year and 10-year time points, but only the differences observed at 10 years were clinically important (based on an improvement of 8.3 or more on a 0-100 scale). However, for the comparison of SAD with conservative therapy the GRADE certainty of evidence is low, due to the available RCTs being of

moderate or high risk of bias (Table 63). This analysis had low heterogeneity and inconsistencies at 2 years ($\chi^2 = 3.04$, $l^2 = 0\%$) and 10 years ($\chi^2 = 0.98$, $l^2 = 0\%$).

Changes compared to the recent Cochrane review include the use of newly imputed SDs (Ketola and Peters) as well as the inclusion of the new data from Paavola (5-year timepoint). Peters did not report data at the 5-year follow-up. Reported outcomes at 36 and 48 months were not included (Peters).

	Subacromia	I decompre	ssion	Conserv	ative the	rapy		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
1.2.1 3 months									
Brox 1993	79.4	25.1	31	72.7	24.2	42	31.9%	6.70 [-4.77, 18.17]	
Haahr 2005	15.5	20.3	41	20.1	15.6	43	36.5%	-4.60 [-12.37, 3.17]	
Ketola 2009	62.6	29.4	43	44.4	30	57	31.6%	18.20 [6.46, 29.94]	
Subtotal (95% CI)			115			142	100.0%	6.21 [-7.34, 19.76]	
Heterogeneity: Tau ² =	115.35; Chi ² =	10.49, df = 2	2 (P = 0.00	05); I² = 81	%				
Test for overall effect:									
1.2.2 6 months									
Brox 1993	84.4	23.4	41	87.8	26.7	49	22.4%	-3.40 [-13.75, 6.95]	
Haahr 2005	19.9	22.8	41	21.3	19.2	43	25.0%	-1.40 [-10.44, 7.64]	
<etola 2009<="" td=""><td>73.4</td><td>26.3</td><td>44</td><td>56.3</td><td>32.4</td><td>56</td><td>20.3%</td><td>17.10 [5.59, 28.61]</td><td></td></etola>	73.4	26.3	44	56.3	32.4	56	20.3%	17.10 [5.59, 28.61]	
Paavola 2009	73.4 59.2	16.5	44 59	58.1	32.4 16.4	67	32.2%	• • •	
Subtotal (95% CI)	09.Z	10.5	185	36.1	16.4		32.2% 100.0%	1.10 [-4.66, 6.86] 2.71 [-4.67, 10.09]	
leterogeneity: Tau ² =	25 26 Chiz - 0	20 df - 2/0		E - 6400		215	100.070	2.71[-4.07, 10.03]	
Fest for overall effect:			- 0.04),	1 - 04%					
I.2.3 1 year									
-	18.8	23.1	41	23	19.8	43	36.1%	12011242 502	
Haahr 2005 ≺etola 2009		23.1	41 51		19.8 35.5			-4.20 [-13.42, 5.02]	•
	75.2			58.4		62	32.4%	16.80 [5.09, 28.51]	
Peters 1997	74	22.5	26 118	75	26.5	36	31.6% 100.0%	-1.00 [-13.24, 11.24]	
Subtotal (95% CI)	05.44 01-7			3 3500		141	100.0%	3.60 [-9.16, 16.37]	
Heterogeneity: Tau² =			² = 0.02);	l≝= 75%					
Test for overall effect:	Z = 0.55 (P = 0.	.58)							
.2.4 2 years									_
Brox 1993	92.2	19.5	39	93.3	23.9	45	17.0%	-1.10 [-10.39, 8.19]	
Farfaras 2016	69.1	21.2	34	61	22.2	21	10.4%	8.10 [-3.77, 19.97]	
<etola 2009<="" td=""><td>75.8</td><td>28.9</td><td>68</td><td>67.1</td><td>35.8</td><td>66</td><td>12.1%</td><td>8.70 [-2.34, 19.74]</td><td></td></etola>	75.8	28.9	68	67.1	35.8	66	12.1%	8.70 [-2.34, 19.74]	
Paavola 2018	79.1	16.7	58	71.2	17	65	41.3%	7.90 [1.94, 13.86]	
Peters 1997	78.9	17.4	32	74	20.3	39	19.1%	4.90 [-3.87, 13.67]	
Subtotal (95% CI)							100.0%		
			231			236	100.0%	5.91 [2.08, 9.74]	◆
				= 0%		236	100.0%	5.91 [2.08, 9.74]	•
				= 0%		236	100.0%	5.91 [2.08, 9.74]	•
Heterogeneity: Tau ² = Test for overall effect: 1.2.5 5 years	Z = 3.02 (P = 0.	.003)	= 0.55); I ^z						•
Test for overall effect: I .2.5 5 years Ketola 2009	Z = 3.02 (P = 0. 83.1	003) 27.6	= 0.55); I ² 57	77.8	26.4	52	36.4%	5.30 [-4.84, 15.44]	▲
Test for overall effect: 1.2.5 5 years Ketola 2009 Paavola 2018	Z = 3.02 (P = 0.	.003)	= 0.55); I ² 57 58		26.4 25.7	52 65	36.4% 63.6%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57]	
Fest for overall effect: I.2.5 5 years Ketola 2009 Paavola 2018 Subtotal (95% CI)	Z = 3.02 (P = 0. 83.1 83.7	27.6 17.3	= 0.55); ² 57 58 115	77.8 79.8		52 65	36.4%	5.30 [-4.84, 15.44]	
Fest for overall effect: I.2.5 5 years Ketola 2009 Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau ² =	Z = 3.02 (P = 0. 83.1 83.7 : 0.00; Chi ^z = 0.0	27.6 17.3 25, df = 1 (P	= 0.55); ² 57 58 115	77.8 79.8		52 65	36.4% 63.6%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57]	
Fest for overall effect: 1.2.5 5 years Setola 2009 Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau ² = Fest for overall effect:	Z = 3.02 (P = 0. 83.1 83.7 : 0.00; Chi ^z = 0.0	27.6 17.3 25, df = 1 (P	= 0.55); ² 57 58 115	77.8 79.8		52 65	36.4% 63.6%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57]	
Fest for overall effect: 1.2.5 5 years Setola 2009 Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau ² = Fest for overall effect:	Z = 3.02 (P = 0. 83.1 83.7 : 0.00; Chi ^z = 0.0	27.6 17.3 25, df = 1 (P	= 0.55); ² 57 58 115	77.8 79.8		52 65	36.4% 63.6%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57]	
Test for overall effect: 1.2.5 5 years Vetola 2009 Vaavola 2018 Subtotal (95% CI) Heterogeneity: Tau ² = Test for overall effect: 1.2.6 10 years Tarfaras 2016	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.0 Z = 1.41 (P = 0. 77.6	003) 27.6 17.3 05, df = 1 (P 16) 17.2	= 0.55); ² 57 58 115	77.8 79.8		52 65	36.4% 63.6% 100.0% 70.1%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19]	
Fest for overall effect: 1.2.5 5 years <etola 2009<br="">Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau² = Fest for overall effect: 1.2.6 10 years Farfaras 2016 <etola 2009<="" td=""><td>Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi² = 0.0 Z = 1.41 (P = 0.</td><td>27.6 17.3 05, df = 1 (P 16)</td><td>= 0.55); ² 57 58 115 = 0.83); ² 38 44</td><td>77.8 79.8 ?= 0%</td><td>25.7</td><td>52 65 117 28 46</td><td>36.4% 63.6% 100.0% 70.1% 29.9%</td><td>5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]</td><td></td></etola></etola>	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi² = 0.0 Z = 1.41 (P = 0.	27.6 17.3 05, df = 1 (P 16)	= 0.55); ² 57 58 115 = 0.83); ² 38 44	77.8 79.8 ?= 0%	25.7	52 65 117 28 46	36.4% 63.6% 100.0% 70.1% 29.9%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]	
Test for overall effect: 1.2.5 5 years ≺etola 2009	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.0 Z = 1.41 (P = 0. 77.6	003) 27.6 17.3 05, df = 1 (P 16) 17.2	= 0.55); ² 57 58 115 = 0.83); ² 38	77.8 79.8 *= 0% 65.5	25.7 19.6	52 65 117 28 46	36.4% 63.6% 100.0% 70.1%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19]	
Fest for overall effect: 1.2.5 5 years <etola 2009<br="">Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau² = Fest for overall effect: 1.2.6 10 years Farfaras 2016 <etola 2009<="" td=""><td>Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi² = 0.1 Z = 1.41 (P = 0. 77.6 77</td><td>003) 27.6 17.3 05, df = 1 (P 16) 17.2 33.1</td><td>= 0.55); ² 57 58 115 = 0.83); ² 38 44 82</td><td>77.8 79.8 *= 0% 65.5 73.3</td><td>25.7 19.6</td><td>52 65 117 28 46</td><td>36.4% 63.6% 100.0% 70.1% 29.9%</td><td>5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]</td><td></td></etola></etola>	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.1 Z = 1.41 (P = 0. 77.6 77	003) 27.6 17.3 05, df = 1 (P 16) 17.2 33.1	= 0.55); ² 57 58 115 = 0.83); ² 38 44 82	77.8 79.8 *= 0% 65.5 73.3	25.7 19.6	52 65 117 28 46	36.4% 63.6% 100.0% 70.1% 29.9%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]	
Fest for overall effect: 1.2.5 5 years Cetola 2009 Paavola 2018 Subtotal (95% Cl) Heterogeneity: Tau ² = Fest for overall effect: 1.2.6 10 years Farfaras 2016 Cetola 2009 Subtotal (95% Cl)	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.1 Z = 1.41 (P = 0. 77.6 77 0.00; Chi ² = 0.3	003) 27.6 17.3 05, df = 1 (P 16) 17.2 33.1 38, df = 1 (P	= 0.55); ² 57 58 115 = 0.83); ² 38 44 82	77.8 79.8 *= 0% 65.5 73.3	25.7 19.6	52 65 117 28 46	36.4% 63.6% 100.0% 70.1% 29.9%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]	
Fest for overall effect: 1.2.5 5 years <etola 2009<br="">Paavola 2018 Subtotal (95% Cl) Heterogeneity: Tau² = Fest for overall effect: 1.2.6 10 years Farfaras 2016 <etola 2009<br="">Subtotal (95% Cl) Heterogeneity: Tau² =</etola></etola>	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.1 Z = 1.41 (P = 0. 77.6 77 0.00; Chi ² = 0.3	003) 27.6 17.3 05, df = 1 (P 16) 17.2 33.1 38, df = 1 (P	= 0.55); ² 57 58 115 = 0.83); ² 38 44 82	77.8 79.8 *= 0% 65.5 73.3	25.7 19.6	52 65 117 28 46	36.4% 63.6% 100.0% 70.1% 29.9%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]	
Test for overall effect: 1.2.5 5 years (etola 2009 Paavola 2018 Subtotal (95% CI) Heterogeneity: Tau ² = Test for overall effect: 1.2.6 10 years (arfaras 2016 (etola 2009 Subtotal (95% CI) Heterogeneity: Tau ² =	Z = 3.02 (P = 0. 83.1 83.7 0.00; Chi ² = 0.1 Z = 1.41 (P = 0. 77.6 77 0.00; Chi ² = 0.3	003) 27.6 17.3 05, df = 1 (P 16) 17.2 33.1 38, df = 1 (P	= 0.55); ² 57 58 115 = 0.83); ² 38 44 82	77.8 79.8 *= 0% 65.5 73.3	25.7 19.6	52 65 117 28 46	36.4% 63.6% 100.0% 70.1% 29.9%	5.30 [-4.84, 15.44] 3.90 [-3.77, 11.57] 4.41 [-1.71, 10.53] 12.10 [3.01, 21.19] 3.70 [-10.20, 17.60]	

Figure 7 Forest plot indicating the mean difference in shoulder function for SAD compared to conservative therapy

Health-related quality of life

Three RCTs were included in comparing SAD and conservative treatment on the patient HRQoL (Figure 8) (Paavola, Farfaras, Ketola). The standardised mean difference (SMD) was used in the meta-analysis due to the use of different measurement tools to evaluate HrQoL (Paavola and Ketola– 15D; Farfaras– SF-36). Caution must be exercised in the interpretation of outcome at 3-month, 6-month and 1-year timepoints because of the inclusion of only one study per timepoint (Paavola).

There were no statistically significant differences reported at any timepoint, ranging from 3 months to 10 years. Heterogeneity at the 2-year ($\chi^2 = 2.49$, $I^2 = 60\%$) and 10-year ($\chi^2 = 3.01$, $I^2 = 67\%$) timepoints were moderate.

The GRADE certainty of evidence is low at all timepoints, based on the availability and quality of RCTs (Table 63).

	Subacromia	l decompre	ssion	Conserv	ative the	rapy		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
1.3.1 3 months									
Paavola 2018 Subtotal (95% Cl)	0.9	0.1	55 55	0.9	0.1	64 <mark>64</mark>	100.0% 100.0%	0.00 [-0.36, 0.36] 0.00 [-0.36, 0.36]	
Heterogeneity: Not ap Test for overall effect:		00)							
1.3.2 6 months									
Paavola 2018 Subtotal (95% CI)	0.9	0	55 55	0.9	0	64 64		Not estimable Not estimable	
Heterogeneity: Not ap Test for overall effect:									
1.3.3 1 year									
Paavola 2018 Subtotal (95% Cl)	0.9	0	54 54	0.9	0.1	62 62		Not estimable Not estimable	
Heterogeneity: Not ap Test for overall effect:									
1.3.4 2 years									
Farfaras 2016	73.9	11.9	34	65.2	14.4	21	41.2%	0.66 [0.11, 1.22]	
Paavola 2018 Subtotal (95% Cl)	0.91	0.1	59 <mark>93</mark>	0.9	0.04	68 89	58.8% 100.0%	0.13 [-0.22, 0.48] 0.35 [-0.16, 0.86]	
Heterogeneity: Tau² = Test for overall effect:			= 0.11); l ^a	²= 60%					
1.3.5 5 years									
Ketola 2009	0.9	0.1	57	0.92	0.1	52	47.0%	-0.20 [-0.58, 0.18]	
Paavola 2018 Subtotal (95% Cl)	0.9	0.04	56 113	0.91	0.06	68 120	53.0% 100.0%	-0.19 [-0.55, 0.16] - 0.19 [-0.45, 0.06]	
Heterogeneity: Tau² = Test for overall effect:			= 0.98); I ²	²= 0%					
1.3.6 10 years									
Farfaras 2016	70.8	9.1	38	65.3	10	28	46.9%	0.57 [0.07, 1.07]	 −−− ∎ −−−
Ketola 2009 Subtotal (95% Cl)	0.9	0.1	44 82	0.9	0.1	46 74	53.1% 100.0%	0.00 [-0.41, 0.41] 0.27 [-0.29, 0.83]	
Heterogeneity: Tau² = Test for overall effect:			= 0.08); I ^z	²= 67%					
Test for overall effect:			- 0.06), 1	- 07 %					-1 -0.5 0 0.5 1 Favours CT Favours Surgen

Figure 8 Forest plot indicating the SMD in HRQoL for SAD compared to conservative therapy

Return to work

hudu an Cultanaun	ubacromial decomp		onservative t		Mainha	Risk Ratio	Risk Ratio
tudy or Subgroup 5.1 3 months	Events	Total	Events	Total	weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
aavola 2018	39	59	47	60	100.0%	0.96 [0.75, 1.22]	
ubtotal (95% CI)		59 59		68 68	100.0%	0.96 [0.75, 1.22] 0.96 [0.75, 1.22]	
otal events	39		47				
eterogeneity: Not appli est for overall effect: Z =							
estitut üverall ellett. Z -	0.30 (F = 0.72)						
5.2 6 months							
rox 1993	19	31	23	33	33.3%	0.88 [0.61, 1.26]	
aavola 2018 ubtotal (95% CI)	48	56 87	50	67 100	66.7% 100.0%	1.15 [0.96, 1.37] 1.05 [0.81, 1.36]	
otal events	67		73				
eterogeneity: Tau ² = 0.1	02; Chi² = 1.84, df = 1	$(P = 0.18); I^2$	= 46%				
est for overall effect: Z =	: 0.38 (P = 0.70)						
5.3 1 year							<u> </u>
aavola 2018	48	56	55		100.0%	0.98 [0.85, 1.13]	
ubtotal (95% CI)	40	56		63	100.0%	0.98 [0.85, 1.13]	-
otal events eterogeneity: Not appli	48 coblo		55				
est for overall effect: Z =							
5.4 2 years							
rox 1993	18	31	26	33	41.5%	0.74 [0.52, 1.04]	
aavola 2018	47	57	53	68	58.5%	1.06 [0.89, 1.26]	
ubtotal (95% CI)		88		101	100.0%	0.91 [0.63, 1.31]	
otal events	65 5. 01-2 54 - 46 - 4	(D = 0.00) /Z	79				
eterogeneity: Tau² = 0.1 est for overall effect: Z =		(P = 0.06); F	= 7.2%				
5.5 5 years							
aahr 2005	20	39	21	40	9.3%	0.98 [0.64, 1.49]	
etola 2009	52	57	41	52	63.9%	1.16 [0.98, 1.36]	↓_
aavola 2018	38	57	45	68	26.8%	1.01 [0.78, 1.29]	
ubtotal (95% CI)		153		160	100.0%	1.10 [0.96, 1.25]	
otal events	110		107				
eterogeneity: Tau² = 0.1 est for overall effect: Z =		(P = 0.50); I ²	= 0%				
5.6 10 years							
etola 2009	43	44	42	46	100.0%	1.07 [0.97, 1.18]	
ubtotal (95% CI)		44		46	100.0%	1.07 [0.97, 1.18]	◆
otal events	43		42				
eterogeneity: Not appli est for overall effect: Z =							
estion overall ellect. Z =	- 1.33 (F = 0.16)						
							0.5 0.7 1 1.5
							0.5 0.7 1 1.5

Figure 9 Forest plot indicating the return-to-work ratio for SAD compared to conservative therapy

Data for return to work were available for Paavola (at 2 and 5 years), Brox (at 6 months and 2 years) and Haahr (at 5 years). Evidence for other studies was not available from publications but was taken from the Cochrane review (Karjalainen et al. 2019b). We were unable to independently verify these results from primary source material, but the data have been included here for comprehensiveness.

There was no significant difference on return to work between shoulder decompression surgery and conservative treatment at all timepoints as shown in Figure 9.

Failure of surgery and reoperations

Treatment failure was not clearly defined in any of the included studies. The definition of treatment failure adapted from the recent Cochrane review as identification of full-thickness tears during the follow-up period was used (Karjalainen et al., 2019b). The study of Ketola et al utilised MRI to identify rotator cuff tears at 5-year follow-up with full-thickness tears of supraspinatus present in 17% (8/48) of patients in the surgery group and 17% (7/42) in the exercise group (risk ratio [RR] 1.00, 95% CI 0.40 to 2.52) (Ketola). Farfaras used US at 13-year follow-up with 5% (2/38) of participants in the surgery group and 15% (4/28) participants in the

exercise group identified as having full-thickness tears of supraspinatus (RR 0.37, 95% CI:0.07 to 1.87).

In Beard and Brox, changes in surgery or deviations from the protocol were reported, but no failures or revision surgery were reported (Table 55).

In Paavola, one patient (1/59 [2%] who received SAD) had a reoperation which included SAD and distal clavicle resection. Of patients who converted to SAD from exercise therapy (N=68), 3/15 (20%) underwent revision surgery (including manipulation under anaesthesia, SAD with long head of biceps tendon repair, and SAD with arthroscopic distal clavicle resection).

There were no reported failures, revisions or changes in planned surgery in all other trials (Table 55).

Clinical claim

Overall, there were no statistically significant differences between SAD and conservative therapy on HRQoL and return to work.

There was a statistically significant difference in favour of SAD at the 3-month timepoint for pain and at the 2-year timepoint for shoulder function. However, the difference was not clinically important.

A statistically significant and clinically important difference was reported in favour of SAD for shoulder function at 10-year follow-up based on two studies. However, for all outcomes the certainty of evidence is low due to the inclusion of RCTs with a moderate or high risk of bias.

2.3.3 SAD versus placebo

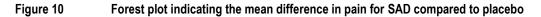
Shoulder pain

The meta-analysis of the recent Cochrane review was updated by including one trial (Brox) into the analysis. In the trial of Brox et al, pain was measured using an activity scale of 1 to 9, which was converted to a 0 to 10 scale using the formula in Appendix B. The missing SDs were calculated as described in Appendix A (Bracken, 1992).

Results shown at Figure 10 indicate that there was no statistically significant difference reported at 3 months (MD = 0.5, 95% CI: -0.41 to 1.41, p = 0.28), 6 months (MD = -1.01, 95% CI: -3.24 to 1.21, p = 0.37), 1 year (MD = -0.27, 95% CI: -0.85 to 0.31) and 5 years (MD = -0.80, 95% CI: -1.71 to 0.11). A significant difference favouring decompression was seen at 2 years (MD = -0.90, 95% CI: -1.80 to 0.00). However, the difference is not clinically important based on the identified minimal clinically important difference (MCID) for shoulder pain (MCID = 1.5 points). Results at 3 months, 2 years and 5 years should be interpreted with caution due to the inclusion of only one study on those timepoints.

Heterogeneity was high at 6 months with $l^2 = 96\%$ ($\chi^2 = 51.82$), low at 1 year with $l^2 = 0\%$ ($\chi^2 = 0.44$) and was not assessed at 3 months, 2 years and 5 years due to the inclusion of only one study on those timepoints. At 12 months, the certainty of the evidence is high (Table 64).

	Shoulder d	ecompres	ssion	Pla	icebo	D		Mean Difference	Mean Difference
tudy or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.1 3 months									
aavola 2018 ubtotal (95% CI)	4.2	2.4	52 52	3.7	2.4		100.0% 100.0%	0.50 [-0.41, 1.41] <mark>0.50 [-0.41, 1.41]</mark>	
eterogeneity: Not app	licable								
est for overall effect: Z	(= 1.08 (P =	0.28)							
1.2 6 months									
eard 2018	4.2	2.8	88	4.1	2.4	91	33.4%	0.10 [-0.67, 0.87]	_ _
rox 1993	2.5	1.3	41	5.6	2.4	91	33.8%	-3.10 [-3.73, -2.47]	
aavola 2018	3.8	2.5	59	3.8	2.5	61	32.9%	0.00 [-0.89, 0.89]	-+-
ubtotal (95% CI)			188			243	100.0%	-1.01 [-3.24, 1.21]	
eterogeneity: Tau² = 3 est for overall effect: Z			2 (P ≤ 0.	.00001)	² = !	96%			
1.3 1 уеаг									
eard 2018	2.9	2.5	85	3	2.6	85	57.6%	-0.10 [-0.87, 0.67]	
aavola 2018	2.3	2.4	55	2.8	2.4	56	42.4%	-0.50 [-1.39, 0.39]	
ubtotal (95% CI)			140			141	100.0%	-0.27 [-0.85, 0.31]	◆
eterogeneity: Tau² = (est for overall effect: Z			(P = 0.5	i1); I² = ()%				
1.4 2 years									_
aavola 2018	1.6	2.5	59	2.5	2.5		100.0%	-0.90 [-1.80, 0.00]	
ubtotal (95% CI)			59			59	100.0%	-0.90 [-1.80, 0.00]	◆
eterogeneity: Not app									
est for overall effect: Z	:= 1.96 (P =	0.05)							
1.5 5 years									_
aavola 2018	1.2	2.4	54	2	2.4		100.0%	-0.80 [-1.71, 0.11]	
ubtotal (95% CI)			54			54	100.0%	-0.80 [-1.71, 0.11]	-
eterogeneity: Not app									
est for overall effect: Z	:= 1.73 (P =	0.08)							
								-	
									-4 -2 0 2 4



Shoulder function

The meta-analysis of Karjalainen et al was updated with the inclusion of the study by Brox et al at the 6-month timepoint and Paavola at the 5-year timepoint. The missing SDs were calculated as shown in Appendix A.

Figure 11 shows shoulder function on a 0 to 100 scale with 100 being the best (MCID = 8.3 points). Result showed no statistically significant difference between shoulder decompression surgery and placebo on shoulder function at 6 months (MD = -0.70, 95% CI: -6.33, 4.93), 1 year (MD = 1.30, 95% CI: -4.53 to 7.13) and 2 years (MD = 4.20, 95% CI: -1.72 to 10.12). A statistically significant difference was observed at the 5-year timepoint (MD = 7, 95% CI: 0.75 to 13.25). However, the result was obtained from only one study and was not clinically significant. Results at 1, 2 and 5 years should be interpreted with caution due to the inclusion of only one study on those timepoints. Heterogeneity was substantially high at 6 months with $I^2 = 59\%$ ($\chi^2 = 4.85$) and was not assessed at 1, 2 and 5 years due to the inclusion of only one study on those timepoints.

The certainty of the evidence is high, although limited by the availability of only one RCT at 1, 2 and 5 years follow-up (Table 64).

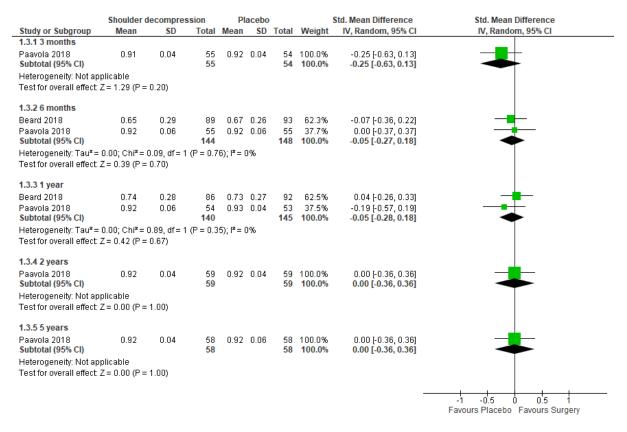
	Shoulder d	lecompre	ssion	PI	acebo			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.2.1 6 months									
Beard 2018	56.5	21.8	82	57.6	17.7	84	34.3%	-1.10 [-7.15, 4.95]	
Brox 1993	84.4	16.1	31	79.4	13.4	42	30.4%	5.00 [-1.97, 11.97]	
Paavola 2018	59.1	16.4	59	64.3	16.1	61	35.3%	-5.20 [-11.02, 0.62]	
Subtotal (95% CI)			172			187	100.0%	-0.70 [-6.33, 4.93]	\bullet
Heterogeneity: Tau² =	14.53; Chi ² =	= 4.85, df=	2 (P = 0)	.09); I² =	59%				
Test for overall effect:	Z = 0.24 (P =	0.81)							
1.2.2 1 year									
Beard 2018	66.2	19.9	76	64.9	17.2	81	100.0%	1.30 [-4.53, 7.13]	
Subtotal (95% CI)			76			81	100.0%	1.30 [-4.53, 7.13]	-
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 0.44 (P =	0.66)							
1.2.3 2 years									
Paavola 2018	77.9	16.5	59	73.7	16.3	59	100.0%	4.20 [-1.72, 10.12]	+
Subtotal (95% CI)			59			59	100.0%	4.20 [-1.72, 10.12]	-
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 1.39 (P =	0.16)							
1.2.4 5 years									
Paavola 2018	82.7	17.3	58	75.7	17.2	59	100.0%	7.00 [0.75, 13.25]	
Subtotal (95% CI)			58			59	100.0%	7.00 [0.75, 13.25]	-
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 2.19 (P =	0.03)							
									-20 -10 0 10 20
									Favours Placebo Favours Surgery
									3-17



Health-related quality of life

Two RCTs were included in the meta-analysis of health-related quality of life comparing SAD and placebo (Figure 12) (Paavola, Beard). SMD was used in the analysis due to the difference tools used in reporting HRQoL (15D by Paavola and the EuroQoL 5-dimension 3-level questionnaire form [EQ-5D] by Beard). Results showed no significant differences at any timepoints: 3 months (SMD = -0.25, 95% CI: -0.63 to 0.13), 6 months (SDM = -0.05, 95% CI: -0.27 to 0.18), 1 year (SMD = -0.05, 95% CI: -0.28 to 0.18), 2 years (SMD = 0.00, 95% CI: -0.36 to 0.36) and 5 years (SMD = 0.00, 95% CI: -0.36 to 0.36). Heterogeneity at 6 months (I² = 0%, χ^2 = 0.76) and 1 year (I² = 0%, χ^2 = 0.35) were low. Heterogeneity was not calculated at other timepoints.

The certainty of the evidence is high, although limited by the availability of only one RCT at 2 and 5 years follow-up (Table 64).





Return to work

The ability to return to work was reported by an updated study by Paavola (Bäck et al., 2021). At the 2-year timepoint, 82% (47/57) of patients in the arthroscopic SAD group and 80% (47/59) in the placebo (diagnostic arthroscopy) group were able to return to work. At the 5-year timepoint, 67% (38/57) of the patients in the SAD group and 69% (41/59) in the placebo group were able to return to work.

Failure of surgery and reoperations

There were no studies comparing SAD and placebo on surgery failure.

In Beard and Brox, changes in surgery or deviations from the protocol were reported, but no failures or revision surgery were reported (Table 55).

In Paavola, one patient (1/59 who received SAD) had a reoperation of SAD and distal clavicle resection. In patients treated with diagnostic arthroscopy, there were 10/55 conversions to SAD. There were no reported reoperations in this cohort.

Clinical claim

Overall, there was no significant difference on the use of SAD versus placebo on outcomes such as pain, shoulder function and HRQoL except on shoulder function measured on the 5-year timepoint, which was statistically significant but not clinically important. The outcome is sourced from only one study.

2.4 Evidence interpretation

Nine RCTs are available of 1,179 randomised participants, with appropriate intervention and comparisons, in line with the PASC-approved PICO Confirmation. Across all trials, the reported outcome measures are validated, and MCIDs are available.

The quality of the included trials is varied. Two trials that included the use of sham surgery (diagnostic arthroscopy) as a placebo are at low risk of bias and higher GRADE certainty. Other trials were of higher risk of bias (low GRADE certainty) commonly due to the lack of a published protocol, the lack of information regarding randomisation, an inability to blind across treatment populations, and imbalances across reported populations at follow-up.

At baseline, populations were well balanced in studies, but reported characteristics varied between studies, including in terms of baseline scores for pain and shoulder function. In one trial, as observed at the time of surgery, not all patients were identified with impingement. While all studies reported including patients who had failed conservative therapy, the nature and duration of these previous interventions is not provided, therefore it is uncertain whether the population reflects that identified in the PICO Confirmation. It is unlikely that any of the published trials had a population who had failed 6 months of conservative therapy. One recent RCT did provide all patients with a 3-month rehabilitation program prior to randomisation to surgery, in line with best practice. However, outcomes are reported mixed with patients who have received rotator cuff tear repair and results were not available for synthesis.

Results are available across a range of measures and follow-up times and are precise and consistent. However, outcomes at certain follow-up times are only available from a smaller number of trials. Where reported, subgroup analyses show no difference, and there were no differences in ITT and per-protocol sensitivity analyses. However, subgroup analyses showed more favourable surgical results in patients with more severe pain and a curved acromion (Paavola), or with worse function scores at baseline (Rahme), although outcomes were not clinically important (see Section 6, Other relevant information). Many patients received interventions other than that to which they were randomised, which may indicate a lack of perceived satisfaction with the therapy.

The strength of effect is small. Clinically significant results are improved for surgery only for one outcome (shoulder function) at 10 years, based on the results of two trials, compared to conservative therapy. Based on GRADE this evidence is uncertain.

Compared to baseline, there was an improvement in outcomes of pain and function for surgery, conservative care and placebo. A recent RCT comparing supervised physiotherapy with best practice home-based exercises also shows improvements in SPADI scores (combined pain and function) from baseline to 1-year follow-up (Hopewell et al., 2021). However, the scores showed that the condition did not resolve completely. Therefore, despite improvements following therapy, ongoing symptoms may still lead some patients to seek further advice, including for surgery.

One study compared arthroscopic SAD with diagnostic arthroscopy (placebo) and no treatment (Beard). For the primary outcome of OSS, there were statistically significant improvements of SAD compared with no treatment at 6 and 12 months, but these differences did not reach clinical importance. For SAD compared with no treatment the Modified Constant-Murley score was improved at 6 months and 1 year (mean difference 9.3 [95% Cl 4.1 to 14.6], p = 0.0012 and 8.3 [95% Cl 2.5 to 11.1], p = 0.0067). These differences reached the MCID of 8.3. One study which compared SAD with no treatment found a statistically and clinically important difference to HrQoL at 6 months (mean difference 0.12 [95% Cl 0.04 to 0.21]; p = 0.0076), but not at 12 months (0.08 [95% Cl 0.00 to 0.16]; p=0.0517) (Beard et al., 2018). For all outcomes there was no difference between SAD and diagnostic arthroscopy.

Safety outcomes were poorly reported by the RCTs. However, based on evidence from 5 observational studies which provide cohort data on procedures for shoulder arthroscopy, including SAD, the risks of serious adverse events from surgery are small.

The applicability to Australian patients is less certain. Based on current and proposed MBS items the patient selection is unclear, and trials did not use a predefined threshold of pain, shoulder function or size of tear as criteria for inclusion. The trials reflect a relatively younger patient cohort, and therefore the applicability of results to older patients is less certain. A range of tests, X-ray, US and MRI were used for patient diagnosis in the trials. How patients will be selected for SAD is unclear, and therefore the applicability of these results to local practice is uncertain. The current and proposed MBS items refer to removal of calcifications from rotator cuff tendons. However, this procedure is not used in any of the included trials and may reflect a broader range of procedures in existing MBS items (available since 1991).

Long-term outcomes from case series supported the results of RCTs in terms of the rate of repeat surgeries. While a variety of studies reported factors considered to be predictive or prognostic of improved outcomes following SAD, this evidence should be treated with caution as none of the identified clinical studies reported being suitably powered to examine subgroups, and it is unclear which, if any, improvements reached clinically important differences. Two case series reported that radiological signs of impingement were consistently associated with a good outcome. There is a lack of high-quality research into subgroups that may benefit from SAD.

In terms of alternative therapies and conservative treatment options, the type, availability and effectiveness of conservative therapy programs accessible to Australian patients is unclear. Therefore, there is uncertainty regarding the effectiveness of conservative therapy in the local population, including for quality of services and equity of access.

2.5 Conclusion of the clinical claim

Comparative data for safety outcomes are not commonly reported. Based on 2 RCTs at low risk of bias, there is moderate GRADE certainty that there is no difference in safety outcomes between SAD and pooled results of conservative therapy and placebo. However, there is a low event rate and RCTs were not powered to examine these rarer outcomes. Absolute safety data from large case series indicate that the rate of adverse events (including mortality) is low, at 1.00% to 1.17%. It is possible that there is an increased rate of adverse events for SAD compared with conservative therapy due to the invasiveness of the surgical procedure, but serious adverse events are rare. The comparative safety is uncertain. Surgery likely has an inferior safety profile compared to conservative therapies, but serious adverse events are rare.

Compared with placebo (diagnostic arthroscopy), there are no clinically important differences for the use of SAD for all outcomes of clinical effectiveness (pain, shoulder function, HRQoL, return to work). GRADE assessment indicates the certainty of this evidence is moderate to high, based on 2 RCTs with a low risk of bias.

Compared with conservative therapy, there was no statistical and/or clinical difference for the use of SAD for pain, HRQoL and return to work. For shoulder function, compared with conservative therapy, SAD reaches clinical significance at the 10-year timepoint, with a mean difference in shoulder function scores of 9.59 (95% Cl 1.98 to 17.19). However, this result is uncertain (very low GRADE certainty) and based on 2 RCTs considered to be at some concern or at high risk of bias. Repeat surgeries are relatively rare, and often include procedures for other shoulder pathologies (e.g. distal clavicle resection, long head of biceps tendon repair). Across all outcomes, the certainty of evidence for SAD compared to conservative therapy is low or very low, with 6 RCTs ranging from low to high risk of bias.

Section 3 Economic analysis

3.1 Introduction

Literature review and sources of data

Three recent economic evaluations were identified, including one costing study.

Based on the recent RCT by Beard, Rombach et al undertook a cost-effectiveness analysis of SAD compared to no treatment or placebo in the context of the UK National Health Service (NHS), using the EQ-5D-3L questionnaire to quantify quality of life (Beard et al., 2018, Rombach et al., 2019). The baseline to 6 months and baseline to 12 months subacromial decompression incremental cost-effectiveness ratios (ICERs) compared with no treatment were £52,100 (~\$AUD95,077) and £21,138 (~\$AUD38,574) respectively per QALY gained.

A health technology assessment in the perspective of the Swiss health system undertook a cost comparison of SAD compared with conservative therapy (Moshi et al., 2021). The inpatient cost of subacromial decompression surgery of Swiss franc (CHF) 8,633 was higher than the estimated conservative management cost of CHF1,350 (15 physiotherapy sessions at CHF90 per session). Compared to no treatment, and based on results from the Beard trial, the ICER for SAD was CHF98,106 (~\$AUD 153,285) per QALY gained.

A study of NHS patients in English hospitals the estimated median cost of SAD to be £4,479 (~\$AUD7,530) in 2016/17, based on the appropriate procedure codes and relevant national tariffs (Jones et al., 2019). A comparison of costs with conservative therapy was not completed.

As described in Section 1.4.11, the clinical pathway for, and experience of, patients with shoulder pain, rotator cuff disease or subacromial impingement in Australia is varied and trends in surgical practice are not well understood (Smythe et al., 2021, Marks et al., 2018, Thorpe et al., 2016). There are likely to be a range of reasons for this including clinical advice, access to services, and preferences and expectations of the patient. Thus, the services used by patients are also likely to vary, in terms of the services used prior to the option of SAD, as well as for the comparator. Also, the applicability of the Beard trial as used in the above economic evaluations to Australian clinical practice is uncertain.

An analysis was undertaken to compare costs of SAD with conservative therapy. A range of evidence and data sources were considered in preparing the cost comparison.

MBS item utilisation data

An analysis of the utilisation of MBS items, including co-claims with physiotherapy and diagnostic imaging, provides some insight into patient care (Section 5.1). However, this analysis was limited by a range of issues, leading to uncertainty in terms of the patterns of co-claiming and the applicability of this information to patients with subacromial impingement.

• Current MBS items for SAD have no specified population or other restrictions or requirements, therefore previous treatments, medical imaging or patient presentation is not defined.

- Co-claiming data were available for one financial year. Any relevant services prior to this have not been identified. Therefore, the utilisation of MBS services for physiotherapy and medical imaging is likely to be underestimated.
- The 3 current MBS items are commonly co-claimed with other surgery items that likely represent shoulder pathologies accompanying subacromial impingement and are therefore relevant to different patient populations. It is therefore uncertain if patients with the sole diagnosis of subacromial impingement have similar or different claiming patterns compared to those obtained for the existing MBS items 48900, 48903 and 48951. MBS item 48951 was most commonly claimed in the absence of other shoulder surgery items (approximately half of all services) and had diagnostic imaging use in line with best practice guidelines, so it has been used to inform this analysis as it is most likely to represent patients with isolated subacromial impingement.
- The MBS administrative data does not provide a clear indication of all clinical services provided to patient with rotator cuff disorder. It is uncertain if all patients represented in MBS items 48900, 48903 and 48951 have been provided with best quality care prior to surgery.

Due to the limitations of the MBS data, and to inform scenario and sensitivity analysis, the cost comparison is supported by additional material.

Clinical practice guidelines

Clinical guidelines were used to identify best practice conservative care for patients with subacromial pain. These are summarised in Section 1. It is noted that in primary care and in the evidence base, patients with subacromial impingement may be included in a broader population of patients with subacromial pain or rotator cuff-related shoulder pain. In line with best practice, the identification of additional pathology including rotator cuff tears uses US or MRI when a patient is being considered for surgery.

The most recent Australian clinical guideline was published in 2013 (Hopman et al., 2013). While the recommendations are broadly in keeping with more recent guidelines, alignment of clinical practice to guidelines is uncertain. Australian GP practice for management of rotator cuff tendinopathy is heterogeneous and not always in line with clinical guidelines (Buchbinder et al., 2013, Naunton et al., 2020, Broadhurst et al., 2004, Johal et al., 2008). A lack of consensus in deciding which patients are suitable for rotator cuff surgery is also found (Thorpe et al., 2017).

In terms of best practice regarding conservative therapy, clinical practice guidelines are consistent in recommending exercise therapy. However, the number of supervised physiotherapy sessions and type of exercise is uncertain; guidelines commonly recommend between 6 and 12 sessions, provided once per week (Klintberg et al., 2015, Pribicevic et al., 2009, Smythe et al., 2020). A recent RCT identified that one session with a physiotherapist, with best practice advice, is non-inferior to 6 physiotherapy sessions for patients with rotator cuff disorders (Hopewell et al., 2021).

Patient experience with exercise is variable and may reflect variability in the quality of physiotherapy (Smythe et al., 2021). Due to this, the cost comparison investigates a range of session frequencies and costs to reflect more senior or experienced physiotherapists (Australian Physiotherapy Association, 2022).

Clinical practice guidelines commonly report corticosteroid injections as an option for patients who receive conservative therapy. Due to risks in damaging the tendons, no more than 2 injections are commonly recommended, usually in the case of moderate-to-severe pain or to facilitate exercises.

Although landmark-guided injections can be provided by GPs or orthopaedic surgeons in the office setting it is suggested that, in Australia, corticosteroid injections are commonly provided with US-guidance (Morrisroe et al., 2018). Therefore, for the purposes of this analysis it has been assumed that injections are provided with US-guidance by a radiographer(Zadro et al., 2021b). If this was provided by a GP or specialist during a consultation there would be cost savings.

Three MBS items are available for US-guided corticosteroid injections to the shoulder (item 55484 musculoskeletal US, in conjunction with a surgical procedure using interventional techniques; item 55850 musculoskeletal US, in conjunction with a surgical procedure using interventional techniques, inclusive of a diagnostic musculoskeletal US service; and item 55054 ultrasonic cross-sectional echography, in conjunction with a surgical procedure using interventional techniques). None of the items are specific in terms of the intervention or the anatomic location. For the purposes of this analysis we have considered that corticosteroid injections are provided for pain, in the absence of a concurrent diagnostic service (that is, items 55484 and 55054). Diagnostic US has been considered separately. In certain cases, practitioners may claim item 55850 for corticosteroid injection in conjunction with a diagnostic service. In this alternative scenario there would be differences in the costs to the MBS.

The safety and effectiveness of other options for multimodal care such as therapeutic US, lowlevel laser therapy and pulsed electromagnetic field is uncertain and have not been included in this cost comparison. These options are likely to be provided as part of a physiotherapy session.

Diagnostic imaging

Clinical practice guidelines are consistent in recommending X-ray as the initial imaging modality, if required, and for US and MRI to be used only in the case of ongoing symptoms and when the patient is being considered for surgery. However, data from Australian practice shows that US is commonly ordered by primary care physicians (Buchbinder et al., 2013, Naunton et al., 2020, Broadhurst et al., 2004, Johal et al., 2008).

Due to clinical practice guidelines recommending US and MRI only in the case of ongoing symptoms, we have assumed across most scenarios that all patients in the cost comparison receive the same tests, as it is only at this stage that any additional pathology may be confirmed with the patient being considered for shoulder surgery other than SAD. Scenario 3 investigates a change in the use of MRI and CT.

The utilisation of services for patients with subacromial pain has also been informed by recent Australian published evidence:

- Naunton 2020 analysed a database of GP care of Australian patients with rotator cuffrelated shoulder pain (Naunton et al., 2020). This was considered to represent a lower estimate of service use. The study also provides information with 'new' and 'old' rotator cuff-related shoulder pain.
- Smythe 2021 surveyed patients with rotator cuff-related shoulder pain recruited from an Australian musculoskeletal imaging radiology centre (Smythe et al., 2021). This was considered to represent a higher estimate of service use, which may be more consistent with patients being considered for surgery. This cohort included patients with rotator cuff tears who may present with more severe symptoms.
- Marks 2018 analysed patients referred for surgery in a public hospital in Queensland (Marks et al., 2018). The surgery types covered a range of shoulder surgeries including SAD with or without distal clavicle excision or biceps procedure and rotator cuff repair. Evidence from this study was not used to inform the cost comparison but was used to confirm assumptions.

It is noted that an increased use of services may not be associated with worsening symptoms or prognoses, but with increased access to care or patient needs or expectations.

Additional service information is provided by recent RCT evidence (Hopewell et al., 2021, Beard et al., 2018, Cederqvist et al., 2021).

The cost comparison has taken a conservative approach to the modelling of services and costs, with assumptions based on clinical practice guidelines, information from the MBS item utilisation analysis (Section 3) and published evidence related to Australian clinical practice (Naunton, Smythe).

3.2 Approach to the cost evaluation

Under advice from the MSAC, we performed a cost analysis to compare the difference between the treatment of subacromial impingement with and without surgical intervention (that is, SAD compared with [continued] conservative therapy). The methodological framework of this cost analysis is the cost-minimisation analysis (CMA). However, this evaluation should not be considered as a model-based CMA, as the underlying assumption of non-inferiority between the 2 treatment arms is not established. This analysis is only to inform various cost components as well as the total pathway cost implication of different treatment options for a patient and the Australian health system.

Due to uncertainties around the safety and effectiveness, as well as high levels of variations in clinical practice, treatment options and pathways in the cost comparison were based on a range of assumptions, which underpins the cost of various medical and surgical services as well as the utilisation of healthcare resources. We performed a range of sensitivity analyses to address these assumptions. Several scenario analyses have also been produced to investigate economic implications under different plausible clinical situations.

The cost analysis was conducted using Microsoft Excel.

3.2.1 Health care resource use and cost

A range of health services are involved in the different treatments for patients with subacromial impingement. These can be categorised into different groups, such as initial point of care, diagnostics, medical services, surgical services, allied health services and medications. Some costs are covered by MBS or PBS and others may be paid by patients out-of-pocket or via private health insurance when appropriate. This cost comparison takes an expanded health system perspective. When MBS bulk bill services are available, we assume that patients are not charged with gaps or other out-of-pocket costs. When MBS reimbursement is unavailable, we assume that the services are paid in full either by patients or by private health insurance providers to allow the treatment to be completed. We have not considered any insurance premium or other systemic costs not directly related to the treatment of healthcare services, as they are highly variable and uncertain. The inclusion of patient out-of-pocket costs and services payable by private health insurance is to ensure the cost comparison captures a complete treatment pathway as per the recommendations of clinical practice guidelines.

The medical services and itemised healthcare resource utilisations are tabulated in Table 18. These items are used in the cost comparisons with weights and adjustments incorporated in the calculation.

Service utilisation for services defined in the clinical flowcharts such as surgical services, corticosteroid injection, GP or specialist consultations or referrals, physiotherapy services and

medications have been quantified as 100%. Where two similar items are available the service utilisation has been split equally (50%). Other service utilisation (e.g. for surgery-related services and diagnostic-imaging services) are quantified from MBS utilisation data and co-claiming patterns for item 48951 (Section 5.1). For the purposes of this analysis it is considered that GPs provide the referrals to corticosteroid injection, X-ray and US, and that surgeons or specialists provide the referrals to MRI or CT. It is noted that the referral for these services may differ between patients, other than for MBS services for shoulder MRI which are not available to GPs.

Service item	Service payer	Service cost	Service utilisation	Service content and rationalisation
Surgical services				
Targeted MBS Items				
MBS 48951	MBS	\$945.55	100.00%	SAD surgery
Hospital admission cost	Patient / PHI*	\$5,797.00	73.62%	Hospital admission cost for the main SAD surgery (IHACPA, 2022)
Medical services				
Surgery related				
MBS 17610	MBS	\$46.15	85.54%	Anaesthetic service
MBS 21622	MBS	\$104.75	89.69%	Arthroscopic procedure
MBS 22041	MBS	\$41.90	63.51%	Nerve block
MBS 22025	MBS	\$83.80	23.62%	Intra-arterial cannulation
MBS 22012	MBS	\$62.85	22.95%	Cannula
MBS 51303	MBS	\$189.11	86.74%	Assistance at operation
Injection related				
Corticosteroid injection	PBS	\$28.30	100.00%	Corticosteroid injection - 1 st
Local anaesthetic	PBS	\$39.67	100.00%	Pain relief for 1 st corticosteroid injection
MBS 55848	MBS	\$142.15	50.00%	US-guided 1 st corticosteroid injection
MBS 55054	MBS	\$113.55	50.00%	US-guided 1 st corticosteroid injection
Corticosteroid injection	PBS	\$28.30	100.00%	Corticosteroid injection - 2 nd
Local anaesthetic	PBS	\$39.67	100.00%	Pain relief for 2 nd corticosteroid injection
MBS 55848	MBS	\$142.15	50.00%	US-guided 2 nd corticosteroid injection
MBS 55054	MBS	\$113.55	50.00%	US-guided 2 nd corticosteroid injection
Diagnostic imaging services				
Referral from surgeon or specialist				
MBS 63325	MBS	\$409.65	100.00%	MRI - imaging for soft tissue
MBS 56627	MBS	\$228.90	100.00%	CT - imaging for bone
Referral from GP				
MBS 55864	MBS	\$113.55	90.38%	US - imaging for soft tissue
MBS 55865	MBS	\$39.35	4.57%	US - imaging for soft tissue
MBS 55866	MBS	\$126.00	4.67%	US - imaging for soft tissue
MBS 55867	MBS	\$43.75	NR	US - imaging for soft tissue
MBS 57700	MBS	\$42.10	1.50%	X-ray - imaging for bone

 Table 18
 Itemised medical services and healthcare resources with costs

Service item	Service payer	Service cost	Service utilisation	Service content and rationalisation
MBS 57703	MBS	\$56.20	98.50%	X-ray - imaging for bone
Services for referrals				
General consultations				
MBS 23	MBS	\$39.75	100.00%	GP consultation – initial standard visit
MBS 23	MBS	\$39.75	100.00%	GP consultation – follow-up visit 2 nd
MBS 23	MBS	\$39.75	100.00%	GP consultation – follow-up visit 3rd
Specialist consultations				
MBS 104	MBS	\$91.80	50.00%	Specialist consultation
MBS 105	MBS	\$46.15	50.00%	Specialist consultation
Allied health services			·	
Physiotherapy ^a				
MBS 10960	MBS	\$65.85	50.00%	Physiotherapy to maximum of 5 services
MBS 10953	MBS	\$65.85	50.00%	Exercise physiology to maximum of 5 services
MBS 721	MBS	\$152.50	100.00%	Chronic disease management plan
MBS 723	MBS	\$120.85	100.00%	Chronic disease management plan
Specialist physiotherapy ^b	Patient / PHI	\$103.00	100.00%	Additional physiotherapy provided by specialist physiotherapists
Post-surgery rehabilitation	Patient / PHI	\$103.00	100.00%	Post-surgery physiotherapy provided by specialist physiotherapists ^b
Prescriptions				
Medications				
NSAIDs	Patient	\$15.99	100.00%	NSAIDs e.g. aspirin
Analgesics for home-based care	Patient	\$19.99	100.00%	Ibuprofen for home-based care
Analgesics for surgical care	Patient	\$19.99	100.00%	Ibuprofen for surgical care

CT = computed tomography, GP = general practitioner, MBS = Medicare Benefits Schedule, MRI = magnetic resonance imaging, NSAIDs = nonsteroidal anti-inflammatory drugs, PBS = Pharmaceutical Benefits Scheme, PHI = private health insurance, SAD = subacromial decompression, US = ultrasound, NR = Not released data value equal to <10 patients.

Note

a = For physiotherapy services provided through the MBS it was assumed that patients may choose either item 10960 or 10953, noting that the fee is the same. The Medicare rebates for the GP was considered to be 721 (preparing a management plan) and 723 (coordinating the preparation of team care arrangements).

b = Specialist physiotherapy is provided by an experienced physiotherapist as the alternative to surgery after the patient has exhausted the physiotherapy sessions available through the MBS chronic disease management plan

*The public hospital admission cost was used as a proxy to estimate this cost

3.2.2 Assumptions for service delivery

A range of weights and probability adjustments is used in the cost comparison. This includes the likelihood of patients receiving different care options, such as referrals to specialist, different diagnostic services, allied health services and surgery. The 2 options (with or without surgical care) involve different assumptions; some are shared by the 2 options and some are unique to specific pathways. We have thus derived the cost comparison base case to represent the cost differential between treatment for subacromial impingement with and without surgery. These assumptions are tested in the sensitivity analysis. Additional assumptions are put forward to construct alternative scenarios.

To describe how these assumptions are utilised in the cost comparison calculations, 2 clinical flowcharts (with or without surgery) are shown to illustrate patient pathways receiving different medical services and using various level of healthcare resources (Figure 13, Figure 14). These flowcharts align with the clinical management algorithms of the ratified PICO confirmation, modified for the purposes of the economic modelling to be more granular so that each node delineates a specific service.

The intended population for the option without surgical care is considered to be identical to the population with surgical care. MBS item 48951 represents the eligible population for both options.

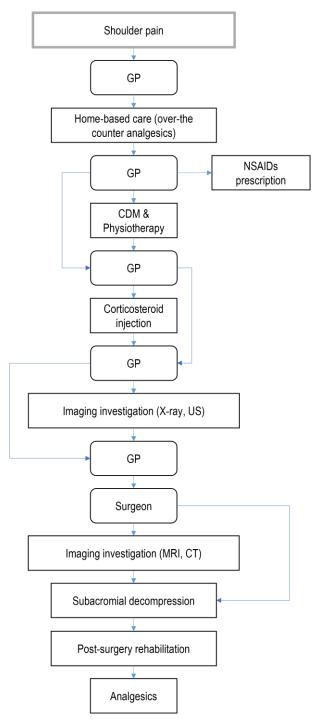
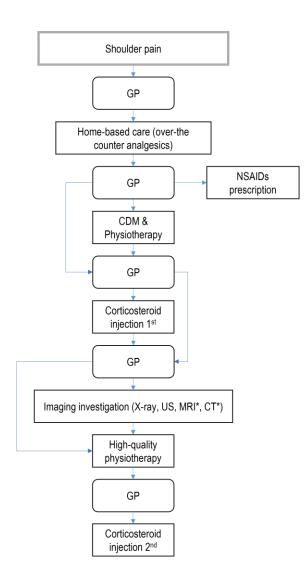


Figure 13 Clinical flowchart for treatment of subacromial impingement with surgical intervention

In the treatment pathway where the surgical intervention is considered, all patients with subacromial impingement are assumed to be referred to a specialist or an orthopaedic surgeon and to then undergo SAD surgery. It is expected that all these patients would have a GP consultation prior to referral to a surgeon, together with post-surgery rehabilitation services and analgesics following surgery. Repeated corticosteroid injections are not considered following surgery.



Notes

* = MRI and CT were assumed to be provided by a specialist or orthopaedic surgeon. In scenario 3, MRI and CT were excluded from the costs of conservative therapy.

Figure 14 Clinical flowchart for treatment of subacromial impingement without surgical intervention

In the treatment pathway without surgical intervention, all patients with subacromial impingement will not undergo SAD surgery and will be treated instead using (continued) conservative therapy. This means that after the initial standard CDM and subsequent MBS-funded physiotherapy sessions have been exhausted, all patients will have a further 2–12 specialist physiotherapy sessions funded through alternative methods. This definition is not a comment on the physiotherapy provided through the MBS, but simply to differentiate these

services with physiotherapy care provided as an alternative to surgery, considered to be provided by a specialist physiotherapist, with costs covered by the patient with or without private health insurance. In some instances, where ongoing pain persists, a corticosteroid injection and a relevant GP consultation will be added to the standardised treatment.

The key assumptions and associated uncertainties are tabulated in Table 19. Three scenarios are investigated in addition to the base case, including a lower utilisation of physiotherapy and diagnostic imaging, a higher utilisation of physiotherapy and diagnostic imaging and the exclusion of MRI and CT from conservative therapy in line with guidelines that do not recommend these services to be available in primary care.

The utilisation of each MBS item for the base case is sourced from the MBS item utilisation review and the co-claiming patterns of SAD item 48951 (Section 5.1). The uncertainty ranges are informed by two recent Australian publications described in Section 3.1, reflective of lower service use in a population from GP care, or higher use from a population of patients at a musculoskeletal imaging radiology centre (Naunton et al., 2020, Smythe et al., 2021). For certain services the uncertainty ranges are higher than the base case value. This is due to the fact that some services delivered some time before surgery (e.g. US) are likely under-represented in the MBS analysis undertaken for this assessment. Alternatively, X-ray and CT services are over-represented in the MBS data compared with the published use of these diagnostic tests. Base case value and ranges for specialist physiotherapy provided as an alternative to surgery were identified from a recent RCT and clinical guidelines ((Hopewell et al., 2021), see also Section 1.4.8 and Section 1.4.10).

As discussed in Section 1.4.7, specialist physiotherapy is assumed to be provided by an experienced physiotherapist as the alternative to surgery after the patient has exhausted the physiotherapy sessions available through the MBS chronic disease management plan.

Service item	Base-case value ^a	Uncertainty ranges	Usage of the assumption in scenarios	Assumption justifications and references
MBS 10960 (Physiotherapy)	20%	12.6%, 80.5%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 10953 (Exercise physiology)	20%	12.6%, 80.5%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 721 (GP management plan)	20%	12.6%, 80.5%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 723 (GP coordinate team care arrangements)	20%	12.6%, 80.5%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 63325 (MRI of shoulder)	43.3%	0.5%, 72%, 0%	Scenario 1, 2, 3	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021), clinical guidelines
MBS 56627 (CT of shoulder)	4.4%	0.2%, 0%	Scenario 1, 3	Natunton (Naunton et al., 2020), clinical guidelines
MBS 55864 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)

 Table 19
 Assumptions and parametric uncertainties involved in cost comparison calculations

Service item	Base-case value ^a	Uncertainty ranges	Usage of the assumption in scenarios	Assumption justifications and references
MBS 55865 (US of shoulder, unilateral)	45.8%	53%, 74%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 55866 (US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 55867(US of shoulder, bilateral)	45.8%	53%, 74%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 57700 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
MBS 57703 (X-ray of shoulder)	51%	19%, 46.8%	Scenario 1, 2	Natunton (Naunton et al., 2020), Smythe (Smythe et al., 2021)
Specialist physiotherapy ^b	6	2, 12	Scenario 1, 2	Hopewell (Hopewell et al., 2021), clinical guidelines
Post-surgery rehabilitation	2	1, 4	Scenario 1, 2	Beard (Beard et al., 2018), Cederqvist (Cederqvist et al., 2021)

Abbreviations

MBS = Medicare Benefit Schedule.

Note

a = The base-case assumptions were taken from utilisation data for item 48951, other than for specialist physiotherapy and post-surgery rehabilitation

b = Specialist physiotherapy is provided by an experienced physiotherapist as the alternative to surgery after the patient has exhausted the physiotherapy sessions available through the MBS chronic disease management plan

Scenario 1 assumptions were based on an overall lower rate of physiotherapy and diagnostic imaging as identified in the literature Scenario 2 assumptions were based on an overall higher rate of physiotherapy and diagnostic imaging services as identified in the literature

Scenario 3 involves the exclusion of MRI and CT from conservative therapy in line with guidelines that do not recommend these services to be available in primary care

3.3 Results

Cost comparison results are presented in this section. The cost difference of treatments with and without surgery is calculated to generate the base-case result, where parametric uncertainties are tested with one-way sensitivity analyses. Due to the variability in clinical practice, 3 separate scenarios were produced as multiway sensitivity analyses to test the cost differences between the 2 treatment pathways in various clinical situations.

3.3.1 Base-case scenario

In this assessment, both the intervention and comparator are currently available; the comparator being a continuation of conservative therapy. It is uncertain if any change in access to SAD would change any aspect of primary care, for example if there would be a difference in the use of diagnostic imaging or corticosteroid injections. In this cost comparison we have assumed no change to primary care with or without surgery.

For the base-case scenario, assumptions for physiotherapy and diagnostic imaging services were taken from the MBS data utilisation analysis for item 48951, supplemented by Naunton 2020

data representing patients with new rotator cuff-related shoulder pain in GP care for corticosteroid injection and use of prescription pain medication (Naunton et al., 2020). Staggered GP visits were estimated in line with best-practice care and referral requirements. As shown in the flow charts, GP consultations were included for the initial presentation, for follow-up for ongoing symptoms and referral to physiotherapy, follow-up for ongoing pain and corticosteroid injections, referral to diagnostic imaging and referral to an orthopaedic surgeon (Figure 13, Figure 14). In the base case, all services and costs up to referral to surgery or continued conservative care were kept the same.

The calculation result of the base-case scenario is provided in Table 20. The calculation was disaggregated by different cost categories where the cost differences of each category are also provided.

Cost component	Intervention with SAD surgery	Intervention without SAD surgery	Cost difference
Referral services	\$234	\$135	-\$100
Prescriptions and medicine cost	\$44	\$24	-\$20
Allied health services	\$327	\$739	\$412
Medical services	\$389	\$75	-\$314
Diagnostic imaging services	\$267	\$267	\$0
Surgical services	\$5,213	\$0	-\$5,213
Total	\$6,474	\$1,239	-\$5,235

Table 20 Cost comparison between interventions with or without surgery – base-case scenario

Abbreviations

SAD = subacromial decompression.

The surgical pathway is more expensive in almost every category of service, ranging from \$100 to \$5,213. The non-surgical pathway costs \$412 more in utilisation of allied health services. This is expected, as the non-surgical pathway will primarily use physiotherapy as the treatment to replace the surgical intervention. No cost difference is observed in utilisation of diagnostic imaging services.

The overall cost difference is estimated at \$5,235 more in the surgical pathway compared to the non-surgical pathway. The most significant contributor to this cost difference is the hospital admission costs and various surgical and medical services directly related to surgery. Disinvestment in surgical intervention may result in an average cost saving of over \$5,000 per patient.

3.3.2 Sensitivity analysis

We identified seven variables across both the intervention and comparator costing pathways that could be considered uncertain. Uncertainty ranges are provided in Table 21, where the high and low ranges were utilised to undertake the cost comparison. The impact of these uncertainties is evaluated separately against treatment with and without surgical intervention. The sensitivity analyses results are tabulated and tornado diagrams produced to visualise the uncertainty impact.

Uncertainty impact of treatment with surgical intervention

Six variables are considered uncertain in the cost estimate of surgical intervention. One-way sensitivity analyses were undertaken to investigate the impact of each uncertain variable. The uncertainty ranges and the resultant cost variations from the base case are presented in Table 21. The associated tornado diagram (see Figure 15) provides a visual interpretation of impact. The base-case value is flagged in both the table and the figure for reference.

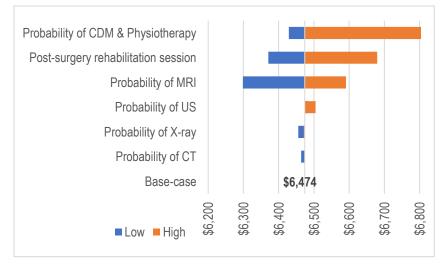
Uncertain variables	Low range	High range	Cost of SAD by low range	Cost of SAD by high range
Probability of CDM & physiotherapy	12.6%	80.5%	\$6,429	\$6,838
Post-surgery rehabilitation sessions	1	4	\$6,371	\$6,680
Probability of MRI	0.50%	72.00%	\$6,298	\$6,591
Probability of US	53.00%	74.00%	\$6,482	\$6,505
Probability of X-ray	19.00%	46.80%	\$6,456	\$6,471
Probability of CT	0.20%	4.40%	\$6,464	\$6,474
Base case = \$6,474		·		*

 Table 21
 Uncertainty ranges and cost impact of the surgical pathway

Abbreviations

CDM = chronic disease management, CT = computed tomography, MRI = magnetic resonance imaging, SAD = subacromial decompression, US = ultrasound.





Abbreviations

CDM = chronic disease management, CT = computed tomography, MRI = magnetic resonance imaging, US = ultrasound.

The one-way sensitivity analysis identified 3 significant cost drivers. The greatest cost driver for the surgical intervention pathway is the likelihood of receiving physiotherapy through the chronic disease management plan. Prior to surgical intervention, patients may still require supervised physiotherapy to manage the condition, and a variation in clinical practice has significant impact on the certainty of the cost estimates. In the extreme cases where patients more commonly receive physiotherapy, it would cost over \$6,700 for a patient to receive the complete set of treatment, which is \$300 more than the base case. Postoperative rehabilitation costs are also uncertain. Patients are likely to require rehabilitation services after surgery, depending on the

preferences of patients and attending clinicians. Both of these cost drivers reflect variable clinical practice in the management of this condition.

Besides these 2 cost drivers, the use of MRI appears to be another cost driver for the estimates. As MRI is commonly associated with the surgical planning, variable usage of MRI in the surgical arm can affect the overall cost of the surgical arm. Omission of MRI could result in the surgical intervention being almost \$200 cheaper than the base case.

Other uncertainties are associated with different diagnostic modalities for diagnosis of the condition; however, these have less impact than the key drivers described above.

Uncertainty impact of treatment with conservative therapy only

Similar to the surgical intervention pathway, six variables were identified as a source of uncertainty in the cost estimate of non-surgical interventions. In the one-way sensitivity analysis, the uncertainty ranges (Table 22) were used to calculate the cost drivers. The associated tornado diagram (see Figure 16) was generated to visualise the impact. The base-case value is flagged in both the table and the figure for reference.

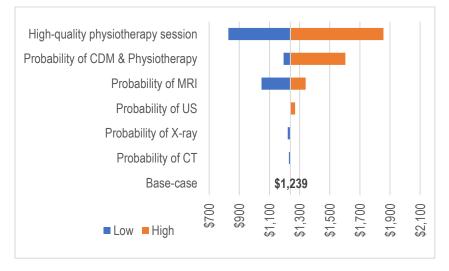
Uncertain variables	Low range	High range	Cost of SAD by low range	Cost of SAD by high range
Specialist physiotherapy session	2	12	\$827	\$1,857
Probability of CDM & physiotherapy	12.6%	80.5%	\$1,194	\$1,603
Probability of MRI	0.50%	72.00%	\$1,047	\$1,340
Probability of US	53.00%	74.00%	\$1,247	\$1,270
Probability of X-ray	19.00%	46.80%	\$1,221	\$1,236
Probability of CT	0.20%	4.40%	\$1,229	\$1,239
Base-case = \$1,239		·		·

 Table 22
 Uncertainty ranges and cost impacts of the non-surgical pathway

Abbreviations

CDM = chronic disease management, CT = computed tomography, MRI = magnetic resonance imaging, SAD = subacromial decompression, US = ultrasound.

Figure 16 Tornado diagram of uncertain variables for non-surgical pathway



Abbreviations

CDM = chronic disease management, CT = computed tomography, MRI = magnetic resonance imaging, SAD = subacromial decompression, US = ultrasound.

In contrast to the cost of the surgical pathway, the cost driver for this pathway is the utilisation of specialist physiotherapy sessions (as the alternative to surgery after services through the CDM have been exhausted). This is in addition to the physiotherapy in the surgical pathway. The distinction between these physiotherapy services is discussed in Section 1.4.7. Due to the high level of variation in clinical practice and costs, frequency of sessions becomes the most significant cost driver for the non-surgical treatment pathway. The difference between the highest and lowest costs could be more than \$1,000, with the most expensive scenario reaching almost \$2,000 per patient. This high level of uncertainty reflects patient requirements, together with the level of acceptance by patients and clinicians for using structured and supervised physiotherapy in managing the condition. Nevertheless, this variation is substantially less impactful than its counterpart in surgical pathways.

The use of conventional physiotherapy and CDM, as well as MRI, are also identified as significant cost drivers. The rationale for these two cost drivers is similar to the surgical scenario. Other uncertain variables are less impactful to the overall cost of the non-surgical pathway.

3.3.3 Scenarios

We performed 3 different scenarios to capture plausible alternative clinical situations for different treatment options for subacromial impingement. Assumptions and healthcare resource usage for these scenarios have been discussed previously.

Scenario 1: lower level of service usage

The study by Naunton 2020 was used to inform a relatively low rate of initial physiotherapy (Naunton et al., 2020). In addition, the utilisation of imaging services, including X-ray, US, MRI and CT, was low in this scenario. From recent published trials by Hopewell 2021 and Beard 2018, we extracted a lower overall use of specialist physiotherapy (for the comparator group) and post-surgery rehabilitation (for the surgery group) in the general population with subacromial shoulder pain (Hopewell et al., 2021, Beard et al., 2018).

Cost component	Intervention with SAD surgery	Intervention without SAD surgery	Cost difference	
Referral services	\$234	\$135	-\$100	
Prescriptions and medicine costs	\$44	\$24	-\$20	
Allied health services	\$179	\$282	\$103	
Medical services	\$389	\$75	-\$314	
Diagnostic imaging services	\$72	\$72	\$0	
Surgical services	\$5,213	\$0	-\$5,213	
Total	\$6,131	\$587	-\$5,544	
Base case	\$6,474	\$1,239	-\$5,235	

Abbreviations

SAD = subacromial decompression.

Compared to the base case, this scenario increases the cost saving from the base case by approximately \$300 dollars (from \$5,235 to \$5,544). This results from the substantially reduced use of physiotherapy in both the surgical and non-surgical arms. This change leads to a more

substantial impact in the non-surgical treatment pathway compared to the surgical pathway, reducing the cost of the non-surgical pathway by approximately one third.

Scenario 2: higher level of service usage

Scenario 2 represents a higher use of services, specifically for physiotherapy and diagnostic imaging.

As the diagnostic imaging services are shared by the two options, there is no incremental cost difference. According to Smythe 2021, the utilisation of diagnostic imaging investigations (X-ray, US and MRI), and initial and secondary physiotherapy sessions was high (Smythe et al., 2021). The probability of having CT remained the same with the base case, as it was not included in Smythe 2021. In this scenario we applied high-range (i.e. 12) sessions of specialist physiotherapy (for the comparator group) as informed by clinical practice guidelines (Section 1.4.7) and 4 sessions of post-surgery rehabilitation (for the surgery group) based on data from Cederqvist 2021 (Cederqvist et al., 2021).

Cost component	Intervention with SAD surgery	Intervention without SAD surgery	Cost difference -\$100	
Referral services	\$234	\$135		
Prescriptions and medicine costs	\$44	\$24	-\$20	
Allied health services	\$897	\$1,721	\$824	
Medical services	\$389	\$75	-\$314	
Diagnostic imaging services	\$413	\$413	\$0	
Surgical services	\$5,213	\$0	-\$5,213	
Total	tal \$7,191		-\$4,823	
Base case	\$6,474	\$1,239	-\$5,235	

Table 24 Scenario 2: higher use of services

Abbreviations

SAD = subacromial decompression.

In contrast with the previous scenario, this scenario reduced the cost saving from the base case by approximately \$400 (from \$5,235 to \$4,823). Increased use of the physiotherapy service resulted in the cost of allied health services being almost doubled in both the surgical and non-surgical treatment pathways. As a result, the cost difference of allied health services also doubled in value, from \$412 in the base-case to \$824 in this scenario, with a greater impact on the non-surgical treatment pathway. Nevertheless, the cost saving from the non-surgical pathway is still substantial.

Scenario 3: exclusion of some diagnostic imaging services

Clinical guidelines commonly recommend that diagnostic imaging, in particular MRI, is not indicated in primary care and should only be offered when surgery is being considered. As shown in Section 3, the referral pattern for diagnostic imaging for MBS item 48951 is in line with best practice. As shown in Section 3, MRI and CT are exclusively or more commonly referred by a specialist or orthopaedic surgeon. In this scenario, it has been assumed that patients who continue with conservative therapy are not referred to a surgeon and thus do not receive MRI or CT, resulting in an incremental cost saving for the intervention with no SAD surgery.

Scenario 3 represents an exclusion of diagnostic imaging services. This scenario analysis examined the cost difference between base case with SAD surgery and an exclusion of MRI and CT from the intervention without SAD surgery.

It should be noted that even in the absence of MBS items for SAD, patients with ongoing symptoms may still be referred to an orthopaedic surgeon and may receive MRI and CT to identify or exclude other shoulder pathologies. Surgery may still be an option for patients with subacromial pain who are subsequently identified with additional or alternative shoulder pathology.

Cost component	Intervention with SAD	Intervention without	Cost difference
·	surgery	SAD surgery	
Referral services	\$234	\$135	-\$100
Prescriptions and medicine costs	\$44	\$24	-\$20
Allied health services	\$327	\$739	\$412
Medical service	\$389	\$75	-\$314
Diagnostic imaging services	\$267	\$79	-\$187
Surgical services	\$5,213	\$0	-\$5,213
Total	\$6,474	\$1,051	-\$5,422
Base case	\$6,474	\$1,239	-\$5,235

Table 25	Scenario 3: reduction in imaging services for conservative therapy
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Abbreviations

SAD = subacromial decompression.

Compared to the base-case analysis, a reduced use of diagnostic imaging for conservative therapy in this scenario results in a lower cost for diagnostic imaging services (from \$267 to \$79). Costs of other components remain unchanged. Therefore, the cost saving in this scenario reduced from the base case of \$5,235 to \$5,422, which is the smallest among the 3 scenarios.

3.4 Conclusions

The cost comparison analysis demonstrates that the management of subacromial impingement via surgical intervention is more expensive than conservative therapy in all scenarios. The disinvestment of surgical intervention could have substantial cost saving to the Australian health system. While the resultant cost saving primarily benefits the health system through public hospitals and the MBS, a higher utilisation of physiotherapy would increase the cost burden to patients or private insurers. The economic impact to patients and insurers is still uncertain due to the variable usage level of physiotherapy in terms of its quality, frequency and cost.

Section 4 Use of the health technology in practice

The assessment aims to estimate the financial and budgetary impact to the MBS for all relevant medical services and therapies for SAD in the management of shoulder impingement. The financial implication to the MBS will be projected to 5-year estimates from the historical data of Medicare claims based on the scope of services currently available in the MBS descriptor (as the base case), plus proposed service scopes under different plausible scenarios. Those scenarios will be compared with the base case to calculate changes if the scenarios should be implemented in the future. Assumptions will be used for both the base-case estimate and the scenarios, due to limitations in the available data. Uncertainties around these assumptions will be investigated and tested in the sensitivity analyses.

4.1 Justification of the selection of approach and data sources

A market-share approach has been used to estimate the financial implication of SAD services in this project. The main data sources used in the estimation and projection of the financial impact include a range of specific data requests for MBS statistics from Services Australia as well as the relevant AIHW data cubes used previously in this report. The data request was mediated by the Department of Health and Aged Care; aggregated MBS claim numbers, patient counts and MBS co-claim patterns were ascertained.

The MBS claim data (and service co-claim patterns) are centred around the 3 surgical service items for this DCAR (MBS item numbers 48900, 48903, 48951). Further, MBS item 48951 (arthroscopic SAD) is used as the basis to estimate patient numbers as well as projected service utilisation in the future. All associated services before and after the surgery are identified through MBS co-claimed patterns and then combined with the surgery to calculate the total impact to the MBS. We also use AIHW data to estimate the number of patients who might have subacromial impingement and be eligible for therapies including surgery with or without physiotherapy. The number of patients and how they are cared for through specific pathways is described in this section in detail, and the financial impact of these pathways is estimated under different scenarios. These estimates may be subject to uncertainties due to certain limitations of the data source and assumptions used.

The epidemiological approach is not considered in this assessment. As previously raised as a major uncertainty (Section 1), there is a lack of defined patient eligibility criteria for SAD and no specific tests or clinical thresholds to characterise patients with subacromial impingement. Patient selections across the included clinical trials appear to be similar, based on the clinical investigations. However, the demographics of the trial patients appear to be restricted to those of relatively younger age; the impact of SAD in older patients is unclear. Therefore, using the epidemiological approach to estimate patient numbers or treatment eligibility is likely to be highly uncertain.

The 3 main sources of information are summarised below in Table 26.

Table 26	Data sources and parameter values applied in utilisation and financial estimates	
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Data	Source and value	Justification
MBS Statistics	Services Australia	MBS claim data is able to provide the status of the service utilisation and provide bases of utilisation projections
MBS co-claim data	Department of Health and Aged Care, data request	MBS co-claim data, including general and specialised consultations, diagnostic imaging, surgery and associated allied care, will inform the pattern of care for SAD treatment
Principal diagnosis for impingement syndrome in hospitals	AIHW data cubes	The principal diagnosis of impingement syndrome of the shoulder in a hospital setting provides an alternative source of information to estimate the number of patients potentially needing SAD

Abbreviations

AIHW = Australia Institute of Health and Welfare, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

4.2 Estimation of use and financial impact of surgical intervention for SAD

This section describes the methodology used for estimating patient numbers for SAD services under the current MBS service scope. All relevant MBS services associated with SAD surgical services (i.e. anaesthesia, diagnostic imaging, medical consultations and allied health services) are identified. Their service costs, benefit levels and utilisation patterns are incorporated into the calculation to derive the financial implications of the SAD surgical service. The level of service usage and claim patterns are based on publicly available data from MBS statistics as well as granular levels of claim data specifically requested for this project, as shown in Section 3. Some calculations involved assumptions and empirical evidence. The uncertainties around the input variables and assumptions are incorporated into the calculations as sensitivity analyses to quantify their impact to the MBS.

4.2.1 Estimation of patient numbers

Using the market-share approach, the number of patients who received SAD MBS services was retrieved from MBS statistics via Services Australia. The volume of historical claims in the past 5 years was used to project the potential use of the relevant MBS services in the next 6 years. The historical data were benchmarked as the basic inputs to predict future eligible patient numbers using a linear assumption. The 3 relevant MBS items were modelled with future projections; however, only the main SAD MBS surgical service (item 48951) was used as the source of estimating future patient numbers. The projection of the other 2 MBS items was used to derive the weighting factors across the utilisation of the 3 items, which was subsequently used to derive the potential MBS cost for the consolidated MBS item under the newly proposed descriptor (see Scenario 1).

The projected patient numbers through this approach are taken in the base case for the calculation of the financial implication for the MBS. The hospital data from AIHW were also considered as an alternative scenario for the estimates as well as a source of validation for the estimation. The results from the model via the AIHW data were used in sensitivity analyses.

The AIHW hospital data presented similar modelling results, with a slight divergent trend where the largest gap of 268 patients is reached in 2027. The historical data and the projection results are illustrated in Figure 17.

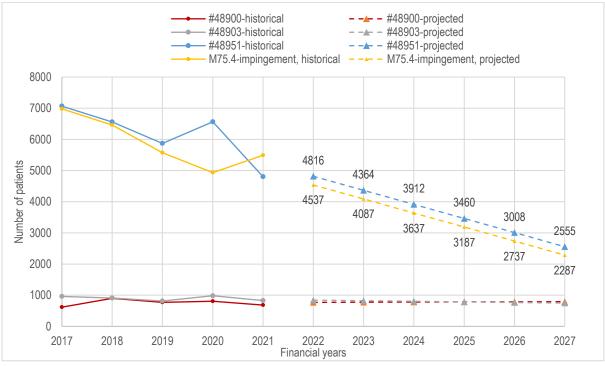


Figure 17 Patient number projection using various data sources for SAD

<u>Notes</u>

M75.4: Impingement syndrome of shoulder with principal diagnoses codes according to ICD-10-AM **Source**

MBS Statistics, AIHW Principal Diagnosis Data Cubes

4.2.2 Identification of relevant MBS services

Several categories of relevant MBS services have been identified through clinical evidence review and MBS data request. The service categories can be broadly divided into 2 groups: 1) services required due to surgery and 2) services used before and after surgery for different SAD pathways. A list of relevant MBS items and their fees used in the calculation of the financial implication to the MBS are tabulated in Table 27 and Table 28.

The MBS data show that the main surgery services for SAD procedures are rarely done in isolation. Three main surgical services are considered relevant to this assessment, as outlined by the PICO. MBS item 48951 is considered the main surgical service to be provided for SAD treatment. The other 2 (48900 and 48903) are considered auxiliary services that may or may not be provided to patients concomitantly with 48951. In other words, it is assumed that only a proportion of surgical patients will receive more than one procedure as a part of SAD management. The usage of concomitant procedures is derived from MBS co-claim data, where variations of the proportions are tested via sensitivity analyses.

The MBS co-claimed data further reveal that several non-SAD surgeries are also performed at the same time when 48951 is undertaken. Three different surgical services are identified through the co-claim pattern data:

- MBS 49590 Excision of ganglion, cyst or bursa of knee, by open or arthroscopic means, performed as an independent procedure, other than a service associated with a service to which another item in this Group applies.
- MBS 48906 SHOULDER, repair of rotator cuff, including excision of coraco-acromial ligament or removal of calcium deposit from cuff, or both not being a service associated with a service to which item 48900 applies.

MBS 48406 – Anatomic or reverse total shoulder replacement, including any of the following (if performed): (a) associated rotator cuff repair; (b) biceps tenodesis; (c) tuberosity osteotomy; other than a service associated with a service to which another item in this Schedule applies if the service described in the other item is for the purpose of performing a procedure on the shoulder region by open or arthroscopic means.

These surgical interventions may have been performed for other indications simultaneously with the SAD procedure for convenience. Although they may not be relevant to the PICO, the substantial proportion of the MBS co-claims reflects how patients may be managed for their shoulder conditions as a whole. While the base-case analysis will not include these services in the calculation, scenario analyses have been designed to investigate the possible financial implication to the MBS when these services are delivered to patients in conjunction with SAD procedures.

Surgery and related MBS services	MBS cost	MBS benefit level assumed	Service content and rationalisation
Service identified in the PICO			
48951	\$945.55	75%	Main surgical service items to be considered in the calculation.
48900	\$298.45	85%	Relevant procedures targeted by the PICO
48903	\$597.15	75%	Relevant procedures targeted by the PICO
Co-claimed service			
49590	\$392.75	75%	Co-claimed MBS surgical services identified through data request
48906	\$597.15	75%	Co-claimed MBS surgical services identified through data request
48406	\$348.40	75%	Co-claimed MBS surgical services identified through data request
Perioperative services			
17610	\$46.15	75%	Anaesthesia consultations required prior to surgery
21622	\$104.75	75%	Anaesthesia procedures, subject to RVG rules
22041	\$41.90	75%	Nerve block procedures relevant to main surgery
22025	\$83.80	75%	Cannulation procedures necessary to anaesthesia process
22012	\$62.85	75%	Monitoring process essential to anaesthesia
51303	\$189.11	75%	Anaesthesia assistance services

Table 27	Relevant MBS services and fees for surgical treatment of SAD

Abbreviations

MBS = Medical Benefit Scheme, RVG = relative value guide, SAD= subacromial decompression.

Notes

The 3 MBS SAD surgery items were targeted by the PASC ratified PICO Confirmation.

Table 28 Relevant MBS services and fees for non-surgical care for SAD before and after surgery

Pathway-related MBS services	MBS cost	MBS benefit level assumed	Service content and rationalisation
Consultations and referrals			
23	\$39.75	100%	Initial contact of patients via general consultation
104	\$91.80	85%	Initial specialist consultation after initial referral from GP

Pathway-related MBS services	MBS cost	MBS benefit level assumed	Service content and rationalisation
105	\$46.15	85%	Follow-up specialist consultation
Imaging services			
63325	\$409.65	85%	MRI (referral) for soft tissue injuries due to impingement
56627	\$228.90	85%	CT (referral) for structural damage due to impingement
55864	\$113.55	85%	Primary US service used in SAD diagnostic pathway
55865	\$39.35	85%	Secondary US services used in SAD diagnostic pathway
55866	\$126.00	85%	Secondary US services used in SAD diagnostic pathway
55867	\$43.75	85%	Secondary US services used in SAD diagnostic pathway
57700	\$42.10	85%	Secondary X-ray service used in SAD diagnostic pathway
57703	\$56.20	85%	Primary X-ray service used in SAD diagnostic pathway
Allied health services			
10960	\$65.85	85%	Physiotherapy sessions by licenced practitioners
10953	\$65.85	85%	Exercise physiotherapy sessions by licenced practitioners
721	\$152.50	100%	Chronic disease management plan initiation by GP
723	\$120.85	100%	GP coordination of team care arrangements

Abbreviations

CT = computed tomography, GP = general practitioner, MBS = Medical Benefit Scheme, MRI = magnetic resonance imaging, SAD = subacromial decompression, US = ultrasound.

Notes

The 3 MBS SAD surgery items were targeted by the PASC ratified PICO Confirmation.

4.2.3 Base-case and alternative assumptions

A range of assumptions were used to estimate potential costs to the MBS over the 6 projected financial years. The assumptions ranged from methodological approaches to how relevant services could be used by clinicians and patients throughout the delivery of SAD therapies. All assumptions used in the calculations are tabulated in Table 29.

Assumptions	Information source	Justification
Linear trend of patient numbers	Not applicable	Simplest option available, where other models may suffer from overfitting or higher levels of uncertainties.
MBS historical claims used for projection	MBS Statistics	Best data relevant and available for the analysis
Level of MBS benefits: 75% for all surgeries and 85% for all out-of-hospital services	MBS	Assuming all surgical services (and associated perioperative medical services) are delivered in hospitals where patients are admitted. All other services delivered as out-of-hospital services in the community setting.
Concomitant surgical services co-claimed for MBS billing not included in the base case	Service Australia	A limited proportion of patients receive multiple operations in one episode of care. The MBS multiple operation rule applies for second or third concomitant procedures for different purposes. The financial impact of simultaneous surgical procedures would likely to be small.
Various utilisation factors applied to anaesthesia services during operations	MBS administrative data request	A range of anaesthesia services were identified together with the MBS SAD services co-claim data request. It was assumed that the various proportions of co-claim patterns reflect the complexity of anaesthesia services required.

 Table 29
 Assumptions and associated values used in the calculation for SAD financial impact

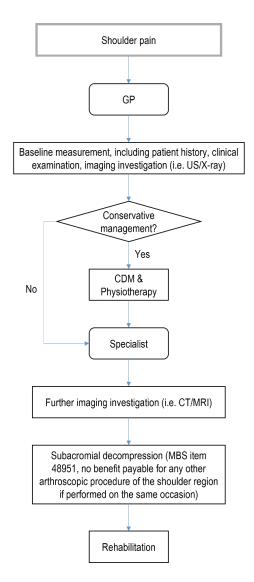
Assumptions	Information source	Justification
Various diagnostic imaging services used to reflect potential patient pathways to access surgical care	MBS administrative data request	Imaging services with or without referral requirement were retrieved and aggregated from the data request and used in the calculation. Variations in different imaging services reflect how patients access surgical intervention through various pathways. Proportions were varied in scenario analyses to test their impact on overall costs.
Patient physiotherapy access through CDM and MBS services	Assumption and MBS administrative data request	It was assumed that patients receive CDM before they can access MBS-reimbursed physiotherapies, and 5 basic sessions would be available for patients under the current reimbursement arrangement.

Abbreviations

CDM = chronic disease management, GP = general practitioner, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

The utilisation of these assumptions forms the basis of the base-case evaluation for MBS SAD services under the current scope defined by the MBS descriptors. A flowchart based on the clinical management algorithm in the ratified PICO confirmation was created to capture key clinical steps from diagnosis to completion of SAD surgical services (Figure 18). The flowchart was also modified in scenario analyses to reflect alternative values of model inputs under the context of MBS service scope modification.

Figure 18 Base case clinical flowchart



Abbreviations

CDM = chronic disease management, **CT** = computed tomography, **GP** = general practitioner, **MBS** = Medicare Benefits Schedule, MRI = magnetic resonance imaging, **US** = ultrasound.

4.3 Financial implication for the MBS

This section presents the base-case estimates of the financial impact of SAD procedures and associated medical services to the MBS. Further, the potential impact of various assumptions used in the calculations are also presented.

4.3.1 Base-case scenario

Based on patient estimates from the historical MBS data, the number of patients projected from financial years 2022–2027 was used as the base to estimate the financial impact. Subsequently, the aggregated costs of relevant categories of MBS services were calculated based on MBS data analyses and assumptions described previously. Total cost implications to the MBS in the base case was thus produced over the 6-year period. Calculation results by medical service categories are presented in Table 30. The base case scenario excludes all MBS items for surgery other than for SAD. The base-case scenario assumes that the ongoing claiming patterns of the 3 SAD items continues unchanged and includes all co-claiming with other surgical items.

2022	2023	2024	2025	2026	2027
·					
4,816	4,364	3,912	3,460	3,008	2,555
\$3,415,610	\$3,094,927	\$2,774,244	\$2,453,560	\$2,132,877	\$1,812,194
\$1,294,249	\$1,172,735	\$1,051,221	\$929,707	\$808,193	\$686,679
\$1,205,750	\$1,092,545	\$979,340	\$866,135	\$752,930	\$639,725
\$453,163	\$410,617	\$368,070	\$325,524	\$282,978	\$240,431
\$ 532,899	\$ 482,866	\$ 432,833	\$ 382,801	\$ 332,768	\$ 282,736
\$6,922,388	\$6,272,417	\$5,622,489	\$4,974,574	\$4,322,653	\$3,672,731
	4,816 \$3,415,610 \$1,294,249 \$1,205,750 \$453,163 \$532,899	4,816 4,364 \$3,415,610 \$3,094,927 \$1,294,249 \$1,172,735 \$1,205,750 \$1,092,545 \$453,163 \$410,617 \$532,899 \$482,866	4,816 4,364 3,912 \$3,415,610 \$3,094,927 \$2,774,244 \$1,294,249 \$1,172,735 \$1,051,221 \$1,205,750 \$1,092,545 \$979,340 \$453,163 \$410,617 \$368,070 \$532,899 \$482,866 \$432,833	4,816 4,364 3,912 3,460 \$3,415,610 \$3,094,927 \$2,774,244 \$2,453,560 \$1,294,249 \$1,172,735 \$1,051,221 \$929,707 \$1,205,750 \$1,092,545 \$979,340 \$866,135 \$453,163 \$410,617 \$368,070 \$325,524 \$532,899 \$482,866 \$432,833 \$382,801	4,816 4,364 3,912 3,460 3,008 \$3,415,610 \$3,094,927 \$2,774,244 \$2,453,560 \$2,132,877 \$1,294,249 \$1,172,735 \$1,051,221 \$929,707 \$808,193 \$1,205,750 \$1,092,545 \$979,340 \$866,135 \$752,930 \$453,163 \$410,617 \$368,070 \$325,524 \$282,978 \$532,899 \$482,866 \$432,833 \$382,801 \$332,768

Table 30 Base-case result of projected financial impact of SAD therapy for financial years 2022–2027

Abbreviations

CDM = chronic disease management, GP = general practitioner, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

The base-case result shows that in the 2022 financial year there would be slightly fewer than 5,000 patients receiving SAD surgical services, based on the current service scope in the existing MBS items. Numbers will decline over the 6-year period to 2,555 patients in 2027. The surgery alone in the first year will cost the MBS over \$3.4 million; total cost of surgical services (including all perioperative costs, not including hospital fees and charges) will exceed \$4.7 million. Considering pathway costs where various GP and specialist consultations, diagnostic imaging and allied health services are all included, the total financial impact for the MBS is estimated at

over \$6.9 million in 2022. Due to the declining patient numbers, the cost will reduce by approximately 46.9% to approximately \$3.8 million in 2027.

4.4 Scenarios

The base-case scenario and cost projections are subject to uncertainties. These uncertainties stem from both the data used in the calculations and how MBS SAD services could change in the future following the outcome of this review. Therefore, it was considered important to undertake multivariate sensitivity analyses to capture financial implications for the MBS under different plausible scenarios of MBS SAD service modification.

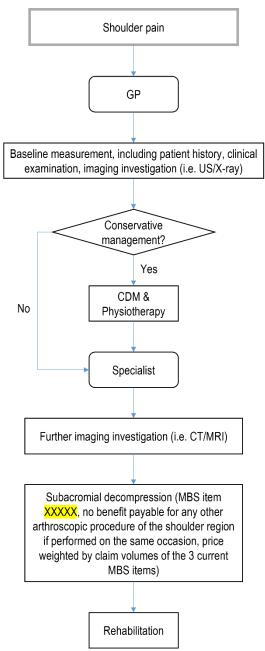
Four scenarios were generated. The service scope modifications were based on findings of the best available evidence in the clinical sections above, as well as from public consultation feedback and information from MBS item utilisation. Each scenario has one or more input variables using alternative values or options to reflect potential changes in service scope of patient options. Flow charts were created to illustrate SAD care pathways under each proposed scenario to compare and contrast with the base case to observe the driver of the main difference. Calculations and evaluation results were tabulated for each scenario. The net impact to the MBS compared to the base case is presented at the bottom of each table.

4.4.1 SAD MBS item consolidation

Based on the results of the MBS Review and from PASC discussion, SAD MBS services are proposed to be consolidated into a new MBS item where all relevant SAD procedures are captured by a single item descriptor. Explicit notes will be provided outlining co-claiming restrictions. The proposed item descriptor has been provided previously (Appendix G). In this scenario, only one surgical item (and its cost) is included in the estimate and all other variables remain unchanged. Based on recommendations from the MBS Review Taskforce Report, the fee for the proposed SAD surgery item was estimated based on the weighted average of the existing SAD surgeries (48900, 48903 and 48951), where the weights for each item were based on the utilisation. Using this approach and for the purposes of this assessment the proposed fee of the new consolidated MBS service item was calculated to be \$793.

A revised clinical flowchart illustrates the newly proposed MBS service (Figure 19). The key modification is highlighted in the relevant segment of the pathway.

Figure 19 Scenario 1 clinical flowchart



Abbreviations

CDM = chronic disease management, CT = computed tomography, GP = general practitioner, MBS = Medicare Benefits Schedule, MRI = magnetic resonance imaging, US = ultrasound.

The financial impact to the MBS under the consolidated MBS service for SAD surgery is presented in Table 31 with the same format as the base-case table.

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Estimated use and cost of the proposed health technology						
Number of people eligible for the proposed new SAD surgical service in the MBS	4,816	4,364	3,912	3,460	3,008	2,555

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Cost of the proposed new SAD surgical service in the MBS	\$2,458,377	\$2,234,675	\$2,010,974	\$1,787,272	\$1,563,570	\$1,339,869
Cost of surgery-related services (e.g. nerve blocks, anaesthesia)	\$1,294,249	\$1,172,735	\$1,051,221	\$929,707	\$808,193	\$686,679
Cost of various diagnostic imaging services	\$1,205,750	\$1,092,545	\$979,340	\$866,135	\$752,930	\$639,725
Cost of allied health services (e.g. CDM, physiotherapies)	\$ 532,899	\$ 482,866	\$ 423,833	\$ 382,801	\$ 332,768	\$ 282,736
Cost of consultations (GP or specialists visits)	\$473,831	\$429,345	\$384,858	\$340,371	\$295,884	\$251,397
Total cost to MBS	\$5,965,105	\$5,412,165	\$4,859,255	\$4,306,286	\$3,753,346	\$3,200,406
Change in use compared to base case						
Net financial impact compared to base case	-\$957,233	-\$860,252	-\$763,270	-\$666,288	-\$569,307	-\$472,325

Abbreviations

CDM = chronic disease management, GP = general practitioner, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

4.4.2 Full preoperative physiotherapy

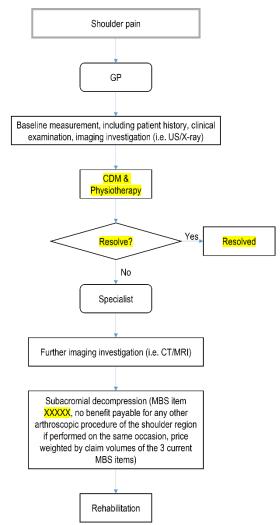
Under this scenario, patients are selected based on the effectiveness of physiotherapy (including general physiotherapies and exercise physiotherapies) before being considered for surgery. To become eligible for surgical intervention and in line with the PICO criteria, patients must have subacromial impingement unresolved for 6 months or more. This would suggest greater levels of physiotherapy. This scenario is consistent with some of the clinical evidence whereby only a proportion of patients underwent surgery after full rehabilitation. Two publications presented relevant data:

- Cederqvist: after 3 months rehabilitation, 39% of participants were subsequently excluded from further participation in the study due to a combination of improved symptoms and change of diagnosis (i.e. no need for surgery after formal rehabilitation) (Cederqvist et al., 2021)
- Holmgren 2012: in patients with shoulder impingement pain who had failed conservative therapy, patients were randomised to specific shoulder strengthening exercises, or to non-specific movement. Following a 12-week program, patients who had received specific exercises were less likely to choose to undergo surgery (20% versus 63%) (Holmgren et al., 2012).

In Australian clinical practice, access to physiotherapy is varied and likely not common. Thus, it would be reasonable to assume that only a proportion of patients still receive surgery despite a full course of physiotherapy. Data from Cederqvist were used for the algorithm as this was considered to be representative of this scenario.

A revised clinical pathway illustrates the updated surgery eligibility criteria incorporating the effectiveness of preoperative physiotherapies (Figure 20). Key modifications are highlighted in the relevant segment of the pathway.

Figure 20 Scenario 2 clinical flowchart



Abbreviations

CDM = chronic disease management, CT = computed tomography, GP = general practitioner, MBS = Medicare Benefits Schedule, MRI = magnetic resonance imaging, US = ultrasound.

The financial impact to the MBS under the full preoperative physiotherapy scheme is presented in Table 32.

Table 32	Scenario 2 result – restricted patient eligibility by effectiveness of preoperative physiotherapy
Table JZ	Scenario 2 result – resultied patient engibility by enectiveness of preoperative physiotherapy

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Estimated use and cost of the proposed health technology						
Number of people eligible for the proposed new SAD surgical service in the MBS	4,816	4,364	3,912	3,460	3,008	2,555
Cost of the proposed new SAD surgical service in the MBS	\$1,499,610	\$1,363,152	\$1,226,694	\$1,090,236	\$953,778	\$817,320
Cost of surgery-related services (e.g. nerve blocks, anaesthesia)	\$789,492	\$715,368	\$641,245	\$567,121	\$492,998	\$418,874
Cost of various diagnostic imaging services	\$875,960	\$793,718	\$711,476	\$629,234	\$546,993	\$464,751
Cost of allied health services (e.g. CDM, physiotherapies)	\$2,664,493	\$2,414,330	\$2,164,167	\$1,914,005	\$1,663,842	\$1,413,679
Cost of consultations (GP or specialists visits)	\$363,703	\$329,556	\$295,409	\$261,262	\$227,115	\$192,967
Total cost to MBS	\$6,193,257	\$5,616,126	\$5,038,991	\$4,461,858	\$3,884,725	\$3,307,592
Change in use compared to base case						
Net financial impact to MBS compared to base case	-\$ 729,081	-\$ 656,293	-\$ 583,504	-\$ 510,716	-\$ 437,928	-\$ 365,139

Abbreviations

CDM = chronic disease management, GP = general practitioner, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

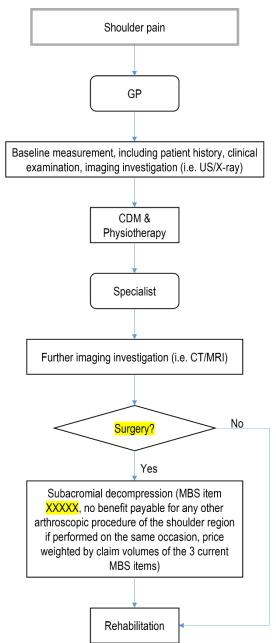
4.4.3 Restrictions in accessing current MBS SAD surgical services

Scenario 3 further restricts eligibility to SAD surgical intervention to groups of patients with findings of radiological changes of impingement. These restrictions were suggested by the Shoulder and Elbow Society of Australia during stakeholder consultation.

One included study showed that approximately 55% of all-surgical patients had radiological changes of impingement, where the impingement sign was linked with better (statistically significant) surgical outcomes (Singh et al., 2014). These patients also had longer symptom duration over 6 months, despite conservative therapies including at least a 3-month course of physiotherapy (by a qualified therapist, as described in Scenario 3) without significant improvement.

A revised clinical pathway illustrates the updated surgery eligibility criteria under the effectiveness of preoperative physiotherapies (Figure 21). Key modifications are highlighted in the relevant segment of the pathway.

Figure 21 Scenario 3 clinical flowchart



Abbreviations

CDM = chronic disease management, CT = computed tomography, GP = general practitioner, MBS = Medicare Benefits Schedule, MRI = magnetic resonance imaging, US = ultrasound.

The financial impact to the MBS under the additional SAD surgical restriction scenario is presented in Table 33, with the same format as for the base-case table.

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Estimated use and cost of the proposed health technology						
Number of people eligible for the proposed new SAD surgical service in the MBS	4,816	4,364	3,912	3,460	3,008	2,555
Cost of the proposed new SAD surgical service in the MBS	\$1,360,958	\$1,237,116	\$1,113,275	\$989,434	\$865,592	\$741,751
Cost of surgery-related services (e.g. nerve blocks, anaesthesia)	\$716,496	\$649,226	\$581,956	\$514,686	\$447,416	\$380,146
Cost of various diagnostic imaging services	\$1,291,109	\$1,169,890	\$1,048,671	\$927,452	\$806,233	\$685,014
Cost of allied health services (e.g. CDM, physiotherapies)	\$2,664,493	\$2,414,330	\$2,164,167	\$1,914,005	\$1,663,842	\$1,413,679
Cost of consultations (GP or specialists visits)	\$473,831	\$429,345	\$384,858	\$340,371	\$295,884	\$251,397
Total cost to MBS	\$6,506,886	\$5,899,906	\$5,292,926	\$4,685,947	\$4,078,967	\$3,471,987
Change in use compared to base case	·	·				·
Net financial impact to the MBS compared to base case	-\$415,452	-\$372,511	-\$329,569	-\$286,628	-\$243,686	-\$200,745

Table 33 Scenario 3 result – financial implication to MBS under additional SAD surgical service restrictions

CDM = chronic disease management, GP = general practitioners, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

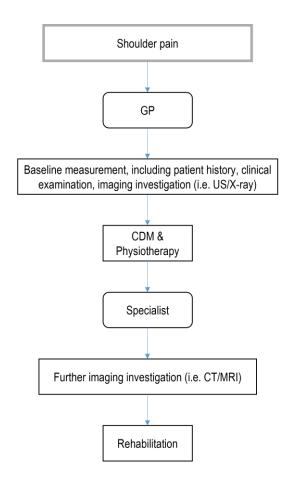
4.4.4 Complete removal of SAD surgical services from MBS

Scenario 4 assumes that SAD surgical services will be completely removed from the MBS; all patients will be managed by GP and allied health services with physiotherapy (including general physiotherapy and exercise physiotherapy) used to treat and manage the condition. In this case, all surgery-related MBS items would no longer be applicable. Due to the uncertainty in clinical management a conservative assumption is made that specialist referrals would remain. This scenario assumes that all required diagnostic imaging is undertaken to investigate the disease regardless of the available therapies, including baseline investigations (US or X-ray) and specialist referral-based modalities (CT or MRI).

It was assumed that patients would be enrolled in one or more CDM plans to access physiotherapy via the Medicare program. It is understood that the number of sessions that patients can access through the MBS is limited and this limited number may not be adequate for disease resolution. Patients may need to access additional physiotherapy sessions via private health insurance or out-of-pocket expense. These costs are not captured by the current calculation.

A revised clinical pathway illustrates the updated surgery eligibility criteria under the effectiveness of preoperative physiotherapies (Figure 22). Surgery is not included in this pathway.

Figure 22 Scenario 4 clinical flowchart



Abbreviations

CDM = chronic disease management, CT = computed tomography, GP = general practitioner, MRI = magnetic resonance imaging, US = ultrasound.

The financial impact to the MBS under the complete disinvestment scenario is presented in Table 34.

Table 34	Scenario 4 result – financial implication to MBS under complete disinvestment of SAD surgical
services from	n MBS

MBS cost evaluations	2022	2023	2024	2025	2026	2027
Estimated use and cost of the proposed health technology						
Number of people eligible for the proposed new SAD surgical service in the MBS	4,816	4,364	3,912	3,460	3,008	2,555
Cost of various diagnostic imaging services	\$1,205,750	\$1,092,545	\$979,340	\$866,135	\$752,930	\$639,725
Cost of allied health services (e.g. CDM, physiotherapies)	\$2,664,493	\$2,414,330	\$2,164,167	\$1,914,005	\$1,663,842	\$1,413,679
Cost of consultations (GP visits)	\$473,831	\$429,345	\$384,858	\$340,371	\$295,884	\$251,397
Total cost to MBS	\$4,344,074	\$3,936,219	\$3,528,365	\$3,120,510	\$2,712,656	\$2,304,801
Change in use compared to base case						
Net financial impact to MBS compared to base case	-\$2,578,265	-\$2,336,198	-\$2,094,131	-\$1,852,064	-\$1,609,997	-\$1,367,930
Abbreviations		1	1		1	

CDM = chronic disease management, GP = general practitioners, MBS = Medical Benefit Scheme, SAD = subacromial decompression.

MBS item utilisation data analysis 5.1

The terms of reference for this assessment include a review of the utilisation of SAD services, as informed by MBS data and other administrative data that may provide additional insight to clinical use. Information from this analysis, in addition to clinical evidence, is used to inform relevant scenarios for the economic evaluation and budget impact of potential recommendations regarding MBS items for SAD (see Section 4 and Section 5).

5.1.1 Existing MBS items for SAD

SAD is commonly performed in Australia and is currently reimbursed through a number of MBS items that include a range of procedures. Three items related to SAD (48900, 48903, 48951) have been available on the MBS since 1 December 1991 under group T8: surgical operations, subgroup 15: orthopaedic, subheading: shoulder (Appendix G).

The item descriptors provide no information for patient selection. Item 48951 is restricted (not being a service associated with any other arthroscopic procedure of the shoulder region). Items 48900 and 48903 have no restrictions on their use.

Item 48951 is specific for arthroscopic surgery. Items 48900 and 48903 are not restricted to any surgical approach. It is likely that open surgery for SAD was more common in 1991 when these items were first available, although the intended use or surgical approach for these items is not stated.

Three separate items in parallel with similar descriptors (items 48900, 48903 and 48951) are available for repair of rotator cuff tendons (Appendix G). The review of the rotator cuff items was not within the scope of this current assessment.

A summary of the number of services per financial year is shown in Table 35. In 2020–21 the number of claims for each item was:

- 48900: 807 services •
- 48903: 983 services
- 48951: 6.566 services

While the number of services claimed for 48900 and 48903 has remained relatively consistent over recent years, there has been a downward trend in the number of services for 48951 (Figure 23).

MBS item	2017–18	2018–19	2019–20	2020–21	2021–22
48900	616	899	772	807	685
48903	960	910	812	983	829
48951	7,066	6,560	5,871	6,566	4,802

Table 35 Number of MBS services per year

Abbreviations

MBS = Medicare Benefit Schedule. Notes

Total percentage may not sum to 100% due to rounding. <u>Source</u> Medicare Item Reports (http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp)

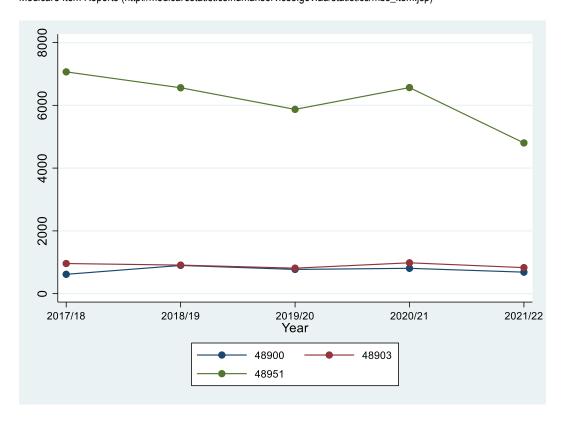


Figure 23 Number of MBS services per year for item 48900, 48903 and 48951 (2017–18 to 2021–22)

Source

Medicare Item Reports (http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp)

5.1.2 Other MBS items that may be associated with SAD

The following MBS services were included to investigate any relationship with SAD.

Diagnostic imaging

- 55864, Shoulder or upper arm, or both, left or right, US scan of (referrer [R])
- 55865, Shoulder or upper arm, or both, left or right, US scan of (non-referrer [NR])
- 55866, Shoulder or upper arm, or both, left or right, US scan of, bilateral (R)
- 55867, Shoulder or upper arm, or both, left or right, US scan of, bilateral (NR)
- 56627, Computed tomography—scan of upper limb, left or right or both, any one region, or more than one region, without intravenous contrast medium (R)
- 56628, Computed tomography—scan of upper limb, left or right or both, any one region, or more than one region, with intravenous contrast medium and with any scans of the upper limb before intravenous contrast injection, when performed (R)
- 57700, Diagnostic radiology, Shoulder or scapula (NR)
- 57703, Diagnostic radiology, Shoulder or scapula (R)
- 63325, MRI—scan of musculoskeletal system for derangement of shoulder or its supporting structures (R)

Physiotherapy

A musculoskeletal condition that has been present or is likely to be present for 6 months or longer is termed a chronic medical condition, and patients are eligible to have Chronic Disease Management (CDM) on the MBS. CDM enables a GP to plan and coordinate a multidisciplinary team, which may include physiotherapists. Under CDM, a patient is allocated 5 sessions per calendar year with a Medicare rebate for allied health services, which includes physiotherapy:

- 10953, Exercise physiology service provided to a person by an eligible exercise physiologist
- 10960, Physiotherapy health service provided to a person by an eligible physiotherapist

Associated MBS services in preparation or review of the CDM are items 721 and 723 for GP consultation¹¹.

5.1.3 AIHW separation and procedures associated with subacromial impingement or SAD

The number of separations per year for the principal diagnoses of rotator cuff syndrome, impingement syndrome of the shoulder, and injury of muscle and tendon of the rotator cuff of shoulder is shown in Figure 29 (Appendix H). In 2020–21 there were 5,492 separations for shoulder impingement, with an average length of hospital stay of 1.14 days (AIHW, 2022a).

The number of patients with a principal diagnosis of impingement syndrome of the shoulder has reduced over recent years.

A summary of procedures in Australian hospitals related to SAD is provided in Figure 30 (Appendix H). In 2020–21 there were (AIHW, 2022b):

- 39 procedures for 48900-00 Excision of coraco-acromial ligament
- 205 procedures for 48900-01 Excision of calcium deposit from rotator cuff
- 796 procedures for 48903-00 Decompression of subacromial space
- 11,098 procedures for 48951-00 Arthroscopic decompression of subacromial space

It is unclear if these procedure codes are used independently of other procedures for the shoulder, therefore it is uncertain if these procedures were used exclusively for patients with subacromial impingement and no other shoulder pathology.

While the number of procedures for arthroscopic SAD in Australian hospitals has increased since its introduction, numbers have plateaued over the past 5 years (Figure 30).

5.1.4 Methods

An analysis of MBS utilisation data provides an opportunity to use administrative data to investigate relationships across different services. Our aim was to analyse claiming patterns for the 3 relevant SAD MBS items in conjunction with other associated services. These data will provide information on MBS item-use for consultation, referrals, diagnostic imaging and treatment across different clinical scenarios, and provide an indication of common themes and variations in care over a patient's care pathway.

For this assessment, the data analysis was structured to:

¹¹ <u>http://www9.health.gov.au/mbs/fullDisplay.cfm?type=note&q=MN.3.1&qt=noteID</u>

- review the use of existing MBS items for SAD
- analyse patterns of co-claiming with other MBS services including diagnostic imaging, physiotherapy and services related to surgery
- investigate population demographic characteristics (age, sex)
- investigate the source of the referral
- investigate claim combinations of services across all service groups (i.e. surgery, imaging, conservative therapies).

A range of datasets was provided for this analysis:

- AIHW Australian hospital procedures and healthcare interventions (11th edition) for separations (by age and sex) for SAD (48903-00) and arthroscopic SAD (48951-00), for 2020-21 (n = 11,894) (AIHW, 2022b)
- AIHW Australian hospitals principal diagnosis (ICD-10-AM 11th edition) for separations (by age and sex) for M75.4 impingement syndrome of shoulder, for 2020–21 (n = 5,492) (AIHW, 2022a)
- 3. MBS services data for items 48900, 48903 and 48951, provided as number of services (by age and sex), for 2020–21 (n = 807, 983 and 6,566, respectively) (MBS, 2022b)
- MBS co-claiming data provided as services for 2020–21 as a percentage of episodes of co-claimed combinations for the top 10 combinations based on trigger items 48900, 48903 and 48951 (provided on the day of surgery and within 14 days of surgery)
- MBS co-claiming data provided as services for 2020–21 as a percentage of episodes of the top 10 co-claimed services based on trigger items 48900, 48903 and 48951 (provided on the day of surgery and within 14 days of surgery)
- 6. MBS diagnostic imaging services, provided as number of services and referrer, reported by surgery patients and surgery services, for items 48900, 48903 and 48951, for financial year 2020–21
- 7. MBS patients who received 48900, 48903 and 48951, and who had exercise physiology or physiotherapy, by number of patients, age and sex
- 8. MBS patients who received 48900, 48903 and 48951, and who had diagnostic imaging services by number of patients, age and sex.

These data were sourced from public datasets (1 to 3) and provided by the Department of Health, Medical Benefits Division, MBS Analytics Section (4 to 8). Data were provided by service volume, patient counts and as percentages of episodes (for co-claimed combinations) for services rendered between 1 July 2020 and 30 June 2021.

For the purposes of this analysis, the data are tabulated or displayed graphically and themes described narratively. The datasets were analysed descriptively using frequency counts and proportions to determine information on the number of surgeries performed, number and type of diagnostic imaging provided and the associated referral pattern, and patient access to allied health interventions (physiotherapy and/or exercise physiology). The output was stratified by age and sex to provide a clear picture of the population characteristics in relation to surgery and diagnostic imaging.

5.1.5 Limitations of this analysis

The analyses were limited in various ways:

- AIHW principal diagnosis data is likely to underrepresent the number of patients diagnosed with subacromial impingement, as patients are commonly identified in primary care.
- Current MBS items for US and CT have been available only since May 2020.

- It is likely that the COVID-19 pandemic has impacted all MBS items in this dataset due to lockdowns and restrictions on patient access to non-emergency services. The qualitative impact of this effect, and whether this is consistent across all surgical, diagnostic and allied health services, is uncertain.
- The claim analysis was not restricted to a specific diagnosis or linked to one specific intervention. Therefore co-claimed services accessed over a certain time period may be associated with other care pathways for other conditions.
- One episode of care can overlap a financial year, therefore co-claimed items accessed prior to this time period are likely to be under-represented (e.g. diagnostic imaging and physiotherapy).
- Detailed analyses were completed on data from one financial year as the number of annual services for each item was deemed to be sufficient. An analysis of a longer time period would have increased the total number of all MBS services, including services claimed by the patient for other indications and reduce the usefulness of the dataset. Data from one financial year provides representative information regarding the use of SAD items in Australia.
- There is limited information on a patient's access to physiotherapy or exercise physiology. While the MBS data provide useful information on allied health services access, it is not possible to determine the exact number of allied health sessions and whether the intervention was accessed before or after surgery.
- For physiotherapy and exercise therapy, patients may choose to access these services prior to, after, or instead of MBS-funded services (e.g. via private health insurance or out-of-pocket payment).
- Co-claiming data are restricted to the top 10 combinations, therefore do not represent the entirety of service provision but do represent the most common uses of the items.

5.1.6 Co-claiming

Data were provided for the 3 SAD MBS items within the co-claimed combination provided during a surgical episode of care. There was no restriction to any pre-specified MBS item or items. Data were presented as the top 10 co-claimed combinations (as a proportion of all episodes) rendered on the day of surgery of the trigger item (49800, 48903 or 48951). These datasets are limited in use as they are not a complete description of all surgical services. They are described here as an indication of the most common co-claimed patterns.

Data were also provided for combinations submitted from 14 days before to 14 days after the trigger item. These data were impacted by a range of additional services, including diagnostic imaging and consultations, which limited the relevance of these datasets as relevant to shoulder surgery. Consequently, the 14-day data were not analysed further and are not presented here.

The results are summarised in Table 70.

Item 48900 (SHOULDER, excision of coraco-acromial ligament or removal of calcium deposit from cuff or both), is commonly claimed in the absence of any anaesthetic service. Item 48900 is co-claimed with US or echography in conjunction with a surgical procedure using interventional techniques (55848, 5850 or 55850) in a total of 91.6% of all episodes (data not shown). Thus it is likely that the most common use of this item is for image-guided removal of calcium deposits with injection (e.g. lavage), by radiologists or in specialist or GP rooms.

Item 48900 is used in conjunction with anaesthesia in only 6.65% of all episodes. Of the top 10 most commonly claimed episodes (representing 81% of all episodes), 48900 is claimed rarely with 48951 (SHOULDER, arthroscopic division of coraco-acromial ligament including

acromioplasty), or with total shoulder replacement (1% and 0.75% respectively) (Appendix H) (Table 70).

Item 48903 (SHOULDER, decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination) is most commonly used in association with other shoulder services. It is co-claimed with 49590, excision of ganglion, cyst (44% of occurrences), 48954, synovectomy of shoulder (40% of occurrences) and 48918 total shoulder replacement (20% of occurrences) (data not shown).

In the top 10 episodes of 2020–21 (representing 18% of all episodes), the MBS item 48903 is less commonly associated with other SAD items and more commonly used in conjunction with surgical items for other shoulder pathology (Table 70).

Item 48951 (SHOULDER, arthroscopic division of coraco-acromial ligament including acromioplasty – not being a service associated with any other arthroscopic procedure of the shoulder region) is used as the only surgical item for 51% of all top 10 episodes (Appendix H) (Table 70). Other uses of this item are in combination with other shoulder services, including removal of ganglion or cyst, tendon and ligament transfer, and rotator cuff repair. In 2020–21, the top 10 episodes of 48951 being the trigger item, represented 24.5% of all use, therefore many less common combined uses of 48951 are not recognised.

Item 48951 is co-claimed with other shoulder surgery items including 49590, excision of ganglion, cyst (39% of top 10 occurrences); 48906, repair of rotator cuff (32% of top 10 occurrences); and 48406, osteotomy of fibula, radius, ulna, clavicle, scapula (other than acromion), rib, tarsus or carpus, for correction of deformity (21% of top 10 occurrences).

5.1.7 Demographic information

The demographic information is based on 3 datasets. Data on patient characteristics (age-group and sex) were sourced from AIHW Australian hospitals principal diagnosis (ICD-10-AM 11th edition) for M75.4 impingement syndrome of shoulder (2020–21). These data do not represent the entire population of patients with shoulder impingement in Australia but provide insights on patient demographic characteristics.

The hospital data show that 55.5% of patients were male. There were similar proportions of patients in the younger (0–54 years, 47.1%) and middle-age (55–74 years, 47.0%) groups (Table 36).

Sex and age group (years)	M75.4	% of total (by age)	% of total (by sex)
Female total	2,445	44.5%	100%
0–54	1,161	44.8%	47.5%
55–74	1,150	44.2%	47.0%
75+	134	44.1%	5.5%
Male total	3,047	55.5%	100%
0–54	1,428	55.2%	46.9%
55–74	1,449	55.8%	47.6%
75+	170	55.9%	5.6%
Total (female and male)	5,492	100.0%	

Table 36	Patient characteristics by age and sex, AIHW principal diagnosis (M75.4 impingement syndrome of
shoulder)	

Sex and age group (years)	M75.4	% of total (by age)	% of total (by sex)
0–54	2,589	47.1%	
55–74	2,599	47.3%	
75+	304	5.5%	

Abbreviations

AIHW = Australian Institute of Health and Welfare.

Total percentage may not sum to 100% due to rounding.

Source

Dataset 2: AIHW Australian hospitals principal diagnosis (ICD-10-AM 11th edition) data

The second dataset is from 2020-21 AIHW data for procedures 48903-00 or decompression of subacromial space and 48951-00 or arthroscopic decompression of subacromial space (Table 37). For both procedures, patients were more often male (58.2% and 57.4%, respectively). For 48903-00, there was a greater proportion of younger males; for 49851-00, females and males were similarly distributed across the 3 age brackets. With slightly more younger patients (0–54) than older patients (55–74), and few elderly patients (75+).

Sex and age group (years)	48903- 00	% of total (by age)	% of total (by sex)	48951- 00	% of total (by age)	% of total (by sex)	Total procedures	% of total (by age)	% of total (by sex)
Female total	333	41.8%	100%	4,728	42.6%	100%	5,061	42.6%	100%
0–54	135	37.6%	40.5%	2,341	42.2%	49.5%	2,476	41.9%	48.9%
55–74	150	41.6%	45.0%	2,159	42.9%	45.7%	2,309	42.8%	45.6%
75+	48	63.2%	14.4%	228	43.9%	4.8%	276	46.4%	5.5%
Male total	463	58.2%	100%	6,370	57.4%	100%	6,833	57.4%	100%
0–54	224	62.4%	48.4%	3,204	57.8%	50.3%	3,428	58.1%	50.2%
55–74	211	58.4%	45.6%	2,875	57.1%	45.1%	3,086	57.2%	45.2%
75+	28	36.8%	6.0%	291	56.1%	4.6%	319	53.6%	4.7%
Total (F, M)	796	100%		11,098	100%		11,894	100.0%	
0–54	359	45.1%		5,545	50.0%		5,904	49.6%	
55–74	361	45.4%		5,034	45.4%		5,395	45.4%	
75+	76	9.5%		519	4.7%		595	5.0%	

Abbreviations

AIHW = Australian Institute of Health and Welfare.

Notes

Total percentage may not sum to 100% due to rounding.

Source

Dataset 1: Australian Institute of Health and Welfare (AIHW) Australian hospital procedures and healthcare interventions (11th edition) data

For MBS data, 2 different denominators were used to calculate patient demographic proportions. The output in Table 38 used the number of surgery services, while the output in Table 39 used the number of surgery patients. Differences in the number of surgery services and patients may be attributed to some patients having bilateral shoulder surgery.

Table 38 and Figure 24 show patient characteristics based on the MBS claims dataset for 2020–21 provided by the Medical Benefits Division. The frequency counts were compared to the number of surgery services (used as the denominator for percentage calculations) obtained from the Medicare item reports. For MBS item 48900, 60.2% of patients were female, of which 55.3% were in the 0–54 age group. For MBS item 48903, 50.7% of patients were female, of which

Notes

53.4% were in the 55–74 age group. For MBS item 48951, 56.5% of the patients were male, of which 55.8% were in the 55–74 age group. Services for this item were similarly distributed by age between male and female patients, with the service most commonly provided to those 55–74 years of age.

Based on the co-claiming information previously described for 48900, this demographic information supports the use of this item for US-guided lavage of calcified tendons, as calcification is more common among females younger than 40 years (Lanza et al., 2015).

Sex and age group	48900	% of total	48903	% of total	48951	% of total
Female total	486	60.2%	498	50.7%	2,859	43.5%
0–54	269	55.3%	128	25.7%	1,004	35.1%
55–74	186	38.2%	266	53.4%	1,595	55.8%
75+	31	6.4%	104	20.9%	260	9.1%
Male total	321	39.8%	485	49.3%	3,707	56.5%
0–54	148	46.1%	199	41.0%	1,320	35.6%
55–74	145	45.1%	224	46.2%	2,070	55.8%
75+	28	8.7%	62	12.8%	317	8.6%
Total	807	100%	983	100%	6,566	100%
0–54	417	51.7%	327	33.3%	2,324	35.4%
55–74	331	41.0%	490	49.8%	3,665	55.8%
75+	59	7.0%	166	16.9%	577	8.8%

Table 38 Patient characteristics by age and sex by MBS item – number of services

Abbreviations

MBS = Medicare Benefit Schedule.

Notes

Total percentage may not sum to 100% due to rounding.

Source

Dataset 3: MBS services data for items 48900, 48903 and 48951 (financial year 2020–21)

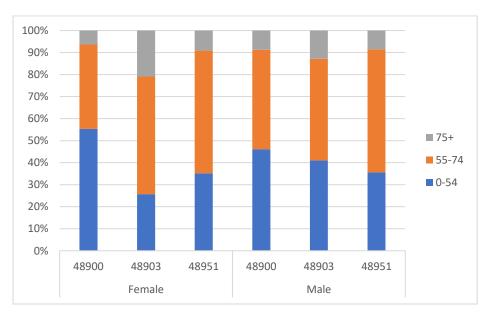


Figure 24 Proportion of patient characteristics by age and sex by MBS item

Source

Dataset 3: MBS services data for items 48900, 48903 and 48951 (financial year 2020-21)

Patient demographic profiles in Table 39 and Figure 25 were calculated from the MBS claims data obtained from the Medical Benefits Division (MBS patients who received item 48900, 48903 and 48951, who had diagnostic imaging services). Proportions were calculated using the number of surgery patients as the denominator. There is a small difference between number of services (6,566) and number of patients (6,404). This is likely the result of a small number of services (162) being provided as a bilateral procedure.

Patient demographics (age, sex) by number of patients (Table 39) are similar to those by number of services (MBS services data for items 48900, 48903 and 48951) (Table 38).

Sex and age group	48900	% of total	48903	% of total	48951	% of total
Female total	450	59.8%	504	50.9%	2,815	44.0%
0–54	253	56.2%	131	26.0%	981	34.8%
55–74	168	37.3%	262	52.0%	1,588	56.4%
75+	29	6.4%	111	22.0%	246	8.7%
Male total	302	40.2%	487	49.1%	3,589	56.0%
0–54	137	45.4%	200	41.1%	1,288	35.9%
55–74	141	46.7%	225	46.2%	1,986	55.3%
75+	24	7.9%	62	12.7%	315	8.8%
Total	752		991		6,404	
0–54	390	51.9%	331	33.4%	2,269	35.4%
55–74	309	41.1%	487	49.1%	3,574	55.8%
75+	53	7.0%	173	17.5%	561	8.8%

 Table 39
 Patient characteristics by age and sex by MBS data – number of patients

Abbreviations

MBS = Medicare Benefit Schedule.

Notes

Total percentage may not sum to 100% due to rounding.

Source

Dataset 8: MBS patients who received 48900, 48903 and 48951 who had diagnostic imaging services, by number of patients, age and sex (financial year 2020–21)

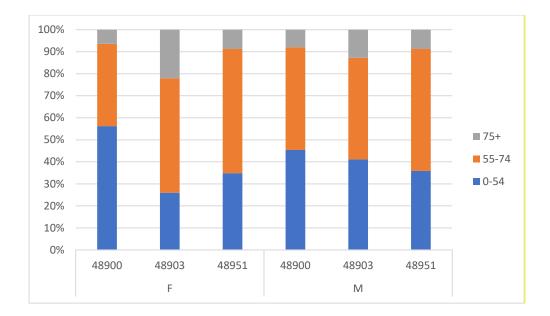


Figure 25 Proportion of patient characteristics by age and sex by MBS data

Source

Dataset 8: MBS patients who received 48900, 48903 and 48951 who had diagnostic imaging services, by number of patients, age and sex (financial year 2020–21)

5.1.8 Use of MBS-funded physiotherapy services

The proportion of patients using MBS items related to SAD that accessed allied health services (physiotherapy and/or exercise physiology) for financial year 2020–21 is presented in Table 40. These allied health services (physiotherapy and/or exercise physiology) were accessed by 18.9% to 22.6% of patients who claimed MBS items 48900, 48903 and 48951.

It should be noted that the numbers of these services likely underrepresent the total number of services as the counts do not include services provided prior to financial year 2020–21.

The low numbers of patients who accessed allied health interventions may also be attributed to their eligibility for CDM which requires the condition to have a duration of 6 months or longer. Eligible patients can receive Medicare rebates for 5 sessions per calendar year. Patients who did not qualify for a CDM plan may still access physiotherapy or exercise physiology in a private setting through their private health insurance or as a full-paying patient (this population subgroup is not covered by this dataset). Patients may also choose to access physiotherapy services through their private health insurance, rather than through the MBS. Data on the frequency, duration and quality of the allied health services were not included in the dataset. The total number of patients who had allied health interventions is not additive. Patients may have sessions with either physiotherapy or exercise physiotherapy or both, as long as it is within the allocated 5 sessions per calendar year. Further information on physiotherapy services available through the MBS is provided in <u>Section 1.6.1</u>.

Table 40	Proportion of patients who had allied health services (physiotherapy and/or exercise physiology) per
MBS item (20	20–21) – number of patients

MBS item	Physiotherapy and exercise physiology (10960 and 10953)	% of total
48900	142	18.9%
(n = 752)		

MBS item	Physiotherapy and exercise physiology (10960 and 10953)	% of total
48903 (n = 991)	224	22.6%
48951 (n = 6,404)	1,448	22.6%

Abbreviations

MBS = Medicare Benefit Schedule.

Source

Dataset 7: MBS patients who received 48900, 48903 and 48951, who had exercise physiology or physiotherapy (financial year 2020-21)

Table 41 and Figure 26 present the proportion of patients who accessed allied health services (physiotherapy and/or exercise physiology) by surgery type, sex and age, from the MBS claims data. Female patients and those age 55–74 years most commonly accessed physiotherapy or exercise physiology services across the 3 MBS items.

Table 41	Patients who accessed physiotherapy and/or exercise physiology services by age and sex per MBS
item – numbe	er of patients

Sex and age group	48900	% of total	48903	% of total	48951	% of total	Total	% of grand total
Female total	97	68.3%	139	62.1%	771	53.2%	1,007	55.5%
0–54	43	44.3%	38	27.3%	197	25.6%	278	27.6%
55–74 and 75+	54	55.6%	101	27.3%	574	74.4%	729	72.4%
Male total	45	31.7%	85	37.9%	677	46.8%	807	44.5%
0–54	11	24.4%	23	27.1%	155	22.9%	189	23.4%
55–74 and 75+	34	75.5%	62	72.9%	522	77.1%	617	76.6%
Grand total	142		224		1,448		1,814	
0–54	54	38.0%	61	27.2%	352	24.3%	467	25.7%
55–74 and 75+	88	62.0%	163	72.8%	1,096	75.6%	1,347	74.2%

Abbreviations

MBS = Medicare Benefit Schedule.

Notes

Total percentage may not sum to 100% due to rounding.

Source

Dataset 7: MBS patients who received 48900, 48903 and 48951, who had exercise physiology or physiotherapy (financial year 2020-21)

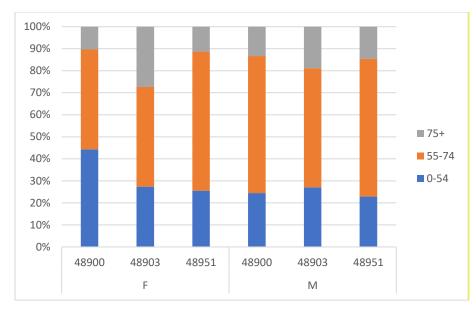


Figure 26 Proportion of patients who accessed physiotherapy and/or exercise physiology services by age and sex per MBS item

Source

Dataset 7: MBS patients who received 48900, 48903 and 48951, who had exercise physiology or physiotherapy (financial year 2020-21)

5.1.9 Use of diagnostic imaging services

The proportion of diagnostic imaging performed for each MBS item is presented in Table 42 and Figure 27. Overall, X-ray and US were the most commonly requested procedures. The most common diagnostic imaging service was US (70.3%) and X-ray (60.1%) for MBS item 48900, X-ray (61.4%) for MBS item 48903, and X-ray (51%) and MRI (43.3%) for MBS item 48951. The high uptake of X-ray may be attributed to guidelines specifying X-ray as the first imaging tool, if indicated, before requests for US or MRI for patients suspected of rotator cuff tears. The use of computed tomography (CT) and MRI for MBS item 48900 is lower (range 3.1–9.3%) compared to the other 2 MBS items. Across all 3 items, patients on average have 1.46 diagnostic imaging tests in the year of surgery.

MBS	X-ray	% of total	US	% of total	СТ	% of total	MRI	% of total
48900 (n=752)	455	60.1%	529	70.3%	23	3.1%	70	9.3%
48903 (n=991)	608	61.4%	392	39.6%	216	21.8%	377	38.0%
48951 (n=6,404)	3269	51.0%	2,931	45.8%	280	4.4%	2,779	43.3%

Table 42	Diagnostic imaging services per MBS item – number of patients
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Abbreviations

CT = computed tomography, MBS = Medicare Benefit Schedule, MRI = magnetic resonance imaging, US = ultrasound. Notes

Total percentage may not sum to 100% due to rounding.

Source

Dataset 8: MBS patients who received 48900, 48903 and 48951, who had diagnostic imaging services (financial year 2020–21)

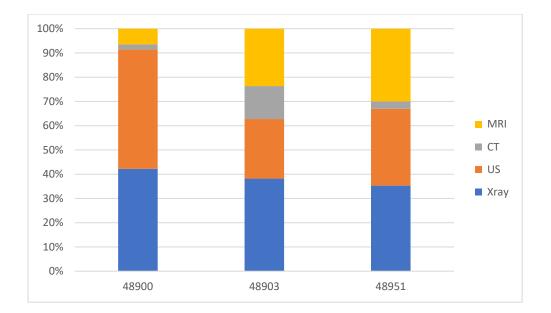


Figure 27 Proportion of diagnostic imaging services per MBS item

Source

Dataset 8: MBS patients who received 48900, 48903 and 48951, who had diagnostic imaging services (financial year 2020-21)

The age and sex distribution of diagnostic imaging was analysed by surgery type using data from dataset 8: MBS patients who received 48900, 48903 and 48951, who had diagnostic imaging services (Appendix H, Table 71, Table 72, Table 73 and Table 74). Overall, male patients and those in the 55–74 age group were most represented in the data. For MBS item 48900, female patients and those in the age group 0–54 were most commonly represented in the dataset, with US being the most commonly requested imaging service. For MBS item 48903, female patients and those in the age group 55–74 were most commonly represented in the dataset, with X-ray as the most commonly requested service. For MBS item 48951, male patients and those in the age group 55–74 were most commonly represented in the group 55–

Table 43 shows the number of patients who had surgery and the number of diagnostic imaging services. The number of diagnostic services requested exceeded the number of patients, which indicates that, on average, patients who use these MBS surgical items have more than one imaging service.

MBS item	Surgery patients	Diagnostic imaging services
48900	752	1,077 (143%)
48903	991	1,593 (161%)
48951	6,404	9,259 (145%)
Total	8,147	11,929 (146%)

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Table 43	Number of surgery patients and number	of diagnostic imaging services

Abbreviations

MBS = Medicare Benefit Schedule.

Source

Dataset 8: MBS patients who received 48900, 48903 and 48951, who had diagnostic imaging services (financial year 2020-21)

5.1.10 Referral patterns (GP and specialist)

The diagnostic imaging referral pattern is presented in Table 44. Overall, X-ray was the most commonly performed imaging service, with 41.2% of the overall diagnostic imaging requests. For item 48900, 79.2% of all imaging requests came from GPs, with the most common services being US (96.4%) or X-ray (74.1%). For MBS item 48903, 55.8% of requests came from a specialist – orthopaedic surgeon (55.8%) with X ray (51.5%) as the most common diagnostic imaging services done. Compared to the other SAD items, CT services were most commonly claimed for item 48903. It is noted that shoulder MRI is not included among the MRI items that can be requested by a GP. Any MRI services referred by GPs and paid privately by patients would not be identified in this dataset.

For MBS item 48951, similar proportions of diagnostic imaging requests came from GPs (48.6%) and specialists – orthopaedic surgery (45.3%). X-ray (38.5%) is the most commonly requested imaging service. All MRI requests and most US services (96.7%) came from specialists, while 56.1% of X-ray requests came from GPs. This is in line with recommendations of clinical practice guidelines that US and MRI should not be provided in primary care for suspected rotator cuff disease or subacromial impingement. This dataset does not include information from patients referred by the GP to undergo MRI as this is not covered by the MBS. The number of patients who have MRI following a referral from a GP is unknown.

Referral	X-ray	%	US	%	СТ	%	MRI	%	Total	%
48900 (n=1,301)	586	45%	610	46.9%	26	2.0%	79	6.1%	1,301	100%
GP	434	74.1%	588	96.4%	<10	Omitte d			1,030	79.2%
Specialist – Other and Orthopaedic surgery	152	25.9%	22	3.6%	18	69.2%	79	100%	271	20.8%
48903 (n=2,309)	1,189	51.5%	437	18.9%	259	11.2%	424	18.4%	2,309	100%
GP	358	30.1%	377	86.3%	26	10.0%			761	33.0%
Specialist – Other	145	12.2%	19	4.3%	47	18.1%	47	11.1%	258	11.2%
Specialist – Surgery – Orthopaedic Surgery	686	57.7%	41	9.4%	186	71.8%	377	88.9%	1,290	55.8%
48951 (n=10,708)	4,121	38.5%	3,140	29.3%	309	2.9%	3,138	29.3%	10,708	100%
GP and Allied Health and Unassigned	2,317	56.2%	37	0.2%	78	25.2%			5,208	48.7%
Specialist – Other	230	5.6%	2,811	89.5%	38	12.3%	282	9.0%	644	6.0%
Specialist – Surgery – Orthopaedic Surgery	1,574	38.2%	225	7.2%	193	62.5%	2,856	91.0%	4,848	45.3%
Total	5,896	41.2%	4,187	29.2%	594	4.1%	3,641	25.4%	14,318	100%

Table 44	Diagnostic imaging referral patterns – number of services
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Abbreviations

CT = computed tomography, GP = general practitioner, MBS = Medicare Benefit Schedule, MRI = magnetic resonance imaging, US = ultrasound.

<u>Notes</u>

Total percentage may not sum to 100% due to rounding.

Source

Dataset 6: MBS diagnostic imaging services, provided as number of diagnostic imaging services and referrer by diagnostic imaging item for 48900, 48903 and 48951 (financial year 2020–21)

5.1.11 Co-claiming patterns for patients who have received SAD items across diagnostic imaging and allied health services (physiotherapy and/or exercise physiology)

A summary of the pattern for patients who had SAD MBS items in relation to the number of diagnostic imaging requests and the number of patients who had allied health services (physiotherapy and exercise physiology) is presented in Table 45. Multiple diagnostic imaging procedures were provided per patient.

 Table 45
 Co-claiming patterns for SAD patients in relation to diagnostic imaging and allied health services – number of patients

Co-claiming patterns as to the total number of patients	48900	% of total	48903	% of total	48951	% of total
Total number of patients	752		991		6,404	
Total number of diagnostic imaging requested	1,077	143%	1,593	161%	9,259	145%
Total number of patients who had physiotherapy or exercise physiology services	142	18.8%	224	22.6%	1,448	22.6%

Abbreviations

MBS = Medicare Benefit Schedule.

5.1.12 Summary of findings

The analysis of AIHW and MBS data for 2020-21 shows the following:

- Item 48951 represented the highest number of claims for financial year 2020–21. The total number of services has reduced over the past 5 years.
- Sex and age groups represented across the 3 SAD MBS items utilised were variable. There were more female patients for item 48900, more male patients for 48903, and similar distribution of male and female patients for 48951. Regarding age group, patients were relatively younger (0–54 years) for item 48900 compared to the other 2 MBS services.
- Across the 3 SAD items patients commonly received more than one imaging service. X-ray was the most commonly requested diagnostic imaging service. The most commonly requested diagnostic imaging services for items 48900 and 48903 were X-ray and US, compared to X-ray and MRI for 48951.
- Referral patterns for diagnostic imaging vary. Higher proportions of requests for X-ray and US came from GPs, while MRI requests were primarily from specialists. CT was rarely used for 48900 and 48951 but was claimed more commonly for 48903 (21.8%). For 48951 GPs commonly referred for X-ray but rarely claimed for US, CT and MRI, in line with best practice for subacromial impingement.
- There was a low uptake of physiotherapy and exercise physiology services through the MBS, although this analysis is limited to one financial year.

- For co-claiming, item 48900 was commonly claimed in the absence of anaesthetic services and in conjunction with surgical procedures using interventional techniques. Item 48903 was commonly claimed with a range of other shoulder services such as excision of ganglion cyst, synovectomy of the shoulder and total shoulder replacement, while 48951 was used as a standalone surgery service in almost half of the top 10 co-claiming episodes.
- In line with guidelines, US and MRI are most commonly requested by specialists and orthopaedic surgeons for item 48951.

5.2 Non-randomised comparative studies

Two non-randomised controlled studies are described in Appendix E, with a total population of 387 patients (Biberthaler et al., 2013, Köhler et al., 2020).

Overall, the results of the non-randomised comparative trials are similar to those reported in the RCTs. However, issues with study design and patient allocation to intervention, as well as aspects of reporting, limit the confidence in these results. In both cases, included patients were similar to those represented in the included RCTs, arthroscopic SAD was consistent with standard practice, and conservative therapy was comprehensive and structured.

The results suggest that older patients may have greater benefit from SAD, compared to the younger cohort in this study, with a median age similar to populations represented in the RCTs. However, Biberthaler at al 2013 is likely at a high risk of bias, based on study design, patient selection and reporting.

In Köhler, the results of adherence to conservative therapy was investigated in a post-hoc subgroup analysis. There were greater improvements in Constant scores and pain in patients who received physiotherapy as recommended by the physician, compared to those who received another protocol, although these differences did not reach significance.

It is unclear whether the differences seen in older patients reflect benefits of arthroscopic SAD or limitations of exercise therapy in this population.

5.3 Long-term follow-up

To supplement long-term outcomes available from RCT evidence, evidence from 7 case series studies with a minimum of 10 years follow-up is provided in Table 46. The risk of bias ranged from moderate to very high (Table 62). Further descriptive information for these publications is provided in Table 58. Objective outcomes of reoperation rates are summarised. Subjective outcomes such as pain or function are not shown due to the lack of a comparator group. Results from imaging studies are shown where reported, noting that pathology identified on MRI or US may not be symptomatic or need any additional therapy.

The rate of repeat surgeries varied from 3% (Norlin and Adolfsson, 2008), 10.5% to 15.6% (Chin et al., 2007, Hultenheim Klintberg et al., 2011, Jaeger et al., 2016), and 22% to 26% (Ranebo et al., 2017, Odenbring et al., 2008) across the populations. Procedures included SAD, distal clavicle excision and rotator cuff repair. Where reported, repeat surgeries were undertaken in patients with intact rotator cuff tendons, PTT and FTT as the index procedure.

In 2 studies there was no reported difference in outcomes at short-term (1 or 8 years) and long-term (13 and 25 years) follow-up (Chin et al., 2007, Odenbring et al., 2008).

As reported in Section 2, RCT evidence shows revision surgeries were not commonly reported. The reported rate varied across different populations from no reoperations (patients who converted to SAD from diagnostic arthroscopy), to 2% (patients randomised to SAD), to 20% (patients who converted to SAD from exercise therapy) (Paavola).

Study ID Follow-up Risk of bias	Number of patients Patient population	Intervention	Long-term outcome (additional procedures or change in outcomes)
Bjornsson 2010 (Bjornsson et al., 2010) Range 13–17 years Very high	N = 70 Patients with subacromial impingement with intact rotator cuffs	SAD	Ultrasound identified 82% (57/70) patients had intact cuffs, 14% (10/70) had PTT and 4% (3/70) had FTT. No significant differences in Constant-Murley score between the 3 groups ($p = 0.274$).
Chin 2007 (Chin et al., 2007) Mean 25 years (range 21–27) High	N = 32 Patients with rotator cuff tendinitis with or without a small supraspinatus tendon (<2 cm)	Anterior (open) acromioplasty, with excision of CAL. 4/32 patients received rotator cuff repair; 6/32 received distal clavicle excision; 1/32 received tendonesis of long head of biceps	5 (15.6%) repeat surgeries (1 distal clavicle excision; 1 revision anterior acromioplasty; 3 rotator cuff repair); 7 (22%) patients underwent treatment in opposite shoulder (1 fracture, 1 conservative therapy of rotator cuff tear, 3 SAD, 2 rotator cuff repair). No reported difference in patient satisfaction at 8 or 25 years follow-up; no difference between operated and non-operated shoulder.
Hultenheim Klintberg 2011 (Hultenheim Klintberg et al., 2011) Range 8–11 years High	N = 95 Patients with primary impingement stage II and early stage III, with radiographs showing acromion type III	Anteroinferior acromioplasty; debridement of PTT; routine excision of lateral clavicle not performed	11 patients underwent reoperation (10.5%; 9 SAD, 2 rotator cuff repairs).
Jaeger 2016 (Jaeger et al., 2016) Mean 19.9 (SD 19.5–20.5) years High	N = 95 Patients with impingement syndrome with or without rotator cuff tears with or without calcific tendinitis.	SAD (including acromioplasty, bursectomy resection of CAL, coplaning, with no rotator cuff repair; torn fibres debrided)	14 of 95 patients (14.7%) underwent revision surgery (10 repeat arthroscopic SAD, 2 open SAD, 2 unknown procedure), with mean time for revision surgery of 10.4 years (SD 5.0). In subgroup comparisons, patients with impingement syndrome and tendinitis calcarea underwent significantly more frequent revisions than did patients with impingement ($p = 0.015$).
Norlin 2008 (Norlin and Adolfsson, 2008)	N = 162 Patients with clinical signs of subacromial impingement	SAD including bursectomy, CAL release.	5/181 patients (3%) underwent revision surgery, 1–12 years after the index procedure. 4 needed repeated SAD (including 1 lateral

Table 46 Long-term follow-up from case series

Mean 11.2 (range 10–13) years Very high		No additional procedures performed	clavicle resection) and 1 underwent cuff repair. Revision surgeries were provided in patients with intact rotator cuff, PTT and FTT at baseline.
Odenbring 2008 (Odenbring et al., 2008) Mean 1 and 13 years Moderate	N = 31 Patients with shoulder impingement syndrome	Arthroscopic acromioplasty. No additional procedures performed	6/23 (26%) cases of revision acromioplasty reported at 6 months to 6 years. Improvement in UCLA score at short-term (1 year) was maintained at long-term follow-up (13 years) (statistical difference not provided).
Ranebo 2017 (Ranebo et al., 2017) Mean 22 (range 21–25) years High	N = 69 Patients with subacromial pain and rotator cuff tears	Arthroscopic SAD alone including acromioplasty, bursectomy and CAL release	Reoperation rate of 22% (15/69 patients) across mean follow-up period of 22 years. 10% (7/69) repeat arthroscopic SAD; 7% (5/69) rotator cuff repair (including Dacron patch); 1 patient with PTT had acromioclavicular resection. One patient each had diagnostic arthroscopy and open capsular shift. Rate of repeat SAD was similar in patients with PTT and FTT at the index procedure (11% and 8%, respectively). No rotator cuff repairs in PTT patients.

Abbreviations

CAL = coracoacromial ligament, FTT = full-thickness rotator cuff tear, PTT = partial thickness rotator cuff tear, SAD = subacromial decompression, SD = standard deviation.

5.4 Predictive or prognostic factors for surgical outcomes

Predictive or prognostic factors that impact outcomes following SAD are listed in Table 60 and summarised in Table 47. Evidence is compiled from clinical practice guidelines, included RCTs, non-randomised comparative studies and case series of greater than 200 patients.

The evidence should be treated with caution as the majority of analyses were retrospective, none of the identified clinical studies reported being suitably powered to examine subgroups, and it is unclear which, if any, improvements reached clinically important differences. Paavola undertook planned sub-group analyses for symptom duration, severity of symptoms, acromial anatomy and the extent of bursal resection. While durations of symptoms of 12 months or less, and the presence of a typ-2 (curved) acromion were associated with statistically improved outcomes of pain, no subgroup analyses in Paavola reached clinically meaningful results. Subgroup analyses were not undertaken for function, which was a secondary outcome. However, the factors shown may be related to improved outcomes compared to the broader populations investigated in the trials.

Commonly reported factors that led to improved outcomes included older age and a worse clinical score at baseline (Table 47).

Other general factors which were reported to impact on recovery after SAD included the length of previous sick leave (more sick leave was associated with increased failure rate), previous use of pain medication (regular pain medication was associated with increased failure rate) (Brox), marital status (living alone was associated with a higher risk of pain), education (lack of professional education was associated with a higher risk of pain) and satisfaction at work (reduced satisfaction was associated with a higher risk of pain) (Ketola) (Ketola et al., 2015).

Presence of factors identified during arthroscopy, such as the status of the bursal space, have not been included here (Khaddabadi et al., 2021).

Factor investigated for prognostic or predictive effect	Reference and key themes of the study			
Positive response to subacromial injection	CPG: Colorado 2015 (Colorado Department of Labor and Employment, 2015) (inaccuracy may limit predictive impact)			
Duration of symptoms	CPG: Diercks 2014 (Diercks et al., 2014)			
	RCT: Paavola 2018 (longer duration is poor prognostic factor)			
Age	CPG: Diercks 2014 (Diercks et al., 2014) (Middle age [45–54] associated with worse outcomes)			
	nRCT: Biberthaler 2013 (Biberthaler et al., 2013) (older patients associated with improved outcome)			
	CS: Inderhaug 2018 (Inderhaug et al., 2018) (age >55 predicted improved outcome); Razmjou 2011 (Razmjou et al., 2011) (older patients reported less disability)			
Psychosocial factors	CPG: Diercks 2014 (Diercks et al., 2014) (play a role in chronic complaints)			
Positive preoperative clinical examination	CPG: Hohmann 2020 (Hohmann et al., 2020) (multiple tests)			
	RCT: Rahme 1998 (Rahme et al., 1998) (for pour-out-of-a-pot function test, but normal for hand-in-neck manoeuvres)			
	CS: Jacobsen 2017 (Jacobsen et al., 2017) (worse Oxford shoulder score predictive of better outcome)			
Workers compensation (negative)	CPG: Hohmann 2020 (Hohmann et al., 2020)			
	nRCT: Lopez 2000 (Lopez et al., 2000), Kharrazi 2007 (Kharrazi et al., 2007)			
	CS: Holtby 2010 (Holtby and Razmjou, 2010)			
Workers compensation (no impact)	nRCT: Nicholson 2003 (Nicholson, 2003)			
Calcific tendinopathy (negative)	CPG: Hohmann 2020 (Hohmann et al., 2020)			
Partial rotator cuff tendon tears (negative)	CPG: Hohmann 2020 (Hohmann et al., 2020)			
Higher pain at baseline (positive)	RCT: Paavola 2018 (Paavola et al., 2018)			
Acromial anatomy	CPG: Diercks 2014, Hohmann 2020 (Hohmann et al., 2020) (type II [curved] or III [hooked] morphology associated with worse outcome)			
	RCT: Paavola 2018 (Paavola et al., 2018) (type II [curved] acromion associated with improved outcome)			
Acromioclavicular degeneration (negative)	RCT: Ketola 2015 (Ketola et al., 2015) (associated with ongoing pain)			
Fibromyalgia (negative)	nRCT: Lopiz 2019 (Lopiz et al., 2019)			

Table 47 Prognostic or predictive factors for surgical outcomes

Factor investigated for prognostic or predictive effect	Reference and key themes of the study
Smoker (negative)	CS: Heyer 2020 (Heyer et al., 2020) (increased risk of adverse events)
Treated hypothyroidism (negative)	CS: Martel 2020 (Martel et al., 2020) (associated with increased risk of developing complex regional pain syndrome)
Previous frozen shoulder (negative)	CS: Evans 2015 (Evans et al., 2015) (increased risk of secondary frozen shoulder)

Abbreviations

CPG = clinical practice guideline, CS = case series, nRCT = non-randomised comparative study, RCT = randomised controlled trial.

Clinical practice guidelines also discuss factors that impact recovery from rotator cuff pathology, rotator cuff surgery or other therapy.

In this broader population, issues related to poorer outcomes after surgery include older age, higher BMI, workers compensation claim, diabetes (AAOS, 2019), lower psychosocial evaluation (Colorado Department of Labor and Employment, 2015, Hopman et al., 2013), atrophy or degeneration on MR imaging, longer duration of complaints and higher patient expectations (Hopman et al., 2013). Factors influencing recovery after rotator cuff syndrome (including tears) were age, gender, pain intensity, fear avoidance, duration of symptoms, unemployment, workers compensation, health status, perceived level of job demands, BMI, culture and poor social support (Hopman et al., 2013). In an Australian population, patients with poor psychological scores before surgery were associated with worse outcomes (American Shoulder and Elbow Surgeons [ASES] score) after surgery for rotator cuff-related shoulder pain or rotator cuff tear (Thorpe et al., 2018).

Further information regarding clinical practice guidelines is provided in Appendix E.

5.4.1 Radiological evidence of impingement

Consultation feedback noted an additional factor for patient selection, being the demonstration of a mechanical cause for the cuff impingement (radiological evidence of abnormal acromial/subacromial morphology, impingement or abrasion). The included clinical trials routinely used radiology to exclude other shoulder pathology, rather than select patients via confirmative diagnostic findings. One RCT reported a subgroup analysis of the shape of the acromion, and noted that a type II [curved] acromion was associated with an improved outcome (p = 0.021), although this did not reach a clinically important difference for the primary outcome (VAS pain at rest) (Paavola et al., 2018).

Case series which investigated the use of radiology to identify subacromial impingement are listed in Appendix E, Table 67. The case series investigated ossifications or bone changes, or the shape of the acromion, either independently or with other factors. Based on the Bigliani-type of acromion, studies reported no difference (Aydin et al., 2011) or an improvement at 6 months for patients with flat or curved acromia (Benson et al., 2009). There was no difference in outcomes based on the acromiohumeral distance (Chui et al., 1997).

One study reported no difference in outcomes based on the presence or absence of ossifications (Erggelet et al., 1999).

Two studies reported significant improvements in patients with radiological signs of impingement as part of a range of criteria including temporary benefit following steroid injection, pain in the

mid-arc of abduction, or a consistently positive Hawkins test (Magaji et al., 2012, Singh et al., 2014). The radiological signs of impingement were consistently associated with a good outcome (p < 0.001), or were seen in all patients meeting the set criteria for an improved outcome.

As a proportion of the total population, these changes were seen in 55% of all patients who remained symptomatic despite 6 months of conservative therapy including a 3-month course of physiotherapy supervised by a qualified therapist (Singh et al., 2014).

5.5 Populations that may benefit more from subacromial decompression

A large number of studies provide evidence for the use of subacromial decompression in other populations not reflected in the key RCTs. These studies represent the broad range of indications where there is a reported use of SAD and are not in line with the current PICO. Local surgical practice for these patients is unclear, and the safety and effectiveness has not been formally determined. Separate MBS items are available for these indications (see Appendix F)

Due to an uncertainty in terms of the population in the current and proposed MBS items, a summary of these additional indications is provided below, for information:

Information from RCTs and non-randomised comparative studies include:

- SAD as an alternative to rotator cuff repair for older patients with PTT (Bidwai et al., 2016)
- SAD as an alternative to rotator cuff repair for older patients with FTT (Flurin et al., 2013)
- SAD with rotator cuff debridement as an alternative to rotator cuff repair in patients with PTT (Basar et al., 2014, Wang et al., 2021, Ogilvie-Harris and Demazière, 1993, Weber, 1999)
- SAD with rotator cuff debridement as an alternative to rotator cuff repair in patients with FTT (Montgomery et al., 1994)
- SAD with rotator cuff debridement for patients with massive irreparable rotator cuff tears (Franceschi et al., 2015)
- In patients with rotator cuff calcifications (Hofstee et al., 2007)
- Use of SAD combined with biceps tenotomy for patients with tenosynovitis of the long head of the biceps tendon (Atalar et al., 2002, Jacquot et al., 2014).

Case series also report the use of subacromial decompression in a variety of other populations, often in conjunction with other procedures. Additional uses identified from case series include:

- Use of SAD in patients with congenital subacromial stenosis (Burkhart, 1995)
- Use of SAD in patients with coexisting glenohumeral or acromioclavicular degenerative joint disease (Ellman et al., 1992, Lozman et al., 1995)
- As a treatment for os acromiale (Wright et al., 2000)
- In conjunction with capsular release for frozen shoulder (Surendran et al., 2020).

Some of these interventions are covered by existing MBS items. As noted in Appendix F, there are existing MBS items for the following procedures:

- Biceps tenodesis
- Removal of calcium deposit from cuff
- Repair of rotator cuff tear
- Shoulder replacement
- Arthrodesis of, with synovectomy, for massive irreparable rotator cuff tears

- Arthroscopic surgery including debridement and removal of loose bodies
- Synovectomy for rheumatoid arthritis
- Joint stabilisation procedure for multidirectional instability of shoulder.

5.6 Ongoing clinical trials

Three ongoing clinical trials were identified from clinicaltrials.gov (search date 15 July 2022) (Table 48). One trial is investigating the impact of SAD following a 3-month period of active nonoperative treatment (NCT00637013).

A search of the Australian New Zealand Clinical Trials Registry¹² identified a completed trial with published results of a patient decision aid (Zadro et al., 2021a).

Trial code Country Year of expected completion	Status	Device/study arms	Participants Follow-up Study type
NCT04644042 Denmark June 2026	Recruiting	Glenohumeral arthroscopy + Arthroscopic Subacromial Decompression versus Glenohumeral arthroscopy + lateral skin incision	 160 participants (patients must have completed at least 3 months supervised shoulder training) 12 months RCT
NCT00428870 Finland December 2024	Active, not recruiting	Arthroscopic decompression versus diagnostic arthroscopy without subacromial decompression versus supervised exercise therapy	210 participants 10 years RCT
NCT00637013 Finland January 2027	Active, not recruiting	Acromioplasty + physiotherapy according to a standardised protocol following a 3-month period of active nonoperative treatment versus physiotherapy according to a standardised protocol following a 3-month period of active nonoperative treatment	100 participants Follow-up time not reported RCT

 Table 48
 Ongoing clinical trials

Abbreviations

RCT = randomised controlled trial.

¹² https://www.anzctr.org.au/

Section 6 Questions for consultation

- 1. In the trials and in usual practice, X-ray, US and MRI are used to exclude other shoulder pathologies or determine the state of rotator cuff tendons, rather than to identify the source of the impingement. A small number of publications use X-ray to identify radiologic causes of impingement. Is this useful in clinical practice and patient selection?
- 2. Are there any other patient characteristics or selection criteria which are relevant for patient selection, or for identifying patients who may best benefit from surgery?
- 3. At baseline, patients in the trials have unclear or varied access to previous conservative therapies including physiotherapy or exercise therapy. Publications suggest that patient experiences of conservative therapies in Australia also varied, although it is unclear if this applies to patients who have surgery. In Australia, do patients with subacromial impingement have appropriate access to best practice conservative therapy prior to being considered for surgery?

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Appendix A Systematic review methods

Research questions

A systematic review has been performed to answer the following questions:

- What is the comparative safety, effectiveness and cost effectiveness of subacromial decompression versus non-surgical therapy in patients with subacromial impingement?
 - Which subpopulations have the greatest benefit from surgery?
 - Which subpopulations have the least benefit from surgery?
- From MBS data modelling, what is the budgetary impact of a range of scenarios?

Note that the requirement for an add-on economic evaluation component will be determined subsequent to the initial clinical results.

Development of a research protocol

Prior to the start of the systematic review, a research protocol was developed based on the PICO confirmation ratified by the PICO Advisory Sub-committee of MSAC.

PICO criteria

The PICO criteria prespecified to guide the systematic literature review for direct evidence are presented in Table 49.

Component	Description
Population	Adult patients with symptomatic subacromial shoulder impingement AND:
	Symptoms unresolved despite conservative therapy for 6 months;
	AND excluding:
	 Patients who require rotator cuff repair AND; Patients with other pathologies of the shoulder e.g. glenohumeral joint osteoarthritis, acromioclavicular arthritis, labral tear including superior labral anterior-posterior (SLAP) tears, adhesive capsulitis/frozen shoulder, tendinopathy of the long head of the biceps, calcific tendinopathy, bicipital tendon disorders, neuropathy, shoulder fractures, shoulder instability/dislocation, malignancy, infection
	Note, the current and proposed MBS items for subacromial decompression do not include population eligibility criteria.
Intervention	Any form of open or arthroscopic subacromial decompression of shoulder (i.e. standalone) Inclusive of, if performed:
	 Coraco-acromial ligament division (MBS items 48900, 48903, 48951, 489XX) Acromioplasty (48903, 48951, 489XX) Coplaning of the clavicle or excision of the acromioclavicular joint (48903, 489XX) Removal of calcium deposit (48900, 489XX)

Table 49	PICO criteria for	patients with	subacromial	impingement

Component	Description				
	Excision of bursa (489XX)				
Comparator/s	Continued conservative therapy (including pain relief, physiotherapy or other type of allied health or primary care)				
Outcomes	 Safety Adverse events Infection Adhesive capsulitis Wasting or avulsion of the deltoid muscle Efficacy/effectiveness Shoulder function specific scores (e.g. Constant Murley, Oxford Shoulder Score etc) Mean pain scores improvement (e.g. visual analogue scale (VAS) etc) Health-related quality of life Failure of surgery or need for revision surgery Return to work or normal function Healthcare resources Consultations in primary care, specialist or surgery Pain management medication Diagnostic tests Consumables and implants for surgery Rehabilitation Indirect costs (work days lost) Cost effectiveness (cost per life year gained, cost per quality-adjusted life year (QALY) gained, incremental cost-effectiveness ratio (ICER)) Total Australian Government healthcare costs Patient-relevant costs (e.g. ongoing physiotherapy, pain relief, loss of time from work or other daily activities)				
Assessment questions	 What is the comparative safety, effectiveness and cost effectiveness of subacromial decompression versus non-surgical therapy in patients with subacromial impingement? All available sub-populations should be reported. Which sub-populations have the greatest benefit from surgery? Which sub-populations have the least benefit from surgery? Note that the requirement for an add-on economic evaluation component to be determined subsequent to the initial results of the DCAR. From MBS data modelling, what is the budgetary impact of a range of scenarios? 				

DCAR = department contracted assessment report, ICER = incremental cost-effectiveness ratio, QALY = cost per quality-adjusted life year, SLAP = superior labrum anterior and posterior, VAS = visual analogue scale.

Literature sources and search strategies

The medical literature was searched 26 April 2022 to identify relevant studies published since inception of the database. Searches were conducted of the databases and sources described in Table 50.

Table 50 Record of search strategies

Source	Date span of search
MEDLINE (via Ovid)	1946 to 22 April 2022
EMBASE (via Ovid)	1974 to 22 April 2022
PubMed	26 April 2022 (no date limits)
Cochrane Library ^a	26 April 2022 (no date limits)
ClinicalTrials.gov	15 July 2022
Australian and New Zealand Clinical Trials Registry	15 July 2022

<u>Notes</u>

a = Includes the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials.

Search terms and strategy were based on those described in the recent Cochrane reviews and are summarised in Table 51 (Karjalainen et al., 2019a, Karjalainen et al., 2019b). EMBASE was limited to exclude MEDLINE journals. No other limits were applied (e.g. date, study design, language or human).

Category	Description	Search terms
Population	Rotator cuff injuries	MeSH terms:
	and subacromial	Shoulder/
	decompression	Rotator Cuff/
		Calcium/
		exp Bursitis/
		Shoulder Pain/
		Shoulder Impingement Syndrome/
		Rotator Cuff Injuries/
		Text words:
		(rotator cuff or supraspinatus or infraspinatus or subscapular\$ or teres).tw.
		((shoulder\$ or subacromial or rotator cuff) adj5 (tendon\$ or tendin\$ or bursitis or calcium or calcif\$ or impinge\$ or tear\$ or pain)).tw.
Intervention	Subacromial	Text words:
	decompression	decompress\$.tw.
		bursectom\$.tw. 714
		acromioplast\$.tw.
		(calcium adj remov\$).tw.
		coplan\$.tw.
		ligament release.tw.
		ligament division.tw.
		[*include known proprietary and nonproprietary names, MeSH terms]

Table 51 Search terms used in Ovid, PubMed and the Cochrane Library

Abbreviations

MeSH = medical subject headings.

The search strategy and results used in Medline (Ovid) are shown in Table 52. Similar searches were used on all other platforms. For clinicaltrials.gov and the Australian and New Zealand Clinical Trials Registry 'subacromial decompression' was used as a search term.

#	Search term	Result
1	Shoulder/	14670
2	Rotator Cuff/	7604
3	1 or 2	21337
4	Calcium/	276463
5	exp Bursitis/	5063
6	4 or 5	281515
7	3 and 6	815
8	Shoulder Pain/	5503
9	Shoulder Impingement Syndrome/	1899
10	Rotator Cuff Injuries/	6978
11	(rotator cuff or supraspinatus or infraspinatus or subscapular\$ or teres).tw.	21450
12	((shoulder\$ or subacromial or rotator cuff) adj5 (tendon\$ or tendin\$ or bursitis or calcium or calcif\$ or impinge\$ or tear\$ or pain)).tw.	21570
13	7 or 8 or 9 or 10 or 11 or 12	35386
14	decompress\$.tw.	50603
15	bursectom\$.tw.	714
16	acromioplast\$.tw.	628
17	(calcium adj remov\$).tw.	351
18	coplan\$.tw.	5617
19	ligament release.tw.	298
20	ligament division.tw.	64
21	14 or 15 or 16 or 17 or 18 or 19 or 20	58040
22	13 and 21	1424

Table 52 Full search strategy (MEDLINE Ovid)

Abbreviations tw = text word.

Study selection

Studies were selected by title and abstract by 1 reviewer (AC). To ensure the accuracy of the studies included for full text review, another reviewer (AA) screened at least 10% of the studies. A disagreement rate of <5% was considered acceptable. Full text review was then performed by a single reviewer (AC).

There was a disagreement rate of 0.4% in the validation screening, considered to be acceptable and well below the 5% limit.

Studies that could not be retrieved, or that met the inclusion criteria but contained insufficient or inadequate data for inclusion, are listed as excluded studies in Appendix C. All other studies meeting the inclusion criteria are listed in Appendix B.

Appraisal of the evidence

Evidence appraisal was conducted in 4 stages:

Stage 1: Appraisal of the risk of bias within individual studies (or systematic reviews) included in the review. Risk of bias items were assessed for the study as a whole.

Stage 2: Appraisal of the precision, size of effect and clinical importance of the results reported in the evidence base as they relate to the prespecified primary outcomes for this assessment.

Stage 3: Rating the overall quality of the evidence per outcome, across studies, based on the study limitations (risk of bias), imprecision, inconsistency of results, indirectness of evidence and the likelihood of publication bias (evidence profile tables, Appendix D).

Stage 4: Integration of the evidence (across outcomes) for conclusions about the net clinical benefit of the test and associated interventions in the context of Australian clinical practice. (Section 2.5).

Data analysis

Dichotomous outcomes were meta-analysed using Review Manager version 5.4 when at least two RCTs were available (The Cochrane Collaboration, 2020). The meta-analysis was performed using random-effects models with the Mantel-Haenszel statistical model. Results were reported as risk ratios (RR) with 95% confidence intervals (CI).

Continuous outcomes were meta-analysed using Review Manager version 5.4 when at least two RCTs were available (The Cochrane Collaboration, 2020). The meta-analysis was performed using random-effects models with the inverse variance method. Analysed continuous outcomes were reported both as mean difference (MD) and standardised mean differences (SMD), which were used to account for differences in the measurement scales reported for outcomes across included studies. When extracted, continuous data were accompanied by a standard deviation and/or a 95% CI. The MDs were interpreted as clinically important following the MCIDs. The SMDs were interpreted following the recommendations detailed in the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0), whereby a SMD of 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect.

Assessment of publication bias

The risk of publication bias was not assessed by testing funnel plot asymmetry, as this requires a minimum of 10 studies included in the analysis. A narrative inspection of publication bias was performed by searching clinical trial registries in order to identify any unpublished trials.

Calculation of missing values

Missing values were calculated using the following formulae:

Standard deviation

Missing standard deviations (SD) were obtained from available means, sample sizes, standard errors and 95% CI or 99% CI using formulae detailed in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2020). The formulae used are detailed below.

```
SD=\sqrt{N} x (upper limit-lower limit)/X
```

Where X is a fixed value established at 3.29 for 90% Cis, 3.92 for 95% Cis, and 5.15 for 99% Cis.

Continuous variable needs to be combined

Where continuous values needed to be combined, the formulae detailed in the Cochrane Handbook for Systematic Reviews of Interventions (version 6.1) was used (Higgins et al., 2020). The formulae used are detailed below.

Sample size=N1+ N2

Mean=N1M1+ N2M2N1+ N2

$$SD = \sqrt{\frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2 + \frac{N_1N_2}{N_1 + N_2}(M_1^2 + M_2^2 - 2M_1M_2)}{N_1 + N_2 - 1}}$$

Continuous variable to be converted from one scale to another

Where a continuous value needed to be converted from one scale to another, the following formula was used.

Value in scale 2=(((Value in scale 1 – Scale 1 minimum)× (Scale 2 maximum – Scale 2 minimum))/(Scale 1 maximum–Scale 1 minimum))+ Scale 2 minimum

Studies with data reported graphically

For studies that reported graphically, the WebPlotDigitizer was used to convert graph points into numerical values (Rohatgi, 2014).

For results communicated in change from baseline and not a value

Where results were communicated in change from baseline and not a value, the following formula was used for conversion.

```
Value in scale=baseline value+change value
```

If data are not available to calculate SD

If data were not available to calculate an SD, it was imputed using the 'impute_SD' function in the R (version 1.4) package 'metagear', following the imputation methods described by Bracken (Bracken, 1992). When a timepoint was represented either by a single study with missing SDs or two studies including one with missing SDs, the study with missing information was omitted to avoid bias in the imputation.

Minimum clinically important differences

The minimum clinically important differences (MCIDs), minimum important change (MIC), minimal important differences (MIDs) and minimal clinically important improvement (MCII) related to the outcomes of interest (VAS, NRS, PainDETECT, Constant-Murley score, EQ-5D and 15D) were identified through a non-systematic targeted search. The identified MCIDs, MIC and MIDs will serve as a guide in the clinical interpretation of statistically significant outcomes and

not as a complete assessment of the literature. Caution must be taken in the extrapolation of MCIDs to the reported outcomes due to the differences in the population characteristics, diagnosis and intervention.

For MCIDs, differences were informed by 2 systematic reviews(Karjalainen et al., 2019b, Moshi et al., 2021) and 3 published studies (Tashjian et al., 2009, Hao et al., 2019, Alanne et al., 2015).

- For pain, on a 0–10 scale 1.5 points was considered to be the MCID (Tashjian 2009, Hao 2019).
- For function, on a 0-100 scale 8.3 points was considered to be the MCID (Hao 2019).
- For health-related quality of life, on a 0–1 scale 0.015 was considered to be the MCID (Hao 2019, Alanne 2015), and on theEQ-5D-3L index (UK version; -0.59 to 1) 0.07 (Hao 2019).

Appendix B Studies included in the systematic review

PRISMA flowchart of included studies

The PRISMA flowchart is a graphic depiction of the results of the literature search and the application of the study selection criteria (Liberati et al., 2009). Due to the broad questions of the systematic review, including an informal review of predictive and prognostic characteristics of patients who may benefit from SAD, selection of studies to supplement the primary RCT evidence was undertaken as described in Section 6, Other Relevant Information.

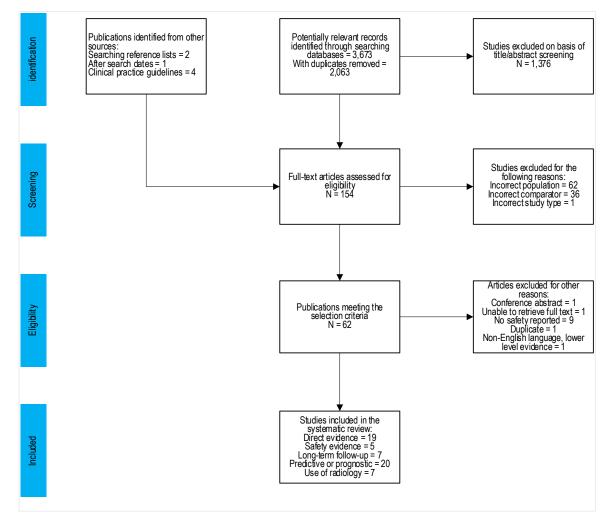


Figure 28 PRISMA flowchart showing screening of studies for this assessment report (Liberati et al., 2009, Moher et al., 2009)

Study profiles of included studies

Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
(Beard 2015, Beard 2018) NCT01623011 UK (30 centres, 38	RCT NHMRC level of evidence II Risk of bias: Low	Patients with subacromial shoulder pain (Patients with full- thickness tears excluded) Planned 300 patients (100 in each of three groups)	Inclusion: Subacromial pain of at least 3 months duration (tendinopathy and partial tear only) Consultant's clinical diagnosis of tendinopathic pain or partial-thickness rotator cuff tear (using local pathways of diagnosis, which may include X-rays, MRI scans or ultrasounds) Eligible for arthroscopic surgery Completion of a conservative management program previously, including both physiotherapy that includes a remedial exercise regimen at least one cortisone injection Exclusion: Full-thickness tear of the rotator cuff tendons or calcific tendinitis evident on routine imaging Other shoulder pathology (non- impingement-related) identified on MRI scan or ultrasound Undergone any of the following surgeries on the affected shoulder: ASAD cuff repair	Intervention: SAD (arthroscopic subacromial decompression) (the coraco-acromial ligament and the AC joint remain intact]) Comparator 1: AO (arthroscopy only) [the GHJ and the subacromial bursa being inspected and irrigated. Structures can be assessed for integrity and damage. The rotator cuff can be assessed for evidence of full-thickness tears] Comparator 2: AMSR (active monitoring with specialist reassessment)	Primary: OSS (oxford shoulder score) at 3 months Secondary: OSS at 12 months post- randomisation Constant-Murley shoulder score] PainDETECT Quantitative sensory testing: measures pain and pain thresholds Complications during and after the treatment EQ-5D Health service use Treatment expectations Patient satisfaction (Oxford Satisfaction Index) Hospital Anxiety and Depression Scale

Table 53 Study profiles for RCTs included in the systematic review

Trial details	Study	Study population	Inclusion criteria	Intervention	Outcomes
Country/sites	design		Exclusion criteria	Comparator	
Funding source	NHMRC				
Conflicts of	level of evidence				
interest					
	Quality appraisal				
			Joint replacement surgery involving the		
			glenohumeral joint (GHJ) in the past 3 years Rheumatoid arthritis or any other		
			inflammatory disorder of the joints		
			Symptomatic cervical spine pathology		
			Previous septic arthritis in the shoulder only		
			History of radiotherapy on same side as		
			affected shoulder		
			Patients who:		
			Are unlikely to be able to perform the		
			required clinical assessment tasks		
			Have significant cognitive impairment or		
			language issues Are unable to provide consent for		
			themselves. Older than 75 years of age		
Brox	RCT	Patients with rotator	Inclusion:	Intervention:	Primary: Neer shoulder
(Brox 1993, Brox		cuff disease	Patients were included if they were age 18–	SAD (arthroscopic subacromial decompression)	score (three parts: pain;
1999)	NHMRC level of	Rotator cuff rupture	66; had had pain in the shoulder for at least three months that had been resistant to	Bursectomy and resection of the anterior and lateral part of the acromion and the coraco-	function; range of motion; anatomical or radiological
Trial number not	evidence II	excluded	outpatient physiotherapy and non-steroid	acromial ligament. Surgery was followed by	assessment)
reported	••••••		and steroid anti-inflammatory drugs; had	physiotherapy.	Secondary:
	Risk of	36 patients planned in	dysfunction or pain on abduction; had a		Pain on activity, rest and at
Norway (single	bias:	each treatment group	normal passive glenohumeral range of	Comparator 1:	night
site, 2	High		movement; had pain during two of the three isometric-eccentric tests (abduction at 0 and	PHYS (supervised exercises) Supervised training (method of Bohmer) twice	Emotional distress (Hopkins symptoms
experienced surgeons)			30 degrees and external rotation); and had	weekly for 3–6 months. Analgesia was allowed.	checklist)
suigeonsj			positive results in tests for impingement.		
Funding source			Lignocaine (6 ml; 10 mg/ml) was injected	Comparator 2:	
not declared			anteriorly into the subacromial space.' The	LAS (placebo, detuned laser)	

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Competing interests not declared			diagnosis was confirmed if pain was appreciably reduced on re-examination after 15 minutes Exclusion: Patients were excluded if they had arthritis of the acromioclavicular joint; had the cervical syndrome; had rotator cuff rupture; had glenohumeral instability; had bilateral muscular pain with tenderness and severely decreased ability to relax the shoulder, neck, and temporomandibular joints on examination; and were reluctant to accept one or more of the treatment regimens of the study	2 treatments per week for 6 weeks Analgesia was allowed	
Cederqvist (Cederqvist 2021) NCT00695981 NCT00637013 Finland (2 sites, 5	RCT NHMRC level of evidence II Risk of bias:	Patients with long- term (>3 months) subacromial pain All patients underwent active rehabilitation before randomisation for 3 months Symptomatic patients	Inclusion: Inclusion criteria for all patients: Pain in abduction of the shoulder Age over 35 years Duration of symptoms at least 3 months Written informed consent by the participating subject Additional inclusion criteria:	Intervention1: SNFTT (surgery, no FTT) Arthroscopic subacromial decompression All patients followed a structured postoperative rehabilitation protocol Intervention 2: SFTT (surgery, FTT)	Primary: VAS for pain Constant-Murley Score for function Secondary: QoL, by the RAND 36-item health survey Serious AEs and
surgeons) Funding from two grant bodies No competing interests declared	Some concerns	Rotator cuff disease with or without full- thickness tendon tears	Additional inclusion criteria: Subacromial impingement without full- thickness tendon lesion Pain in two of the three isometric tests (0 or 30 degrees of abduction or external rotation) Subacromial injection of lidocaine significantly reduced pain Full-thickness tendon rupture	Rotator cuff repair via either an arthroscopic or mini open approach When necessary, patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps All patients followed a structured postoperative rehabilitation protocol	reoperations

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
		100 in each arm (surgical group divided into two)	Full-thickness rotator cuff rupture in one to three tendons documented with MRI arthrography Exclusion: Exclusion criteria Previous surgery of the same shoulder High-energy trauma before symptoms Inflammatory arthritis Adhesive capsulitis Instability of the affected shoulder Severe glenohumeral or acromioclavicular joint osteoarthritis Cervical syndrome/radiculopathy Progressive cancer A too-high risk for operation Any disease, social problem or other reason reducing the ability to cooperate and jeopardising informed consent Irreparable rotator cuff tear on MRI arthrography	Comparator: R = No surgery/ rehabilitation Continuation of the rehabilitation program Unsuccessful patients (severe pain or poor subjective shoulder function) – patients were offered surgery	
Farfaras (Farfaras 2016, Farfaras 2018) Dnr 1077-11 Sweden (single site, single surgeon)	RCT NHMRC level of evidence II Risk of bias: High	Patients with subacromial impingement syndrome Partial or complete tears of the rotator cuff excluded	Inclusion: Subacromial pain for at least six months Exclusion: Diabetes mellitus, any neurological or spinal disorder, radiographic osteoarthritis, chronic joint disorders such as rheumatoid arthritis and total rotator cuff rupture	Intervention 1: O (open surgery) Acromioplasty; CAL release; coplaning Ice, sling and pain relief, followed by physiotherapy as in the comparator group Intervention 2: A (arthroscopic surgery)	Primary: Constant score; 10-point difference was considered to be of clinical importance (MCID) SF-36 questionnaire, the Watson and Sonnabend score, range of motion in terms of active elevation

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Funding from a research body Competing interests declared		40 patients planned in each treatment group	And chronic impingement syndrome (partial or complete tears of the rotator cuff)	Bursectomy; acromioplasty. Ice, sling and pain relief, followed by physio as in the comparator group Comparator: P (physiotherapy) Physiotherapy by the method of Bohmer Formal training with standardise protocol, 1hr per day (twice a week with a physiotherapist) for 3-6 months.	and internal rotation and strength in abduction
Haahr (Haahr 2005, Haahr 2006) Trial number not reported Denmark (one site, two experienced surgeons) Funding source not declared Competing interests declared	RCT NHMRC level of evidence II Risk of bias: Some concerns	Shoulder pain with subacromial impingement Patients with signs of a rupture of the rotator cuff were excluded Target 40 patients in each group	Inclusion: Fulfilment of all diagnostic criteria (provided), report of shoulder symptoms between six months and three years (because surgery in general was not offered to cases with symptoms of shorter duration), and age between 18 and 55 years Previous treatment with rest, non-steroidal anti-inflammatory drugs, subacromial injection and physiotherapy were allowed Normal passive glenohumeral movement was a requirement Exclusion: Patients were excluded for the following reasons: impaired rotation in the glenohumeral joint, a history of acute trauma, previous surgery or previous fracture in the proximity of the affected	Intervention: SAD Bursectomy with partial resection of the antero- inferior part of the acromion and the coraco- acromial ligament; the patient was instructed regarding physiotherapy after the surgery Comparator: P (physiotherapy) Physiotherapy. 19 sessions each of up to 60 minutes given by two experienced therapists Heat/cold packs; active training and strengthening of muscles of the shoulder joint Supervision 3x per week (first 2 weeks); 2x per week (2 weeks); 1x per week (7 weeks) At home daily for at least 12 weeks, then at home 2–3 times per week	Baseline, 3, 6, 12 months Primary: Constant score Secondary: Pain (VAS) limitations in activities of daily living Active range of motion Isometric shoulder strength Questionnaire at 12 months

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Ketola (Ketola 2009 protocol, Ketola 2015, Ketola 2016, Ketola 2017) Trial number not reported Finland (two sites, one experienced surgeon) Funding source not declared No competing interests declared	RCT NHMRC level of evidence II Risk of bias: Some concerns	Stage II shoulder impingement syndrome Patients with full- thickness rotator cuff tears excluded Target 70 patients in each group	shoulder, known osteoarthritis in the acromioclavicular or glenohumeral joints, calcifications exceeding than 2 cm in the rotator cuff tendons, or signs of a rupture of the cuff or cervical root syndromes Inclusion: The inclusion criteria were a positive Neer's test, pain in the shoulder that was resistant to rest, anti-inflammatory drugs, subacromial glucocorticosteroid injections, physiotherapy, and symptoms that had persisted for at least 3 months All patients had thus been treated with physiotherapy at their primary hospital before inclusion in the study Patients were aged 18 to 60 years Exclusion: The exclusion criteria were glenohumeral or acromioclavicular osteoarthritis, signs of glenohumeral instability, previous surgery to the affected shoulder, a full-thickness tear of the rotator cuff, cervical radicular syndrome, adhesive capsulitis, or neuropathy of the shoulder region	Intervention: AA (arthroscopic acromioplasty) Debridement and decompression; if the coraco- acromial ligament felt tight or thick, it was released Acromioplasty was performed Patients received similar individually planned and progressive training programs to the exercise group As in the other group, progress was evaluated during 6 physiotherapy visits NSAIDs were allowed as necessary Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program Comparator: EG (exercise group) Information was first given by a trained physiotherapist A home program was individually planned for each patient according to the same principles Elasticated stretch bands and light weights were used in training, which was based on long painless series and repetitions aiming at tendon strengthening	Primary: VAS at 24 months after randomisation MCID was two points on the VAS Additional outcomes: Disability Pain at night Working ability Shoulder questionnaire score Number of painful days in the previous three months Proportion of pain-free patients

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Paavola (Paavola 2017 protocol, Paavola 2018, Paavola 2021, Bäck 2021) NCT00428870 Finland (3 sites, number of surgeons unclear) Funding from four research bodies Competing interests declared	RCT NHMRC level of evidence II Risk of bias: Low	Subacromial impingement syndrome Patients with full- thickness rotator cuff tears were excluded Target 70 patients in each group	Inclusion: 1. Adult men or women ages 35 years to 65 years 2. Subacromial pain for greater than 3 months with no relief from nonoperative means (physiotherapy, non-steroidal anti- inflammatory medication, corticosteroid injections and rest) 3. Pain provoked by abduction and positive painful arc sign 4. Positive impingement test (temporary relief of pain by subacromial injection of lidocaine) 5. Pain in at least two out of three of isometric tests (abduction 0° and 30° or external rotation) 6. Provision of informed consent from the participant 7. Ability to speak, understand and read in the language of the clinical site	The sessions were performed at least four times a week using nine different exercises with 30 to 40 repetitions three times There were a minimum of 7 controlled visits to the therapist until patient was able to perform independently NSAIDs were allowed as necessary Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program Intervention: A (arthroscopic surgery) Bursectomy. Resection of the bony spurs and projecting anterolateral undersurface of the acromion. One visit to physiotherapist, guidance for home exercises, then standardised rehabilitation program from each centre. Comparator 1: DA (diagnostic arthroscopy) bursal tissue could be stretched or resected, keeping resection to a minimum Additional pathology identified or treated meant that patient was excluded PTT included. FTT excluded One visit to physiotherapist, guidance for home exercises, then standardised rehabilitation program from each centre Comparator 2:	Primary: VAS, pain at rest and pain at activity, 0–100 (extreme pain); 15 was MCID Secondary: Constant- Murley score (MCID=17), SST (simple shoulder test) (MCID=2 points) HqoL: 15D, SF-36 Patient satisfaction, return to previous leisure activities, return to work, patient perception of operative group assignment Complications and AEs Healthcare resources and costs also collected

		Exclusion: 1. Full-thickness tear of the RC tendons diagnosed on clinical examination (marked weakness in any of the examined muscles)	P (physiotherapy) Standardised protocol but updated for best practice exercise therapy	
		 or magnetic resonance arthrography 2. Osteoarthritis of the glenohumeral and/or acromioclavicular joint diagnosed on clinical examination and on X-rays 3. Substantial calcific deposits in the RC tendons found in the preoperative imaging 4. Previous surgical procedure on the affected shoulder 5. Evidence of shoulder instability (positive apprehension/positive sulcus sign) 6. Symptomatic cervical spine pathology 7. History of alcoholism, drug abuse, psychological or psychiatric problems that are likely to invalidate informed consent 8. Patient declined to participate 	Daily home exercises 15 physio visits, once a week Aim to restore function, no pain No timelines provided	
RCT NHMRC level of evidence II Risk of bias: High	Grade II outlet impingement syndrome Patients with full- thickness rotator cuff tears were excluded	Inclusion: The clinical examination was carried out according to a standardised examination scheme Included there was regular tenderness in the front upper shoulder joint area and pain in anteversion and abduction of the arm. As clinical impingement tests were routinely the painful arch, the	Intervention: SAD arthroscopic in 15 cases subacromial decompression in the Ellmann technique or an open acromioplasty to Neer (17 cases) Intraoperatively, 18 patients had partial rotator cuff lesions described by which joint-side parts in	Subjective Shoulder Rating Scale (SSRS) (including all subscores of pain, function/mobility)
NI le' e\ Ri	HMRC vel of vidence II sk of	impingement HMRC syndrome vel of vel of vidence II Patients with full- thickness rotator cuff thickness rotator cuff sk of tears were excluded	examination and on X-rays3. Substantial calcific deposits in the RC tendons found in the preoperative imaging 4. Previous surgical procedure on the affected shoulder4. Previous surgical procedure on the affected shoulder5. Evidence of shoulder instability (positive apprehension/positive sulcus sign) 6. Symptomatic cervical spine pathology 7. History of alcoholism, drug abuse, psychological or psychiatric problems that are likely to invalidate informed consent 8. Patient declined to participateCTGrade II outlet impingement syndromeInclusion: The clinical examination was carried out according to a standardised examination scheme Included there was regular tenderness in the front upper shoulder joint area and pain in anteversion and abduction of the arm. As clinical impingement tests were routinely the painful arch, the impingement test to Neer to check the	examination and on X-rays 3. Substantial calcific deposits in the RC tendons found in the preoperative imaging 4. Previous surgical procedure on the affected shoulder 5. Evidence of shoulder instability (positive apprehension/positive sulcus sign) 6. Symptomatic cervical spine pathology 7. History of alcoholism, drug abuse, psychological or psychiatric problems that are likely to invalidate informed consent 8. Patient declined to participateIntervention: SAD arthroscopic in 15 cases subacromial decompression in the Ellmann technique or an open acromioplasty to Neer (17 cases)CTGrade II outlet impingement syndromeInclusion: The clinical examination was carried out according to a standardised examination scheme Included there was regular terderness in the front upper shoulder joint area and pain in anteversion and abduction of the arm. As clinical impingement tests were routinely the painful arch, the impingement test to Neer to check theIntervention: SAD arthroscopic in 15 cases subacromial decompression in the Ellmann technique or an open acromioplasty to Neer (17 cases)

Trial details Country/sites Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Funding source not declared Competing interests not declared			the Hawkins impingement test to check the coracoidal performed impingements. In which additionally performed local anaesthetic test were 10 ml of a 1% local anaesthetic injected subacromial. Furthermore, the abduction, inner and external rotation and flexion examined against resistance. At least a positive impingement test and a positive failure of the subacromial Infiltration tests were considered Inclusion criteria required. For clinical instability check has been the apprehension test, the sulcus sign and both the ventral and the dorsal drawer sign performed. Before the start of treatment X- rays of those affected shoulder in the standard posterior to anterior projection, axillary and trans-scapular according to Morrison. X-ray showed either a type II acromion or III or exclusively or additionally a spur formation in the area of the acromioclavicular joint. Exclusion: Patients with sonographic evidence a complete rotator cuff tear were excluded from the study.	From the fourth postoperative week came strengthening exercises against resistance added Comparator: NO (nonoperative) Implementation of conservative treatment Hospitalised for 2 weeks It became a treatment program with intense physical therapy carried out. Non-steroidals were supportive anti-inflammatory drugs (e.g. ibuprofen 2 times 400 mg p.o.) if no gastrointestinal problems in the anamnesis templates Further took place an infiltration of the subacromial space with corticosteroids such as triamcinolone 5 mg in 10 ml physiological NaCl solution There have been up to a maximum of 3 injections administered	
Rahme (Rahme 1998)	RCT	Patient population not explicitly defined ('Patients with isolated	Inclusion: Isolated shoulder disease; working age; pain for which the duration of at least one	Intervention: OAA (open anterior acromioplasty) (open: according to Neer)	Pain (VAS) – 50% reduction

Trial detailsStud designedCountry/sitesNHM levelFunding sourceNHM levelConflicts of interestevide qual appred	gn IRC I of ence lity raisal		Inclusion criteria Exclusion criteria	Intervention Comparator	Outcomes
Sweden (one site, number of Risk	of a po ence II impir of Inclu High of ro not r Targ	ositive ingement sign') usion or exclusion otator cuff tears reported get number of ients not reported	year had been present at rest and was reported to be accentuated by movements involving elevation; a positive impingement sign (pain is elicited by forced elevation and internal rotation, a positive impingement test) – pain on elevation is markedly reduced by lidocaine in the subacromial bursa Exclusion: Patients requiring resection of the lateral end of the clavicle as well as those with glenohumeral osteoarthritis were excluded.	Physiotherapy (as per comparator) was provided three months after the operation Comparator: P (physiotherapy) Cross-over to surgery was allowed after 6 months Physiotherapy, according to Bohmer; when the pain had subsided: Information of anatomy and biomechanics of shoulder Advice on how to avoid positions for wear and tear of the subacromion structures Unloaded movements of the shoulder Measures to normalise the scapulohumeral rhythm and to increase postural awareness Strengthen the shoulder muscles, endurance training Initially, patients were seen 2-3 times per week. The intervals between treatments were successively increased as the patient became more familiar with the object of the exercises	

Abbreviations

AA = arthroscopic acromioplasty, AC = acromioclavicular, AE = adverse event, AMSR = active monitoring with specialist reassessment, AO = arthroscopy only, ASAD = arthroscopic subacromial decompression, CAL = coraco-acromial ligament, DA = diagnostic arthroscopy, EG = exercise group, EQ-5D = EuroQol 5-dimension questionnaire, GHJ = glenohumeral joint, MCID = minimum clinically important difference, MRI = magnetic resonance imaging, NaCI = sodium chloride, NHMRC: National Health and Medical Research Council, NO = nonoperative, NSAID = non-steroidal anti-inflammatory, OAA = open anterior acroioplasty, OSS = Oxford Shoulder Score, QoL = quality of life, RC = rotator cuff, RCT = randomised controlled trial, SAD = subacromial decompression, SFTT = surgery, full-thickness tear, SNFTT = surgery, no full-thickness tear, SST = simple shoulder test, VAD = ventricular assist device.

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
Beard (Beard 2015, Beard 2018) SAD=arthroscopic subacromial decompression AO=arthroscopy only) NT=no therapy, active monitoring with specialist reassessment	Subacromial shoulder pain Diagnosis confirmed by an experienced shoulder surgeon – details (e.g. use of X-ray, US, physical tests) other than inclusion and exclusion criteria not provided	Not reported	Exercise therapy and at least one steroid injection – detail not provided	Age: SAD=52.9 [10.3] AO=53.7 [10.5] NT=53.2 [10.2] Sex: SAD=51% [54/106] AO=50% [52/103] NT=50% [52/104]	Maybe (FTT excluded) Diagnosis as assessed during surgery: Bursal and joint-side PTTs. N=patients receiving operation SAD=36% (n=31 of 89) AO= 29% (n=22 of 80) NT=8% (n=2 of 24) Impingement lesion SAD=75% (67 of 89) AO=61% (46 of 80) NT=75% (n=18/24) Size of tears not reported	Pain Detect: SAD=11.7 (6.6) AO=11.0 (5.9) NT=11.9 (6.6) Mean pain (0- 10) 2.9	OSS: SAD=25.2 (8.5) AO=26.7 (8.8) NT=25.5 (8.3) 'well balanced for all baseline characteristics' Constant: SAD=38.4 (13.9) AO=43.1 (15.5) NT=38.3 (14.2)	EQ-5D- 3L: SAD=0.52 [0.30] AO=0.55 [0.29] NT=0.50 [0.33]	2975 assessed for eligibility 740 eligible for inclusion 313 randomised SAD: 106; AO: 103; AMSR/NT: 104

 Table 54
 Study design – patient selection criteria and baseline population characteristics (included RCTs)

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
Brox (Brox 1993, Brox 1999) SAD=arthroscopic subacromial decompression PHYS=physiotherapy LAS=placebo, detuned laser	Patients aged 18–66 years of age with rotator cuff disease for at least 3 months and whose condition was resistant to treatment Diagnosis was with physical tests and lignocaine injection (X-ray, MRI or US not used)	<6 months SAD=18% Phys=12% LAS=17% 6–12 months SAD=18% Phys=0% LAS=17% Over 1 year SAD=64% Phys=76% LAS=65%	Not reported	Age: SAD=48 Phys=47 LAS=48 Sex: SAD=36% (16/45) Phys=56% (28/50) LAS=50% (15/30)	Rotator cuff rupture excluded (no detail provided on methods) Size of tears not reported	Neer pain score SAD=13.8 Phys=14.7 LAS=14.8 Mean pain (0- 10) 40%	Neer overall score SAD=63.3 Phys=66.2 LAS=64.7	NR Hopkins for emotional distress: SAD=1.6 Phys=1.6 LAS=1.6	444 assessed for eligibility 125 were randomised 249 excluded due to other diagnoses 70 excluded as they did not fill criterial for randomisation SAD=45 (13 had different treatment) PHYS=50 (8 had different treatment) LAS=30 (4 had different treatment) They stopped randomising to placebo (laser)
Cederqvist (Cederqvist 2021) SNFTT=surgery, no full-thickness tear SFTT=surgery FTT	Patients with long-term (>3 months) subacromial pain All patients underwent active	Surgery=12 months (IQR 8 to 36) Rehab=12 months (IQR 8 to 21)	Had performed physiotherapist- guided exercises: Surgery= 56% (53/95) Rehab=63% (60/95) Had performed home exercises: Surgery=46% (44/95)	Surgery=56 [8] Rehab= 56 [8] Surgery=45% [47/94]	Rotator cuff tears included (PTT and FTT): patients with FTT treated with rotator cuff repair reported separately	VAS at rest, Surgery=36 [25] Rehab=37 [26] (also shown at activity and at night)	Constant: Surgery=57 [17] Rehab=55 [16]	Only reported for all patients, or by with or without FTT – not reported	664 assessed for eligibility 247 excluded 187 (190 shoulders) Randomised: Surgery=94 (95 shoulders)

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
R=no surgery/ [continued] rehabilitation	rehabilitation before randomisation for 3 months Symptomatic patients were randomised. Diagnosis: MRI arthroscopy and evaluated by a specialist orthopaedic surgeon (including physical tests) Patients were diagnosed as or without a full- thickness tear, and randomised to surgery or no		Rehab=55% (52/95) Had corticosteroid injections: Surgery=74% (67/95) Rehab=68% (65/95)	Rehab=47% [45/93]	Size of tears not reported			by treatment group	SNFTT=45 SFTT=50 R=93 (95 shoulders) (of which 48 had FTT)
Farfaras (Farfaras 2016, Farfaras 2018) O=open surgery A=arthroscopic surgery	Subacromial impingement syndrome Ultrasound for total rotator cuff	Duration of symptoms: 6–12 months [O=2, A=2, P=0];	Conservative therapy (non-structured physiotherapy, nonsteroidal anti- inflammatory drugs, and local corticosteroid	Age: O=52.1(8.4) A=47.0(9.1) P=48.1(9.7), p = 0.22	Maybe Size of tears not reported	Not reported	Constant- Murley: O=48.6 [15.2] A=54.3 [12.0] P=56.1 [12.6]		95 assessed for eligibility 87 randomised [O:24; A:29; P:34] 55 assessed [O:15; A:19; P:21]

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
P=physiotherapy	ruptures; X-ray for osteoarthritis; medical history Patients also tested positive for impingement (Neer sign and Hawkin test)	11–36 months [O=13, A=9, P=10]; >36 months [O=8, A=11, P=17], p = 0.11	injection) – detail not provided	Sex: O=52% [12/11] A=56% [13/10] P=45% [14/17]	Total ruptures, osteoarthritis, rheumatoid arthritis excluded		p = 0.25 between groups		(9 with missing values; 11 declined operation; 3 physio group operated on; 2 died; 7 no follow- up) at mean follow-up 30 months 66 assessed [O:20; A:18; P:28] (2 died; 5 declined operation; 3 physio group operated on; 11 no follow-up) at mean follow-up 10 years
Haahr (Haahr 2005, Haahr 2006) SAD=subacromial decompression P=physiotherapy	Shoulder pain with subacromial impingement Diagnostic criteria: Shoulder pain, pain on shoulder abduction with	<6 months: SAD=4/41 P=3/43 6-12 months: SAD=3/41 P=10/43 >12 months: SAD=34/41 P=29/43	Previous treatments with rest, anti- inflammatories, subacromial injections and physiotherapy were allowed. Physio, passive: SAD=58.5% (24/41) P=67.4% (29/43) Physio, active:	Age: SAD=44.3 (SEM 1.3) P=44.5 (SEM1.2) Sex: SAD=70.7% (29/41) P=67.4% (29/43)	Patients with signs of a rupture of the rotator cuff were excluded No complete tear was identified in the surgery group	VAS (0-15): SAD=4.2 (SEM 0.4) P=4.3 (SEM 0.4) Mean pain (0- 10) 72%	Constant- Murley: SAD=33.7 (SEM 2.3) P=34.7 (SEM2.2)	Not reported	Number assessed for eligibility not reported. 90 randomised (45 in each group). Participants: SAD=41 P=43 (reasons for drop-out provided)

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
	painful arch, a positive impingement sign, and a positive impingement test (relief of pain within 15 minutes after injection of local anaesthetic into the subacromial space) Rheumatologist assessed all patients All patients received X-ray and US		SAD=34.1% (14/41) P=39.5% (17/43) Previous injection: SAD=48.8% (20/41) P=65.4% (28/43)		Size of tears not reported				
Ketola (Ketola 2009 protocol, Ketola 2015, Ketola 2016, Ketola 2017) AA=arthroscopic acromioplasty ET=exercise therapy	Stage II shoulder impingement syndrome Diagnosis by a specialist in rehabilitation or orthopaedic surgeon	Mean: AA=2.5 (range 0.25-17) ET=2.6 (0.25-20)	All patients had received previous physiotherapy. Further details including other therapies not provided.	Age: AA=46.4 (range 23.3 to 60) ET=47.8 (26.8 to 59.2) Sex: AA=59% (41/70)	FTT excluded Size of tears not reported	VAS (0 to 10) AA=6.4 (range 2 to 10) ET=6.5 (range 1 to 10)	Shoulder Disability Questionnaire AA=78 (range 0 to 100) ET=82.5 (range 0 to 100)	NR	None of the eligible patients refused to participate 140 patients randomised AA=70 (of these 13 patients did not have surgery)

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
	The range of movement and muscle strength was tested Impingement test (lidocaine injection into the subacromial space) All patients underwent plain radiography and MR imaging of the shoulder			ET=67% (47/70) BMI: AA= 27.0 kg/m ² (range 15.2 to 41.2) ET= 27.4 kg/m ² (range 19.5 to 46.3)					ET=70 (of these, 14 had surgery)
Paavola (Paavola 2017 protocol, Paavola 2018, Paavola 2021, Bäck 2021) A=arthroscopic surgery DA=diagnostic arthroscopy P=physiotherapy	Subacromial impingement syndrome Detailed clinical examination of the shoulder was performed on all referred patients to rule out possible instability, clinical signs of RC rupture, frozen shoulder	A=18 [14] DA=18 [19] P=22 [23]	Rest, pain medication, topical pain medication, corticosteroid injection, US/laser etc., physiotherapy/exercise therapy – detail not provided	Age: A=50.5 (7.3) DA=50.8 (7.6) P=50.4 (6.6) Sex: A=71% [42/17] DA=73% [46/17] P=66% [46/24]	Maybe Size of tears not reported	VAD at rest A=41.3[25.8] DA=41.6[25.5] P=41.7[27.5] VAD at exercise A=71.2[23.6] DA=72.3[21.7] P=72.4[20.8]	Constant- Murley A=32.2 [15.8] DA=31.7 [14.0] P=35.2 [16.2]	15D score A=0.89 [0.06] DA=0.98 [0.07] P=0.88 [0.08]	281 assessed 210 at first randomisation 193 at second randomisation (baseline population) A=59 DA=63 P=71 At 24 months A=59 DA=59 P=68

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
	or other causes of symptoms. Standard X- rays [to exclude OA] and MRI [to exclude other pathologies] were obtained from all potential participants and assessed by both a musculoskeletal radiologist and an orthopaedic surgeon								
Peters (Peters 1997) SAD=arthroscopic subacromial decompression NO=nonoperative	Grade II outlet impingement. The diagnosis of impingement syndrome was based on the statement of chronic shoulder problems,	Not reported	Not formally reported: Previously had already a conservative treatment of about 6 months	Age: SAD=56 (37-78) NO=59 (37-82) Sex: SAD=44% (14/32) NO=30% (12/40)	FTT excluded (as identified by US) SAD=18/32 had PTT Intraoperatively, 18 patients had partial rotator cuff lesions described by	Do you have pain in the diseased shoulder: SAD=10/35 NO=20/35 Mean pain (0–10) 29–57%	SSRS: SAD=median score 54 NO=median score 59	Not reported	Number of patients assessed not reported 72 patients randomised: SAD=32 NO=40

Trial/study Intervention/ Comparator	Diagnosis Method of diagnosis/ assessment for eligibility	Duration of symptoms (mean months [SD])	Previous therapies	Age (years [SD]), sex (%F [F/M])	Presence of rotator cuff rupture (or other pathology) Size of tear	Baseline characteristics (pain)	Functional score (mean [SD])	Health- related QoL	Number of participants (assessed for eligibility; enrolled; received the intervention)
	aggravated by overhead work Method of diagnosis: Clinical examination, X- rays, SSRS (Subjective Shoulder Rating Scale)				which joint-side parts in 11 patients of the rotator cuff were affected Size of tears not reported				
Rahme (Rahme 1998) OAA=anterior acromioplasty (open: according to Neer) P=physiotherapy Cross-over to surgery was allowed after 6 months	Diagnosis not reported (beyond the inclusion criteria). Method of diagnosis was physical tests (VAS, pour-out- of-a-pot, range of motion, hand grip strength); X-ray	For the total cohort: 4 years	Not reported	Age: In the total cohort: 42 (range 28–63) Sex: In the total cohort: 55% female (23/42)	5 full-thickness tears were repaired Size of tears not reported	Not reported	Not reported	Not reported	Number of patients assessed not reported 42 patients randomised OAA=21 P=21

Abbreviations

A = arthroscopic surgery, AA = arthroscopic acromioplasty, AO = arthroscopy only, BMI = body mass index, DA = diagnostic arthroscopy, ET = exercise therapy, F/M = female/male ratio, FTT = full-thickness tear of the rotator cuff, IQR = interquartile range, LAS = placebo, detuned laser, MRI = magnetic resonance imaging, NO = nonoperative, NT = no therapy, active monitoring with specialist reassessment, O = open surgery, OA = osteoarthritis, OAA = open anterior acromioplasty, OSS = Oxford Shoulder Score, P/PHYS = physiotherapy, PTT = partial-thickness tear of the rotator cuff, R = no surgery/[continued] rehabilitation, RC = rotator cuff, SAD = arthroscopic subacromial decompression, SD = standard deviation, SFTT = surgery, FTT, SNFTT = surgery, no FTT, SSRS = subjective shoulder rating scale, US = ultrasound, VAS = Visual Analogue Scale.

Study ID	Target population	Baseline	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number
ITT or per-protocol design			of patients; 6 months	of patients; 12 months	of patients; 2 years	of patients; 5 years	of patients; 10 years
Beard ITT and per-protocol analyses done "The per-protocol analyses showed similar results and the results were not sensitive to missing data" SAD=arthroscopic subacromial decompression AO=arthroscopy only AMSR/NT=no therapy, active monitoring with specialist reassessment	Required 85 per group (3 groups) 90% power to detect a difference in the OSS of 4.5 (SD 9.0) (further definition of MCID not provided) 300 planned	313 randomised SAD: 106; AO: 103; AMSR/NT: 104	6 months Assessed SAD: 90; AO: 94; AMSR/NT: 90 The following did not receive their defined intervention: SAD: 24 (23%) AO: 43 (42%) AMSR/NT: 12 (12%) At 6 months non- protocol: SAD: 28% AO: 42% 9 (9%) had surgery incl SAD) AMSR/NT: 12%; 11 (11%) had surgery incl SAD Diagnosis as assessed during surgery SAD (n=89): 67 (75%) has impingement; 31 (36%) had PTT AO (n=80): 46 (61%) had impingement; 22 (29%) had PTT AMSR/NT (n=24): 18 (75%) had impingement lesion	12 months Assessed SAD: 88 AO: 93 AMSR/NT: 84 The following did not receive their defined intervention: SAD: 19 (18%) AO: 35 (34%) AMSR/NT: 26 (25%) At 12 months non- protocol: SAD: 25% AO: 34% 10 (10%) had surgery incl SAD) AMSR/NT: 25%; 25 (24%) had surgery incl SAD There were no reported revision surgeries.			

Study ID	Target population	Baseline	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number
ITT or per-protocol design			of patients; 6 months	of patients; 12 months	of patients; 2 years	of patients; 5 years	of patients; 10 years
			2 (8%) had PTT				
Brox No power calculation or MCID reported ITT SAD=arthroscopic subacromial decompression PHYS=physiotherapy LAS=placebo, detuned laser	Not reported	125 were randomised SAD=45 PHYS=50 LAS=30 They stopped randomising to placebo (laser) Average time between randomisation and first day of treatment was 2 months.	6 months Assessed: SAD=41 (13 had different treatment) (4 did not attend FU) PHYS=50 (8 had different treatment) LAS=30 (4 had different treatment)		 2.5 years Assessed: SAD=39 ITT, 45 (14 different treatment including adhesive capsulitis (1), other diagnoses (3), muscular pain (1), condition improved (3), had exercises (3), did not attend follow-up (5)) PHYS=45 50 ITT (17 different treatment, 11 (24%) had surgery) LAS=29 30 ITT (17 different treatment, 15 (59%) had surgery) There were no reported failures or revision surgeries 		
Cederqvist	Planned 100 per group (2 groups,	417 patients with subacromial pain			2 years		
ITT and per-protocol	surgery divided into	underwent 3 months			Surgery: 80		
analyses done	two)	rehabilitation. 187			shoulders		
	Based on a power calculation for a 30%	(190 shoulders) Randomised:			Non-surgery: 81 shoulders		
SNFTT=surgery, no full-thickness tear	difference between	Surgery= 94 (95					
SFTT=surgery, FTT	treatment groups	shoulders)			Surgery: 36 (38%)		
	(also considered to	SNFTT= 45			improved and did not		
	be MCID)	SFTT= 50			undergo surgery		

Study ID	Target population	Baseline	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number
ITT or per-protocol design			of patients; 6 months	of patients; 12 months	of patients; 2 years	of patients; 5 years	of patients; 10 years
R=no surgery/ [continued] rehabilitation		R = 93 (95 shoulders) (of which 48 had FTT) Any delay between randomisation and surgery not reported.			Non-surgery/R: 12 (13%) had severe pain and were given surgery 75% shoulders treated per protocol No patients required reoperation		
Farfaras Per-protocol analysis O=open surgery A=arthroscopic surgery P=physiotherapy	Required 36 per group 40 per group planned A 10-point difference in Constant score was considered to be of clinical importance The randomisation process was closed after recruiting 87 patients (took too long)	87 randomised [O:24; A:29; P:34] Any delay between randomisation and surgery not reported.			30 months 55 assessed [O:15; A:19; P:21] (9 with missing values; 11 declined operation; 3 physio group operated on; 2 died; 7 no follow-up) at mean follow-up 30 months		10 years (mean 13.7 years) 66 assessed [O:20; A:18; P:28] (2 died; 5 declined operation; 3 (11%) physiotherapy group operated on; 11 no follow-up) at mean follow-up 10 years No patients had reoperations or revision surgeries
Haahr ITT No reported per- protocol analysis	40 per group planned Based on a power calculation of a 13 point difference (MCID) in the	90 randomised Participants: SAD=45 P=45 (reasons for drop-out provided)		1 year Analysed SAD=41 (4 did not receive therapy) P=43 (2 did not		4-8 years (mean not provided) Analysed SAD=39 P=40	
SAD=subacromial decompression P=physiotherapy	Constant score at 12 months	Intervention in both groups began four		receive therapy) In P group		In P group 11 (26%) operated on (extra 5)	

Study ID	Target population	Baseline	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number	Follow-up/number
ITT or per-protocol design			of patients; 6 months	of patients; 12 months	of patients; 2 years	of patients; 5 years	of patients; 10 years
		weeks after enrolment		6 patients were operated on due to lack of improvement (5 SAD, 1 rotator cuff tear repair) In those who received surgery there were no FTT		No patients had reoperations or revision surgeries	
Ketola ITT Also analysed per protocol AA=arthroscopic acromioplasty ET=exercise therapy	70 per group planned 45 patients per group required based on power calculations, for a MICD change of VAS at 24 months of 1.5 (SD 2.5)	140 patients randomised AA= 70 ET= 70 Following randomisation there was a mean delay of 1.2 months (0.2 to 4.6) to the commencement of treatment in the exercise group and 8.3 months (1.4 to 11.8) for the patients who underwent arthroscopy			24 months Assessed: AA=66 (of randomised patients 13 did not have surgery) ET=68 (of randomised patients, 14 had surgery) Per-protocol analysis not undertaken	5 years 109 assessed AA=57 (12 patients in total did not have surgery) ET=52 (additional 4 patients – so total 19 [37%] – had SAD [3] and rotator cuff repair [1]) Per-protocol analysis was undertaken (this and ITT reported) No differences between groups	10 years (mean 12.3 years) 90 assessed (questionnaires) AA=44 ET=46 No reported difference in surgery between groups compared to that reported in year 5 Per-protocol analysis was undertaken (this and ITT reported) No differences between groups No patients had reoperations or revision surgeries
Paavola	70 per group planned (for 90% power to detect a	193 at second randomisation (baseline population)			24 months	5 years	

Study ID ITT or per-protocol design	Target population	Baseline	Follow-up/number of patients; 6 months	Follow-up/number of patients; 12 months	Follow-up/number of patients; 2 years	Follow-up/number of patients; 5 years	Follow-up/number of patients; 10 years
ITT Results remained unaltered in the pre- specified sensitivity analyses (as treated and per protocol) and subgroup analyses A=arthroscopic surgery DA=diagnostic arthroscopy P=physiotherapy	difference of at least the MCID (15 points) in the two primary outcomes between SAD and DA)	A=59 DA=63 P=71 Surgery was within 12 weeks of randomisation			A=59 (1 had conversion to manipulation under anaesthesia) DA=59 (9 (15%) had conversion to SAD and one (1) rotator cuff repair) P=68 (15 (22%) patients were unblinded: treatment converted to SAD) Conversions were all within 4 months of unblinding. Reoperations: A=1 (arthroscopic distal clavicle resection conversion This patient had a reoperation of SAD and distal clavicle resection) DA=0 P=3 (Of those patients converted to SAD, 3 had reoperations: 1 to manipulation under anaesthesia	A=53 (2 had conversions, additional was to distal clavicle resection) DA=55 (10 [18%] had conversion to SAD – one extra from trauma) P=62 (16 had conversion to SAD) (All missing data due to patient withdrawal or loss to follow-up) Reoperations (no change as shown at 24 months)	

Study ID ITT or per-protocol design	Target population	Baseline	Follow-up/number of patients; 6 months	Follow-up/number of patients; 12 months	Follow-up/number of patients; 2 years	Follow-up/number of patients; 5 years	Follow-up/number of patients; 10 years
					1 to SAD and long head of biceps tendon repair 1 to SAD and arthroscopic distal clavicle resection) (All missing data due to patient withdrawal or loss to follow-up)		
Peters ITT or per protocol SAD=arthroscopic subacromial decompression NO=nonoperative	Not reported	72 patients randomised: SAD=32 NO=40 Time to surgery not provided		1 year SAD=26 NO=36	2 year SAD=32 NO=39	3 year SAD=28 NO=37	4 year SAD=23 NO=25 No reported or different intervention or reoperation
Rahme ITT undertaken and per protocol (although this is not very clear) OAA=anterior acromioplasty (open: according to Neer) P=physiotherapy	Not reported	42 patients randomised OAA=21 P=21 6 months after physio patients were allowed surgery Time to surgery not provided	6 months OAA=21 P=18	1 year OAA=21 P=6 AA after P=12 (57% had surgery) No reported reoperations or revision surgeries			

Abbreviations

A = arthroscopic surgery, AA = arthroscopic acromioplasty, AMSR/NT = no therapy, active monitoring with specialist reassessment, AO = arthroscopy only, CSAW = Can Shoulder Arthroscopy Work?, DA = diagnostic arthroscopy, ET = exercise therapy, FIMPACT = Finnish Shoulder Impingement Arthroscopy Controlled Trial, FTT = full-thickness tear of the rotator cuff, FU = follow-up, ITT = intention-to-treat, LAS = placebo, detuned laser, MCID = minimum clinically important difference, O = open surgery, OAA = open anterior acromioplasty, OSS = Oxford Shoulder Score, P/PHYS = physiotherapy, PTT = partial-thickness tear of the rotator cuff, R = no surgery/ [continued] rehabilitation, SAD = arthroscopic subacromial decompression, SD = standard deviation, SFTT = surgery, FTT, SNFTT = surgery, no full-thickness tear, VAS = visual analogue scale.

Table 56	Study design – intervention and comparators
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Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
Beard (Beard 2015, Beard 2018)	ASAD (arthroscopic subacromial decompression) Removal of bursa and soft tissue within the subacromial space, release of the coraco-acromial ligament, and removal of the subacromial bone spur through posterior and lateral portals. The procedure is performed with the patient under general anaesthesia. Skin incisions are made for the introduction of the arthroscope and required instruments. The procedure involves insertion of the arthroscope into the glenohumeral joint, where the joint surface is inspected along with the intraarticular portion of the long head of biceps and the joint surface of the rotator cuff tendons. Once this has been performed, the arthroscope is removed and inserted into the subacromial bursa, which lies outside the rotator cuff tendons and beneath the acromion process of the scapula. In the bursa, the acromion and superior surface of the rotator cuff are assessed to ensure that the coraco-acromial ligament and the AC joint remain intact. The projecting undersurface of the distal part of the acromion is resected. The intervention is considered a well-established and well- documented procedure. Postoperative physiotherapy involved advice and between one and four routine treatment sessions.		AO (arthroscopy only) The AO arm is the surgical comparison group. The procedure is performed with the patient under general anaesthesia. Patients will undergo a routine investigational arthroscopy of the joint and rotator cuff tendon. The operation will be performed in exactly the same manner as that in the ASAD group. Investigational arthroscopy has all the same essential operative components (and risks) of ASAD, but it does not involve surgical removal of any spurs or bursal tissue or release of the coracohumeral ligament. The procedure does involve the glenohumeral joint and the subacromial bursa being inspected and irrigated. Structures can be assessed for integrity and damage. The rotator cuff can be assessed for evidence of full-thickness tears. The synovium and lining of the shoulder can be assessed for evidence of capsulitis, arthritis or frozen shoulder. The time spent in the operating theatre will be similar to that for the ASAD group. These measures provide the AO group with the characteristics necessary to provide a reasonable comparison and account for the placebo effects of surgery. Postoperative physiotherapy involved advice and between one and four routine treatment sessions.	AMSR (active monitoring with specialist reassessment) Patients will be advised that they will undergo active monitoring. They will attend a reassessment appointment 3 months after entering the study. At that appointment, they will be asked to complete questionnaires related to their shoulder pain and undergo a clinical assessment of the shoulder, including a record of any further conservative treatment. If, at the end of the 6-month assessment period, patients remain sufficiently symptomatic to require further intervention (based on clinical judgement), then additional treatment options will be discussed. It should be noted that the inclusion criteria state that all patients will have undergone conservative treatment (including physiotherapy and injection) before entering the trial. From an ethical standpoint, it is emphasised that it is quite within normal practice to have a period of active monitoring.

Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
Brox (Brox 1993, Brox 1999)	SAD (arthroscopic subacromial decompression) Bursectomy and resection of the anterior and lateral part of the acromion and the coraco-acromial ligament. Average time between randomisation and first day of treatment was 2 months. Physiotherapy started within the first week. The exercises prescribed by the surgeon were performed against low resistance and repeated many times. Patients visited a physiotherapist where they lived, so several physiotherapists were engaged and somewhat different approaches used. Unrestricted activities were usually allowed after four to six weeks. Analgesics, including anti-inflammatory drugs but not cortisone injections, were allowed.		PHYS (physiotherapy) The patients who were randomised to receive supervised exercises and placebo laser treatment were all treated by the same experienced physiotherapist at the department of physical medicine and rehabilitation at this hospital. The training continued for 3 to 6 months, with the supervision gradually being reduced. In addition, 3 lessons were given on the anatomy and function of the shoulder, pain management and ergonometrics. Analgesics, including anti-inflammatory drugs but not cortisone injections, were allowed.	LAS (placebo, detuned laser) Placebo treatment was given in 12 sessions. Each consisted of exposure to a detuned soft laser and was scheduled twice weekly for six weeks. Analgesics, including anti-inflammatory drugs but not cortisone injections, were allowed. No exercise of physiotherapy was provided.
Cederqvist (Cederqvist 2021)	SNFTT (surgery, no full-thickness tear repair) When necessary, patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps. All patients followed a structured postoperative rehabilitation protocol (provided).	SFTT (surgery with full-thickness tear repair) Patients with full-thickness tears received rotator cuff repair with single-row technique, with one or more bone anchors, via either an arthroscopic or mini open approach. When necessary, patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps. All patients followed a structured postoperative rehabilitation protocol (provided).	R (no surgery/[continued] rehabilitation) Continuation of the rehabilitation program Unsuccessful patients (severe pain or poor subjective shoulder function) – patients were offered surgery.	
Farfaras (Farfaras 2016,	O (open surgery)	A (arthroscopic surgery) A = bursectomy; acromioplasty.	P (physiotherapy) Physiotherapy by the method of Bohmer Formal training with standardised	

Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
Farfaras 2018)	Acromioplasty; CAL release; coplaning. Ice, sling and pain relief, followed by physiotherapy as in the P group An osteotome was used to remove the anterior edge and the lateral portion of the undersurface of the acromion. The removed bone included the attachment of the coraco-acromial ligament. The piece of bone was about 6–9 mm wide and 20 mm long. Proximal to the coracoid, the coraco-acromial ligament was cut. Palpation of the undersurface of the acromion was performed to detect any fragments of bone or prominences. The undersurface of the acromioclavicular joint was palpated and inspected. If osteophytes were present, they were excised. No acromioclavicular joint resections were performed.	Ice, sling and pain relief, followed by physiotherapy as in the P group A portal for the arthroscope was created on the dorsal side of the shoulder. The glenohumeral joint was first evaluated for cartilage changes, disorder of the biceps tendon, labrum and the rotator cuff. Using the same arthroscopic portal, the subacromial space was visualised and a bursectomy was performed with a shaver introduced from a lateral portal. A resection of the anterior edge of the acromion of about 5–8 mm was then carried out, followed by a resection of about 5–8 mm of the anterior–inferior third of the undersurface of the acromion all the way to the acromioclavicular joint.	protocol, 1 hour per day (twice a week with a physio) for 3–6 months	
	At discharge, the patients received a prescription of pain medication and an ice pack in a sling to be used during the first postoperative weeks to reduce pain and swelling. The postoperative rehabilitation supervised by five local physiotherapists was the same as in the physiotherapy group. The rehabilitation started as soon as the pain permitted.			
Haahr (Haahr 2005, Haahr 2006)	SAD (subacromial decompression) Bursectomy with partial resection of the antero-inferior part of the acromion and the coraco-acromial ligament. Before discharge, the patient was instructed in performing light movements of the arm within the limits of pain. The patient was		P (physiotherapy) Physiotherapy. 19 sessions each of up to 60 minutes given by two experienced therapists. Heat/cold packs; active training and strengthening of muscles of the shoulder joint. Supervision 3x per week (first 2 weeks); 2x per week (2	

Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
	instructed by a physiotherapist to carry out increasingly active exercises, including exercises for strengthening the rotator cuff muscles. The team instructing the surgery group was different from the group treating the control (training) group. The surgeon then saw the patients after six to eight weeks.		weeks); 1x per week (7 weeks). At home daily for at least 12 weeks, then at home 2–3 times per week. Intervention in both groups began four weeks after enrolment.	
	Intervention in both groups began four weeks after enrolment.			
Ketola (Ketola 2009 protocol, Ketola 2015, Ketola 2016, Ketola 2017)	AA (arthroscopic acromioplasty) Debridement and decompression were done through an anterolateral portal by shaver and/or vaporiser. If the coraco- acromial ligament felt tight or thick, it was released. Acromioplasty was then performed, starting anteriorly and progressing posterolaterally with a burr drill. The range of movement was tested under arthroscopic visualisation to check for any local impingement. After recovery patients received similar individually planned and progressive training programs to the exercise group. As in the other group, progress was evaluated during physiotherapy control visits, which generally numbered six. NSAIDs were allowed as necessary. Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program.		ET (exercise therapy) Information was first given by a trained physiotherapist. A home program was individually planned for each patient according to the same principles. Elasticated stretch bands and light weights were used in training, which was based on long painless series and repetitions aiming at tendon strengthening. The sessions were performed at least four times a week using nine different exercises with 30 to 40 repetitions three times. There were a minimum of 7 controlled visits to the therapist until patient was able to perform independently. NSAIDs were allowed as necessary. Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program.	
Paavola (Paavola 2017 protocol, Paavola	A (arthroscopic surgery) Surgery within 12 weeks of randomisation. Additional pathology identified or treated meant that patient was excluded. PTT included. FTT		DA (diagnostic arthroscopy) Surgery within 12 weeks of randomisation. Under GA. No bursectomy, but bursal tissue could be stretched – or resected, keeping	P (physiotherapy) Supervised, progressive, individually designed physiotherapy was started within 2 weeks of randomisation. Standardised protocol but updated for

Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
2018, Paavola 2021, Bäck 2021)	excluded. Debridement of the entire subacromial bursa (bursectomy). Resection of the bony spurs and projecting anterolateral undersurface of the acromion. Postoperative care: One visit to physiotherapist, guidance for home exercises, then standardised rehabilitation program from each centre. Details on other conservative therapies (pain medications, subacromial injections) not provided.		resection to a minimum. Additional pathology identified or treated meant that patient was excluded. PTT included. FTT excluded. Postoperative care: One visit to physiotherapist, guidance for home exercises, then standardised rehabilitation program from each centre. Details on other conservative therapies (pain medications, subacromial injections) not provided.	best practice exercise therapy. Daily home exercises. 15 physio visits, once a week. Aim to restore function, no pain. No timelines provided. Details on other conservative therapies (pain medications, subacromial injections) not provided.
Peters (Peters 1997)	 SAD (subacromial decompression) Arthroscopic in 15 cases subacromial decompression in the Ellmann technique or an open acromioplasty to Neer (17 cases). Intraoperatively, 18 patients had partial rotator cuff lesions described by which joint-side parts in 11 patients of the rotator cuff were affected. From the fourth postoperative week came strengthening exercises against resistance added. 		NO (nonoperative) Implementation of conservative treatment. Hospitalised for 2 weeks. It became a treatment program with intense physical therapy carried out. Non-steroidals were supportive anti- inflammatory drugs (e.g. ibuprofen 2 times 400 mg p.o.) if no gastrointestinal problems in the anamnesis templates. Further took place an infiltration of the subacromial space with corticosteroids such as triamcinolone 5 mg in 10 ml physiological NaCl solution. There have been up to a maximum of 3 injections administered.	
Rahme (Rahme 1998)	OAA (open anterior acromioplasty) (open: according to Neer) Anterior acromioplasty according to Neer (open). Physiotherapy (as per comparator) was provided three months after the operation.		P (physiotherapy) Physiotherapy, according to Bohmer; when the pain had subsided: Information of anatomy and biomechanics of shoulder. Advice on how to avoid positions for wear and tear of the subacromial structures. Unloaded movements of the shoulder.	

Trial/study	Intervention 1	Intervention 2	Comparator 1	Comparator 2
			Measures to normalise the scapulohumeral rhythm and to increase postural awareness. Strengthen the shoulder muscles, endurance training. Initially, patients were seen 2-3 times per week. The intervals between treatments were successively increased as the patient became more familiar with the object of the exercises. Patients not satisfied with the results of the surgical treatment were allowed to choose surgery.	

Abbreviations

A = arthroscopic surgery, AA = arthroscopic acromioplasty, AC = acromioclavicular, AMSR = active monitoring with specialist reassessment, AO = arthroscopy only, ASAD = arthroscopic subacromial decompression, CAL = coraco-acromial ligament, DA = diagnostic arthroscopy, ET = exercise therapy, FTT = full-thickness tear, GA = general anaesthetic, LAS = placebo, detuned laser), NaCI = sodium chloride, NO = nonoperative, NSAIDs = non-steroidal anti-inflammatories, O = open surgery, OAA = open anterior acromioplasty, P/PHYS = physiotherapy, PTT = partial-thickness tear, R = no surgery/ [continued] rehabilitation, SAD = subacromial decompression, SFTT = surgery with full-thickness tear repair, SNFTT = surgery, no full-thickness tear repair.

Table 57 Summary of safety evidence: RCTs

Trial/study	Population	Follow-up	Intervention	Comparator	Adverse events
Beard (Beard 2018, Beard 2015)	Total: n=313 SAD: n=106 Diagnostic arthroscopy: n=103 No treatment: n=104	6 months and 12 months	Subacromial decompression	Arthroscopy No treatment	Frozen shoulder: Total: 2.5% (n=6) SAD: 2.8% (n=2) Placebo: 3.1% (n=2) Conservative treatment: 3.1% (n=2)
Paavola (Paavola 2018, Paavola 2017, Paavola 2021)	Total: n=193 SAD: n=59 Diagnostic arthroscopy: n=63 Conservative treatment: n=71	24 months	Subacromial decompression	Placebo surgical intervention (diagnostic arthroscopy) Conservative or nonoperative (exercise therapy)	Temporary swelling in the brachial area related to a brachial plexus block: Total: 0.8% (n=1) Placebo: 1.6% (n=1) Frozen shoulder: Total: 3.3% (n=4) ASD: 5.1% (n=3) Placebo: 1.6% (n=1) Conservative treatment: 2.8% (n=2)
Cederqvist 2021	Total: n=417 Surgical: n=190 Conservative management: n=190	24 months	Subacromial decompression (with or without rotator cuff repair)	(Continued) rehabilitation protocol	No adverse events

Abbreviations

SAD = arthroscopic subacromial decompression.

Table 58 Summary of case series

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population			Follow-up times Outcomes
Safety					
Shields 2015 (Shields et al., 2015)	-	cases from the adult		Shoulder arthroscopy	30-day postoperative period Complications
USA The authors report the	Level IV	2005 and 2011	CPT codes: 29827 Rotator cuff repair		30-day mortality 30-day morbidity (major and minor complications)
following potential conflict of interest or source of funding: One author receives support from Zimmer, Arthrex, Acumed, Pfizer and ArthroCare			29827 Rotator cum repair 29826 SAD with acromioplasty 29807 SLAP lesion repair 29806 Capsulorrhaphy 29824 Distal claviculectomy 29823 Extensive debridement 29822 Limited debridement 29825 Lysis and resection of adhesions with or without manipulation		Major complications: Return to operating room Pulmonary embolism Myocardial infarction Death Unplanned intubation Organ/space SSI

Country Funding source Conflicts of interest	Study design NHMRC evel of evidence Quality appraisal	Study population		Follow-up times Outcomes
			29828 Biceps tenodesis 29821 Complete synovectomy 29819 Foreign-body removal 29820 Partial synovectomy Exclusion: younger than 18 years old, had preoperative sepsis, systemic inflammatory response syndrome or septic shock or had preoperative wound infections and/or their operative wounds were classified as clean/contaminated, contaminated or dirty/infected	Septic shock Cardiac arrest requiring CPR Cerebrovascular accident Sepsis Deep incisional SSI Wound disruption Ventilator for >48 h Acute renal failure Minor complications: Superficial SSI Urinary tract infection Deep vein thrombosis Pneumonia Bleeding transfusion Peripheral nerve injury

Study details Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Follow-up times Outcomes
Heyer 2020 (Heyer et al., 2020) USA The authors declared no conflict of interest No source of funding is stated			Inclusion Patients identified with the CPT for knee or shoulder arthroscopic procedures, including shoulder arthroscopy with SAD	SAD	Thirty-day complications. Cardiac [myocardial infarction (MI) or cardiac arrest], renal [acute kidney injury (AKI) or dialysis], wound [superficial surgical site infection (SSI), deep SSI, or organ space infection or dehiscence], sepsis (sepsis or septic shock), clotting [pulmonary embolism or deep vein thrombosis (DVT)], and pulmonary (pneumonia, prolonged intubation, reintubation) events, and mortality. A composite was positive if any of these occurred and negative if none occurred
Hill 2017 (Hill et al., 2017) USA The authors declared no conflict of interest		Surgeons NSQIP database from 2011 and 2013	Inclusion Major procedures: 29827 Rotator cuff repair 29807 Superior labrum anterior and posterior lesion repair 29806 Capsulorrhaphy 29828 Biceps tenodesis	Intervention Elective arthroscopic shoulder surgery	30-day postoperative period 30-day readmission Complications (major and minor complications) Major complications: Pulmonary embolism

Study details Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Follow-up times Outcomes
No source of funding is stated			Minor procedures: 29826 Subacromial decompression with acromioplasty 29823 Extensive debridement 29822 Limited debridement 29824 Distal claviculectomy 29825 Lysis and resection of adhesions with or without manipulations 29820 Partial synovectomy 29819 Foreign-body removal 29821 Complete synovectomy Exclusion Only those patients undergoing a primary elective procedure, cases with preoperative sepsis or pneumonia, wound	Sepsis Organ/space SSI Myocardial infarction Unplanned intubation Deep incisional SSI Acute renal failure Ventilator for >48 hours Cerebrovascular accident Septic shock Cardiac arrest requiring cardiopulmonary resuscitation Wound dehiscence Total major complications Minor complications: Superficial SSI Urinary tract infection

Study details Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal		Inclusion criteria Exclusion criteria		Follow-up times Outcomes
			infection (wound class 2, 3 or 4), coma, preoperative transfusion, hospital stay >30 days, or ASA classification of '5-Moribund'		Deep vein thrombosis Pneumonia Bleeding transfusion Peripheral nerve injury
Rees (Rees et al., 2022) UK Conflicts of interest were declared. There was no support from any organisation for the submitted work. Authors reported various grants, consultancy fees, patents that were external to the submitted work.	Level IV	whom 103,211 underwent SAD from the Hospital Episode Statistics for NHS England database	Inclusion Patients as identified using the Office for Population Censuses and Surveys Classification of Interventions and Procedures (OPCS-4) codes; diagnoses as identified using ICD-10 Age 16 years and older who received surgery between 1 April 2009 and 31 March 2017 Exclusion current diagnosis of primary or secondary malignancy of the shoulder girdle, a history of a shoulder girdle fracture or shoulder operation in the preceding six months, or a history of ipsilateral shoulder replacement surgery at any time	Arthroscopic SAD	90 day postoperative period Mortality, pulmonary embolism, pneumonia, myocardial infarction, acute kidney injury, stroke, and urinary tract infection associated with inpatient care

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Follow-up times Outcomes
supported by funding from a research centre.					
al., 2014)		165,820 patients who underwent shoulder arthroscopy from the PearlDiver Patient		Intervention Shoulder arthroscopic surgery	Infections requiring reoperation (open or closed surgical drainage, represented by CPT codes 20000, 20005, 23030, 23031, 23040, 23100, 23105, 23107, and 29819- 29821 within 30 days of the
USA		Record Insurance database (US)	Including CPT codes 29806 (capsulorrhaphy), 29807 (superior labrum anterior-posterior [SLAP] tear repair), 29824		index procedure)
The authors declared one conflict of interest, that one author has stock options in the database.			(claviculectomy), 29826 (decompression), and 29827 (rotator cuff repair)		
No source of funding is stated.					
Long-term follow-up					·

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria		Follow-up times Outcomes
Bjornsson 2010 (Bjornsson et al., 2010) Sweden No conflict of interests were reported. No source of funding is		impingement		SAD	13 to 17 years (mean not provided) Results of high-resolution ultrasonography
chin 2007 (Chin et al.,	Level IV	Patients with moderate or	Inclusion:	Intervention	Mean 25 (range 21 to 27) years
2007) US No conflict of interests were		severe shoulder pain, with impingement syndrome.	Painful arc on active elevation; positive Neer impingement sign; positive impingement test (injection of local anaesthetic); failed previous conservative therapy	Anterior (open) acromioplasty, with excision of the CAL. 4/32 patients received	Patient Shoulder Questionnaire Simple Shoulder Test American Shoulder and Elbow Surgeons evaluation
reported.				, ,	

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Follow-up times Outcomes
No source of funding is reported.				tendonesis of the long head of the biceps	
Hultenheim Klintberg 2011 (Hultenheim Klintberg et al., 2011) Sweden The authors report no financial conflict of interests. The publication was supported through grant funding.		stage if and in	Inclusion Diagnosis of impingement by clinical examination, positive impingement test and X-ray. US or MRI used if there was indication of rotator cuff tear. Exclusion Conditions that interfere with shoulder function, medium size FTT identified at surgery	lateral clavicle was not performed. Postoperative physiotherapy	8-11 years Western Ontario Osteoarthritis Shoulder Index EQ-5D Physical activity Pain (VAS)
Jaeger 2016 (Jaeger et al., 2016) Germany			Inclusion Diagnosis confirmed by US followed by X- ray. Clinical examination included Neer sign and Hawkins-Kennedy test. Exclusion	no rotator cuff repair; torn	19.9 (19.5 to 20.5) years Constant score Revision surgery

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	,,,,	Inclusion criteria Exclusion criteria		Follow-up times Outcomes
The authors report no conflict of interests. No source of funding is reported.			Patients with instability; older than 60 at surgery).		
Norlin 2008 (Norlin and Adolfsson, 2008) Sweden		signs of subacromial impingement	Inclusion More than 6 months of shoulder pain; positive impingement sign according to Neer or Hawkins-Kennedy; positive impingement test (injection of local anaesthetic).	bursectomy, CAL release. No additional debridement, resection of calcific deposits, biceps tenotomy or lateral clavicle resection	11.2 (10-13) years Clinical examination Constant-Murley score DASH score
No conflict of interests were reported. No source of funding is reported.			Exclusion Osteoarthritis in the gleno-humeral joint, instability, adhesive capsulitis, neurologic disorders or rheumatoid arthritis.		

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Follow-up times Outcomes
Odenbring 2008 (Odenbring et al., 2008) Sweden The authors report no conflict of interests. The publication was supported by a research grant.			Inclusion Diagnosis of shoulder impingement syndrome based on positive Neer and Hawkins impingement signs and a positive impingement test, shoulder pain at least with heavy activities, and a lack of improvement after at least 6 months of nonoperative treatment. X-rays to exclude osteoarthritis of the glenohumeral joint Exclusion Trauma, workers compensation claims		1 and 13 years University of California, Los Angeles (UCLA) DASH (Disability of the Arm, Shoulder and Hand score) SF-36 EQ-5D
Ranebo 2017 (Ranebo et al., 2017) Sweden The authors report no financial conflict of interests.		Patients with subacromial pain and rotator cuff tears		bursectomy and CAL release Postoperative rehabilitation	22 (range 21-25) years Western Ontario Rotator Cuff Index Constant-Murley score X-ray Ultrasonography

Country Funding source Conflicts of interest	Study design NHMRC level of evidence Quality appraisal	 Inclusion criteria Exclusion criteria	Follow-up times Outcomes
The publication was supported by funding from a medical research council.			

Abbreviations

ASA = American Society of Anesthesiologists, CPT = current procedural terminology, ICD-10 = international classification of diseases, 10th revision, NHMRC = National Health and Medical Research Council, NSQIP = National Surgical Quality Improvement Program, SAD = subacromial decompression, SLAP = superior labrum anterior and posterior, SSI = surgical site infection, USA = United States of America.

Adverse event	Intervention	Comparator
Randomised controlled trials		
Frozen shoulder	 1.9% (2/106) Beard 5.1% (3/59) Paavola 	Conservative therapy • 1.9% (2/104) Beard • 2.8% (2/71) Paavola Placebo • 1.9% (2/103) Beard • 1.6% (1/63) Paavola
Low back pain		Conservative therapy • 1.4% (1/71) Paavola
Temporary swelling postoperative		Placebo • 1.6% (1/63) Paavola
Overall adverse event rate (p = 0.86)	3.0% (5/165) Beard, Paavola	3.7% (9/241) Beard, Paavola
Case series		
Death	 0.01% (2/15,015) Hill 2016 0.03% (4/10,255) Shields 2015 0.04% (5/32,228) Heyer 2020 0.06% (61/103,211) Rees 2022 	
Major complications		
Return to operating room	 0.27% (40/15,015) Hill 0.33% (34/10,255) Shields 0.40% (418/103,211) Rees (reoperation) 	
Pulmonary embolism	 0.13% (20/15,015) Hill 0.07% (7/10,255) Shields 0.24% (77/32,228) Heyer (including pulmonary or venous thromboembolism) 0.06% (63/103,211) Rees 	
Sepsis	• 0.01% (1/10,255) Shields	
Organ/space SSI	• 0.02% (3/15,015) Hill	
Myocardial infarction	 0.02% (3/15,015) Hill 0.04% (4/10,255) Shields 0.07% (24/32,228) Heyer 2020 (myocardial infarction or cardiac arrest) 0.11% (112/103,211) Rees 	
Unplanned intubation	 0.05% (7/15,015) Hill 0.03% (3/10,255) Shields 	
Deep incisional SSI	 0.007% (1/15,015) Hill 0.01% (1/10,255) Shields 	

Table 59 Safety evidence: RCTs and case series

Adverse event	Intervention	Comparator
	0.05% (51/94,819) Rees (reoperation for deep infection within 1 year)	
Acute renal failure	 0.01% (2/15,015) Hill 0.01% (1/10,255) Shields 0.01% (2/32,228) (Heyer 2020) 0.08% (79/103,211) Rees 	
Ventilator >48 hours	 0.01% (2/15,015) Hill 0.01% (1/10,255) Shields 0.16% (51/32,228) Heyer (including pneumonia, prolonged intubation, reintubation) 	
Cerebrovascular accident	 0.03% (4/15,015) Hill 0.02% (2/10,255) Shields 0.07% (72/103,211) Rees 	
Septic shock	 0.02% (3/15,015) Hill 0.02% (2/10,255) Shields 0.03% (11/32,228) Heyer 	
Cardiac arrest requiring cardiopulmonary resuscitation	 0.007% (1/15,015) Hill 0.02% (2/10,255) Shields 	
Wound dehiscence	 0.007% (1/15,015) Hill 0.02% (2/10,255) Shields 	
Minor complications		1
Superficial SSI	 0.16% (24/15,015) Hill 0.17% (17/10,255) Shields 0.18% (58/32,228) Heyer (including superficial SSI, deep wound infection, organ infection or dehiscence) 0.27% (450/165,820) Yeranosian (reoperations for surgical drainage) 	
Urinary tract infection	 0.13% (19/15,015) Hill 0.15% (15/10,255) Shields 0.18% (188/103,211) Rees 	
Deep vein thrombosis	 0.14% (21/15,015) Hill 0.08% (8/10,255) Shields 	
Pneumonia	 0.09% (13/15,015) Hill 0.07% (7/10,255) Shields 0.29% (296/103,211) Rees 	
Bleeding transfusion	 0.05% (7/15,015) Hill 0.05% (5/10,255) Shields 	
Peripheral nerve injury Abbreviations	 0.01% (2/15,015) Hill 0.02% (2/10,255) Shields 	

Abbreviations RCT = randomised controlled trial, SSI = surgical site infection. <u>Notes</u>

Heyer = subacromial decompression cases from the American College of Surgeons NSQIP database, **Hill** = shoulder arthroscopy cases from the American College of Surgeons NSQIP database, **Rees** = subacromial decompression cases from the Hospital Episode Statistics for NHS England database, **Shields** = shoulder arthroscopy cases from the adult American College of Surgeons NSQIP database, **Yeranosian** = shoulder arthroscopy cases from the PearlDiver Patient Record Insurance database.

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (text taken from the publication)
AAOS 2019 Clinical practice guideline	Management of rotator cuff injuries	Not applicable	Not applicable	Intervention Rotator cuff repair	Not reported	Strong evidence supports that older age is associated with higher failure rates and poorer patient reported outcomes after rotator cuff repair Moderate evidence supports that higher BMI is correlated with higher re-tear rates after rotator cuff repair surgery; however, strong evidence supports that there is no correlation between higher BMI and worse patient-reported outcomes following rotator cuff repair Strong evidence supports the presence of a worker's compensation claim is associated with poorer patient reported outcomes after rotator cuff repair Moderate evidence supports the association of poorer patient reported outcomes in patient with more comorbidities Moderate evidence suggests that patients with diabetes will have higher re-tear rates and poorer quality of life and patient reported outcome scores after rotator cuff repair Moderate evidence correlates higher preoperative patient expectations for surgery with higher patient reported outcomes after rotator cuff repair
Colorado 2015 Clinical practice guideline	Shoulder injury medical treatment guidelines	Not applicable	Not applicable	Range	Not reported	Personality/Psychological/Psychosocial Evaluations may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for pre-operative evaluation as well as a possible predictive value for post-operative response. The subacromial injection has generally been considered the gold standard for differentiating range of motion loss from impingement versus rotator cuff tears The inaccuracy of the injection and patient response in some cases may contribute to its inability to

 Table 60
 Predictive and prognostic factors for outcomes of rotator cuff disease and subacromial impingement

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
						completely predict the amount of recovery from subacromial decompression
Diercks 2014 Clinical practice guideline	Subacromial pain syndrome	Not applicable	Not applicable	Range (including exercise therapy, surgery)	Not reported	There is consistent evidence that a longer duration of symptoms (> 3 months) is a poor prognostic factor (level of evidence 1). There is an association between being middle-aged (45–54 years) and worse outcome (level of evidence 1). There is evidence that psychosocial factors play a role in chronic complaints (level of evidence 2). There are indications that a worse outcome is associated with a worse score at the start, longer duration of symptoms, and type II or III acromion morphology (level of evidence 3).
Hohmann 2020 Clinical practice guideline	Patients considered for subacromial decompression	Not applicable	Not applicable	Arthroscopic subacromial decompression	Not reported	Positive Hawkins-Kennedy (in neutral and abduction), Neer, and Jobe tests were valid predictors of outcome. In patients with all tests positive, the outcome was significantly better compared with 3 or fewer positive tests. Patients receiving workers compensation; calcific tendinopathy and partial-thickness rotator cuff tears were associated with poorer outcomes. Patients who had a complete division of the coracoacromial ligament had a 33% failure rate compared with 10% with an intact ligament; Bigliani Type 2 and 3 acromion shapes had a 35% and 26% failure rate, respectively, compared with 14% in Bigliani type 1.
Hopman 2013 Clinical practice guideline	Rotator cuff syndrome	Not applicable	Not applicable	Rotator cuff surgery	Not reported	Age: Patients of older age are more likely to have slower or less recovery. MRI tear characteristics: Supraspinatus and infraspinatus muscle atrophy and fatty degeneration have been found to have a negative effect on both tendon healing and clinical outcomes Workers compensation status: Conflicting findings with regard to workers compensation and its effect on postsurgical outcomes.

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						Some studies suggest workers compensation status is associated with less favourable outcomes after rotator cuff repair. Other studies have identified that there are other confounding pre- operative factors that need to be considered. For example 'WC recipients were younger and more likely to smoke, have a traumatic injury, and undergo surgery within 6 months of injury' Body mass index (BMI): Conflicting findings with one study indicating people with a higher BMI are more likely to have less recovery following rotator cuff surgery, while another identified that BMI had no impact on pain or disability measures. Psychological wellbeing: Psychological status, particularly depression, has been identified as a factor for reduced recovery following the development of rotator cuff syndrome. Duration of complaints: The longer a person experiences pain the more likely they are to have less recovery. High somatisation or multiple region complaints: A person who experiences a high pain intensity or pain in a number of body regions is more likely to have less recovery. Expectations: Patients that have high pre-operative expectations with regards to pain relief, range of motion and continuing ability to perform activities of daily living may be more likely to experience reduced recovery following rotator cuff surgery. References provided Note that this guideline also provides yellow flags that may influence recovery and return to work following rotator cuff syndrome.
Brox 1999 RCT	Patients with rotator cuff disease	Age: SAD=48 Phys=47 LAS=48	Inclusion Age 18–66; pain in the shoulder for at least three months that had been	Intervention SAD Comparator 1 Supervised exercises	Retrospective (only provided in the later follow-up)	Prognostic factors analysed included age, sex, duration of disease, pain medication, professional education, sick leave, emotional distress, and isometric abduction endurance. Including all patients who underwent operation, the success rate in those not on sick leave (19 of 21) before surgery was higher

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	125 (45 arthroscopic surgery; 30 placebo laser; 50 supervised exercise) Randomised		resistant to outpatient physiotherapy and non-steroid and steroid anti- inflammatory drugs; had dysfunction or pain on abduction; had a normal passive range of movement; had pain during two of the three isometric- eccentric tests; and had positive results in tests for impingement Exclusion Arthritis of the acromioclavicular joint; had the cervical syndrome; had rotator cuff rupture; had glenohumeral instability; had bilateral muscular pain with tenderness and severely	Comparator 2 Detuned laser		compared with those on sick leave (18 of 36) (adjusted odds ratio 5.6 [1.2 to 29.2]). Similar results were observed for patients not receiving versus those receiving regular pain medication before surgery (adjusted odds ratio 4.2 [1.2 to 75.8]). There was no reported association with any other factor.

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Ketola 2015	Stage II shoulder	Age:	decreased ability to relax the shoulder, neck, and temporomandibular joints on examination Inclusion	Intervention	Retrospective	The authors analysed recovery across all patients (intervention
RCT	impingement syndrome	AA=46.4 (range 23.3 to 60) ET=47.8 (26.8 to 59.2)	Positive Neer's test, pain in the shoulder that was resistant to rest, anti-inflammatory drugs, subacromial glucocorticosteroid injections, physiotherapy, and symptoms that had persisted for at least 3 months All patients had thus been treated with physiotherapy Age 18 to 60 years Exclusion Glenohumeral or acromioclavicular osteoarthritis, glenohumeral instability, previous surgery, a full-	AA (arthroscopic acromioplasty) Comparator EG (exercise group)	(published as a separate, later analysis)	 and comparator groups were combined) Baseline factors investigated for association with outcomes at 2 and 5 years were: Age, gender, BMI, marital status, basic education, professional education, challenges at work, loads lifted per workday, working arm raised, satisfaction at work, symptom duration, sick leave prior to randomisation, acromion morphology, acromioclavicular compressing supraspinatus tendon, acromioclavicular degeneration. The following factors had a statistically significant impact on pain: Marital status: Living alone was associated with a higher risk of having pain at 2 years (OR = 3.3, 95% CI: 1.4–7.8). Lack of professional education: At 2 years, the OR was 3.7 (95% CI: 1.2–11) for those with no education and 3.0 (95% CI: 0.93– 9.5) for those who had gone through an occupational course. Duration of symptoms: All of the 18 patients in the exercise group who wanted surgery had had symptoms over 1 year (p = 0.04).

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Paavola 2018 RCT	Subacromial impingement syndrome	Age: A=50.5 (7.3) DA=50.8 (7.6) P=50.4 (6.6)	thickness tear of the rotator cuff, cervical radicular syndrome, adhesive capsulitis, or neuropathy of the shoulder region Inclusion 1. Age 35 years to 65 years 2. Subacromial pain for greater than 3 months with no relief from nonoperative means 3. Pain provoked by abduction and positive painful arc sign 4. Positive impingement test 5. Pain in at least two out of three of	Intervention A (arthroscopic surgery) Comparator 1 DA (diagnostic arthroscopy) Comparator 2 P (physiotherapy)	Prospective (planned subgroup analyses)	Long periods of sick leave: The risk of having pain was higher at 2 years (OR = 2.5, 95% CI: 1.1–5.8) and at 5 years (OR = 3.8, 95% CI: 1.4–11). Satisfaction at work: Patients with pain had a quite low or very low level of satisfaction (overall $p = 0.01$). Challenges at work: Patients with pain were more likely to report challenges at work ($p = 0.01$) Acromioclavicular degeneration: Patients with pain were more likely to have moderate or severe degeneration of the acromioclavicular joint ($p = 0.01$) Therefore, some patients are more likely to have ongoing shoulder pain despite therapy. The authors suggest that these issues are likely related to the natural history of the disease Four subgroup analyses investigated the potential effect of modifying of the duration and severity of symptoms, the acromial anatomy and the presence/absence of bursal resection on shoulder pain. Compared to the overall results there were no clinically important differences for the subgroup analyses. The extent of bursal resection (no, minimal or extensive) had no effect on the pain at rest or on activity ($p = 0.11$ to 0.85) For patients with higher pain (VAS ≥ 70) and with a curved acromion, improvements were more in favour of patients treated with SAD compared with diagnostic arthroplasty ($p = 0.058$ and $p = 0.021$ respectively).

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
			isometric tests (abduction 0° and 30° or external rotation) Exclusion 1. Full-thickness tear of the RC tendons 2. Osteoarthritis of the glenohumeral and/or acromioclavicular joint diagnosed on clinical examination and on X-rays 3. Substantial calcific deposits 4. Previous surgical procedure 5. Evidence of shoulder instability			 For patients with symptoms of less than 1 year, pain at rest (p = 0.071) and pain on activity (p = 0.031) were improved compared to patients with symptoms for more than 1 year (p = 0.449 and p = 0.253 respectively). It should be noted that the study was not powered to investigate differences in subgroup analyses, so these results should be treated with caution. However, this suggests that patients with a defined acromion anatomy, and worse pain at baseline, may benefit more from SAD
Rahme 1998 RCT	Diagnosis not reported (beyond the inclusion criteria)	Age: In the total cohort: 42 (range 28–63)	Inclusion Isolated shoulder disease; working age; pain for which the duration of at least one year had been present at rest and was reported to be	Intervention OAA (open anterior acromioplasty Comparator P (physiotherapy)	Retrospective	Patients with very high postoperative pain were diagnosed with psychogenic pain syndrome and had poor outcomes following SAD (all were considered failures (with a less than 50% reduction in pain). Patients with worse preoperative scores for POP (pour-out-of-a- pot function test) (POP 1 or 2) were associated with improved outcomes after surgery (p < 0.02).

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			accentuated by movements involving elevation; a positive impingement sign Exclusion Patients requiring resection of the lateral end of the clavicle as well as those with glenohumeral osteoarthritis were excluded			Patients with normal preoperative scores for HIN (hand-in-neck manoeuvres) (HIN 5) were associated with improved outcomes (complete pain relief) after surgery (p < 0.02).
Biberthaler 2013 nRCT	Patients with subacromial impingement SAD: n=142 Conservative therapy: n=165	Median age 57 (75% confidence interval 48-63) years	Inclusion Age between 20 and 82 years, presence of shoulder pain for more than three and less than six months and meeting the following criteria: -pain on abduction of the shoulder with a painful arc -positive Neer and Hawkins testing -positive impingement test	Intervention Arthroscopic SAD Comparator Standardised physiotherapy and exercises	Retrospective	 Patients were reported in groups based on age – younger or older than the median age (57 years). In the younger cohort there was no difference in all outcomes. There was a borderline significant improvement in older patients (>57 years of age) following SAD (Biberthaler et al. 2013). (a change in Constant score from 71 to 77 points, p = 0.05). However, issues with study design and patient allocation to intervention, as well as aspects of reporting, limit the confidence in these results.

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
Lopez 2000 nRCT	Impingement syndrome/rotator cuff tendinopathy 23 patients Consecutive Grouped according to workers compensation status	52.3 years	Exclusion Patients with any other pathology such as rotator cuff tear, gleno- humeral instability, cartilage damage, acromioclavicular joint osteoarthritis, calcifying tendinitis, biceps pathology or signs of cervical root or temporomandibular symptoms Nil Retrospective review of patients who received acromioplasty	Intervention Acromioplasty (open or arthroscopic)	Unclear Retrospective	Non-workers compensation scores had lower (worse) scores. There were significant differences in pain ($p < 0.003$), function ($p < 0.04$, strength of forward flexion ($p < 0.0019$) and total UCLA score ($p < 0.0008$). Mean change in outcomes not provided.

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Nicholson 2003 nRCT	Subacromial impingement syndrome 106 patients Consecutive patients, grouped according to workers compensation status	Workers compensation group: 41.7 years Non-workers compensation group: 46.5 years	Inclusion Positive impingement sign; a positive impingement test (local anaesthetic injection) and had failed to improve with conservative therapy. Exclusion Previous surgery, shoulder instability, FTT, adhesive capsulitis, neurologic involvement, or previous fracture	Intervention Arthroscopic acromioplasty	Prospective	Postoperatively, there were no significant differences between the Workers' Compensation and non-Workers' Compensation groups with regard to the American Shoulder and Elbow Surgeons (ASES) score ($p = 0.1080$), the Simple Shoulder Test (SST) score ($p = 0.0501$), or the VAS for pain ($p = 0.0807$).
Lopiz 2019 nRCT	Fibromyalgia and subacromial pain syndrome 20 patients (6 were excluded as they were lost to follow-up) 20 control patients with no fibromyalgia were chosen	50.6 (SD 6.2) years Control group 47.7 (SD 8.6) years At baseline, patients with fibromyalgia had worse disability arm and hand	Inclusion Patients with preoperative diagnosis of fibromyalgia who received arthroscopic SAD Exclusion Other procedures associated with SAD: acromioclavicular resection, long	Intervention Arthroscopic SAD	Retrospective	The mean postoperative DASH was significantly worse (higher score) among the patients in the FM group when compared with the control group (38.9 vs. 20.7; $p = 0.009$). There were no statistically significant post-operative differences in the range of movement, strength or pain between the FM group and the control group. A trend towards signification was seen ($p = 0.05$) on the section of activities of daily living, the item having the worse score in the FM group. There was no statistical difference in failure and revision surgery or use of analgesics following surgery.

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	(matched by demographic profile) Consecutive	scale (DASH) score (p = 0.02)	portion of the biceps, labrum repair, rotator interval or suture of the rotator cuff tendons, trauma, those who were over the age of 65 years (due to the possibility of presenting degenerative joint changes)			Patients with fibromyalgia were less likely to be satisfied (p = 0.03).
Heyer 2020 CS	Patients who received shoulder and knee arthroscopic surgery 134,822 Shoulder arthroscopy with SAD 29,826 Consecutive	55.8 (SD 12.0)	All patients included in the National Surgery Quality Improvement Program (NSQIP) database between 2010 and 2016.	Intervention Arthroscopic SAD	Prospective	Patients were at higher risk of 30-day complications and mortality of they were a smoker (odds ratio 1.462 [95% confidence interval 1.030 to 2.075], p = 0.033).

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Kharrazi 2007 CS	Patients who received SAD with or without acromioclavicular joint surgery 1,482 Consecutive	Not reported	Inclusion Patients who received SAD with or without acromioclavicular joint surgery Exclusion Rotator cuff, labrum, capsule, or biceps pathology.	Intervention Arthroscopic SAD with and without concomitant acromioclavicular joint surgery	Retrospective	The overall acromioclavicular reoperation rate was the same in patients who had received arthroscopic SAD with and without concomitant acromioclavicular joint surgery (1.5%). Workers compensation status was found to be a statistically significant factor in the rate of acromioclavicular joint reoperation (2.4% versus 0.8%, p < 0.05).
Khaddabadi 2021 CS	Patients with shoulder impingement 1,000 Consecutive	51 (range 30 to 75) years	Inclusion Patients with isolated shoulder pain without any comorbidity. Neers sign and Hawkins Kennedy test were employed to diagnose impingement clinically and confirmed with Neers Test (steroid injection relieved pain for minimum of four hours). Exclusion Patients with secondary	Intervention Arthroscopic SAD	Prospective	Based on arthroscopic findings, the presence of a kissing lesion and an empty bursal space under the acromion is a high predictor of successful outcome after arthroscopic decompression (a percentage change of 48% versus 20%, P not provided).

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			frozen shoulder or history of previous shoulder injury			
Koorevaar 2017 CS	Patients undergoing elective shoulder surgery 505 patients Consecutive	47 years	Inclusion (1) presenting for a planned elective shoulder surgery; (2) at least 16 years of age Exclusion (1) frozen shoulder before surgery; (2) fracture/non-union or malunion; (3) stiffness caused by glenohumeral osteoarthritis (including shoulder arthroplasty); (4) shoulder arthrodesis; (5) diagnostic shoulder arthroscopy; (6) preoperative neurological disorder or complication (e.g., stroke, Parkinson's	Intervention Various elective operative shoulder procedures	Prospective (the potential predictors were gender, diabetes mellitus, type of physiotherapy, arthroscopic surgery and DASH score)	Postoperative frozen shoulder was identified in 11% of the total cohort, and in 12% after SAD Prognostic factors for postoperative frozen shoulder after shoulder surgery: gender (odds ratio [OR] 2.05, 95% confidence interval [CI] 1.16-3.60, p = - 0.013]), diabetes mellitus (OR 3.36 [95% CI 1.44-9.19], p = 0.006), type of physiotherapy (OR 0.38 [95% CI 0.21-0.67], p = 0.001) and DASH score (OR 1.02 [95% CI 1.01-1.04], p = 0.005) Arthroscopic surgery was not associated with an increased risk (OR 1.81 [95% CI 0.89-3.71], p = 0.1) The authors developed a prediction model with diabetes mellitus, specialised shoulder physiotherapy, DASH score and arthroscopic surgery which had a discriminative ability with an area under the curve of 0.712.

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
			disease); (7) postoperative deep infection			
Inderhaug 2018 CS	Patients with symptomatic chronic subacromial pain syndrome treated surgically by subacromial decompression (n = 180, of which 40 were lost to follow-up) and patients undergoing repair of a degenerative small to medium sized rotator cuff tear (n = 180, of which 33 were lost to follow-up) Consecutive Patients undergoing decompression and cuff repair were matched,	52 years (SAD only)	Inclusion Symptoms for at least 6 months; insignificant improvement of conservative treatment (3–6 months);12 MRI verified cuff tendinopathy and reduced subacromial space; positive Neer sign and Hawkins test; and normal passive ROM was required for surgical treatment to take place Exclusion Previous surgery in the same shoulder; significant shoulder trauma; significant concomitant pathology (e.g. osteoarthritis,	Intervention Arthroscopic SAD Comparator Rotator cuff repair with combined arthroscopic SAD	Unclear, likely retrospective	Across all patients (SAD with and without rotator cuff repair), age above 55 at surgery predicted better postoperative VAS of function (84 vs 77, p = 0.04). Results for SAD alone not provided. There were no other differences reported, other than for patients who received SAD with rotator cuff surgery.

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	with regard to sex and age, with a patient that underwent isolated subacromial decompression within a week before or after		adhesive capsulitis, chondral lesions, labrum avulsions and loose bodies); American Society of Anesthesiologist (ASA) 3 and higher; and inability to undertake postoperative rehabilitation. Acute, traumatic cuff lesions; massive, irreparable lesions; and lesions requiring more than a single-row suture repair			
Martel 2020 CS	Patients who underwent surgery for a subacromial extraarticular shoulder pathology 287 patients	61 (SD 11.1) years	Inclusion adult patients (> 18 years of age) who underwent shoulder surgery for a subacromial space pathology. Rotator cuff tendon repair, tenotomy or tenodesis of the	Intervention Rotator cuff tendon repair, tenotomy or tenodesis of the long biceps, acromioplasty, acromioclavicular arthroplasty or	Retrospective data, prospective analysis	Clinical (range of joint motion, mobility, strength, pain, constant score), demographic [gender, age, co-morbidity(ies)] and therapeutic (surgical intervention) variables were investigated. The primary study aim was to investigate the risks of developing Complex Regional Pain Syndrome type 1 (CRPS1) In total, 38 (13%) presented with post-operative CRPS1

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	Consecutive		long biceps, acromioplasty, acromioclavicular arthroplasty or exeresis of calcification. Exclusion emergency surgery, surgical history involving the affected shoulder, surgery involved glenohumeral prosthetic arthroplasty, instability surgery, or osteosynthesis of the proximal end of the humerus	exeresis of calcification		Treated hypothyroidism (OR = 3.79 ; 95% CI 1.58 to 9.07; p = 0.003), open surgery (OR = 2.92; 95% CI 1.35 to 6.32; p = 0.007) and the level of daily physical activity from the Constant score (OR = 0.088; 95% CI 0.79 to 0.97; p = 0.015) were found to be significantly associated with the onset of CRPS1.
Jacobsen 2017 CS	Shoulder impingement syndrome, patients selected from a database 244 patients Unclear if participants were consecutive	52.5 (95% CI 51.6 to 53.9) years	Inclusion Patients selected for surgery following national clinical guidelines of SIS treatment Exclusion Osteoarthritis Major cartilage defects	Intervention Arthroscopic SAD	Unclear if subgroups were planned a priori	For the complete study group, an OSS (primary outcome) change of 10 (8.8-11.2; p = 0.0001) was found at 6-month follow-up. No significant difference was found between the genders (p = 0.17). The largest clinical effect from the intervention was found in the low preoperative OSS (pre-OSS) group (worse, median pre- surgery OSS = 17, post-surgery = 34), in which a mean change of 17 was found (between low and high groups p = 0.001, between low and moderate groups, p = 0.03). There were no differences by gender or age for OSS.

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Holtby 2010 CS	Patients who had undergone a decompression or rotator cuff repair	48 (SD 10)	Complementary acromioclavicular resection Glenohumeral instability Complete rotator cuff lesions Acute trauma or fracture on affected shoulder during last 6 months before surgery Previous surgery on the affected shoulder Inclusion Patients who had undergone rotator cuff surgery and had completed their 1- year	Intervention Arthroscopic SAD or rotator cuff repair	Retrospective	There was no difference in EQ-5D according to pre-OSS group or age. EuroQol visual analogue scale (EQ-VAS): According to the EQ- VAS, the overall difference for the pre-OSS groups was 31.5 (27.8-35.3). The largest clinical effect from an ASD was found in the low and moderate pre-OSS groups, with a mean difference of 41.2 (29.4-53.1) and 38.7 (33.6-43.9), respectively. The high pre- OSS group had a mean VAS difference of 20.6 (14.9-26.1). Between low and high groups $p = 0.03$, between moderate and high groups, $p = 0.0001$, between low and moderate groups $p = 0.54$. There was no difference in EQ-VAS by age. The compensation group had a significantly lower level of improvement (change from pre- to post-op) than the non- compensation group (p values ranging from 0.0367 to < 0.0001). Western Ontario Rotator Cuff (WORC)
	220 patients (patients with workers compensation were matched with historical controls) Consecutive		surgical follow-up Exclusion			Having a work-related injury (F = 12.42, p = 0.0007) and pre- operative WORC (F = 7.27, p = 0.009) were important predictors of postoperative disability

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
Razmjou 2011 CS	Rotator-cuff pathology (patients with impingement syndrome and/or rotator cuff tear) 170 patients (50% female) Consecutive (recruitment of women continued)	Men 55 (SD 11.28) Women 59 (SD 10.64)	Inclusion Age ≥18 years, a diagnosis of impingement syndrome and/or rotator cuff disease, and unremitting pain in the affected shoulder that had not responded to conservative treatment (oral medication, physical therapy, or subacromial injection) for at least 6 months since onset Exclusion Previous shoulder surgery on the affected side, evidence of major joint trauma causing fracture, infection, underlying metabolic or inflammatory disease, avascular	Intervention Arthroscopic or open decompression Arthroscopic or open repair of rotator cuffs	Prospective	A review of sex and gender differences in outcomes. Women were statistically significantly older (p = 0.0228) and had a slightly higher level of comorbidity (p = 0.03). Women reported more disability both prior to and after surgery based on ASES (p = 0.0053 and p = 0.002) and Quick DASH (p = 0.0002 and p < 0.0001). Post-operative disability was associated with age (p = 0.0173) with older patients reporting less disability.

Trial/study Study design	Population (N) Consecutive, or method of randomisation	Patient age (mean)	Inclusion Exclusion	Intervention Comparator	Prospective or retrospective intent to identify predictive or prognostic factors	Predictive or prognostic factor (<i>text taken from the publication</i>)
			necrosis, frozen shoulder, major medical illness, and psychiatric illness that precluded informed consent. Patients with massive tears.			
Evans 2015 CS	Patients who underwent simple arthroscopic surgery of the shoulder 200 patients Consecutive	SAD: 55.4 (SD 13.8) years SAD and acromioclavicular joint excision: 58.0 (SD 14.1) years)	Inclusion Patients in the senior surgeons logbook Exclusion Not provided	Intervention Arthroscopic SAD; or SAD in combination with arthroscopic acromioclavicular joint excision	Retrospective	Overall rate of frozen shoulder: SAD: 5.2% SAD in combination with arthroscopic acromioclavicular joint excision: 5.8% Across the entire cohort patients aged between 46 and 60 years and a previous history of frozen shoulder increase the relative risk of secondary frozen shoulder by 7.8 (95% confidence interval (CI) 2.1 to 28.3, p = 0.002) and 18.5 (95% CI 7.4 to 46.3, p < 0.001) respectively. There was no difference in females or patients with diabetes.

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Klintberg IH, Svantesson U and Karlsson J 2010. Long-term patient satisfaction and functional outcome 8-11 years after subacromial decompression. Knee Surgery, Sports Traumatology, Arthroscopy, 18, 394-403.

Lower level evidence, non-English language (k=1)

Hartig A and Rojczyk M 1993. [Arthroscopic sub-acromial decompression. Comments on indications and surgical technique]. Unfallchirurg, 96, 109-15.

Appendix D Evidence profile tables

Risk of bias of the RCTs was assessed using the RoB2.0 tool (Guyatt et al., 2013).

Trial/study	D1	D2	D3	D4	D5	Overall bias
Beard (Beard 2015, Beard 2018)	Low	Low	Low	Low	Low	Low
Brox (Brox 1993, Brox 1999)	Low	High risk	Low	Low	Some concerns	High risk
Cederqvist (Cederqvist 2021)	Low	Low	Low	Some concerns	Low	Some concerns
Farfaras (Farfaras 2016, Farfaras 2018)	Low	High risk	Some concerns	Low	Some concerns	High risk
Haahr (Haahr 2005, Haahr 2006)	Low	Low	Low	Some concerns	Some concerns	Some concerns
Ketola (Ketola 2009 protocol, Ketola 2015, Ketola 2016, Ketola 2017)	Low	Low	Low	Low	Some concerns	Some concerns
Paavola (Paavola 2017 protocol, Paavola 2018, Paavola 2021, Bäck 2021)	Low	Low	Low	Low	Low	Low
Peters (Peters 1997)	Some concerns	High risk	Some concerns	High risk	Some concerns	High risk
Rahme (Rahme 1998)	Some concerns	High risk	High risk	Low	Some concerns	High risk

Table 61 RCT risk of bias

Abbreviations

RCT = randomised controlled trial.

D1: Randomisation process

D2: Deviations from intended interventions

D3: Missing outcome data

D4: Measurement of outcome

D5: Selection of the reported results

The methodological quality of the included case series studies was assessed using the checklist for quality appraisal of case series developed by the Institute of Health Economics (IHE) (Guo et al., 2016, Institute of Health Economics, 2022).

For estimating the risk of bias for each study, 'partial' responses were considered 'yes,' and 'unclear' responses were considered 'no.' A study with 0-2 'no' responses was considered to have a low risk of bias, 3-5 'no' responses a moderate risk, 6-8 'no' responses a high risk, and 9 or more 'no' responses a very high risk of bias (Bexkens et al., 2017).

<u>Notes</u>

Table 62	Quality assessment of the included case series studies
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Quality domain	Shields 2015	Hill 2016	Heyer 2020	Rees 2022	Yeranosian 2014	Bjornsson 2010	Chin 2007	Hultenheim Klintberg 2011	Jaeger 2016	Norlin 2008	Odenbring 2008	Ranebo 2017		
Study objective	Study objective													
Objective clearly stated	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Study design														
Prospective	N	N	N	N	N	N	Y	N	N	N	Y	N		
Multicentre	Y	Y	Y	Y	Y	Ν	N	N	N	N	N	Ν		
Consecutive recruitment	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Study population												_		
Were patient characteristics included?	Y	Y	Y	Y	N	N	Y	Р	Y	Y	Y	Y		
Eligibility criteria clearly stated	Y	Y	Y	Y	Ν	Y	Y	Y	Р	Y	Y	Y		
Did patients enter the study at a similar point in the disease	U	U	U	U	U	U	U	U	U	U	U	U		
Method of diagnosis and co-intervention														
Was the intervention of interest clearly described?	Р	Р	Р	Р	Р	Р	Y	Y	Y	Y	Y	Y		

Quality domain	Shields 2015	Hill 2016	Heyer 2020	Rees 2022	Yeranosian 2014	Bjornsson 2010	Chin 2007	Hultenheim Klintberg 2011	Jaeger 2016	Norlin 2008	Odenbring 2008	Ranebo 2017
Were additional interventions clearly described?	N	N	N	N	N	N	N	Y	Y	Ν	Ρ	Y
Outcome measures												
Were relevant outcome measures established a priori?	Y	Y	Y	Y	N	N	N	N	N	N	Р	N
Were outcome assessors blinded?	U	U	U	U	U	N	N	U	N	N	N	Ν
Were the outcomes measured using appropriate objective methods?	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y
Were the relevant outcome measures made before and after the intervention?	NA*	NA*	NA*	NA*	NA*	Ν	Ρ	Ν	N	N	Ρ	N
Statistical analysis												
Were the statistical tests used to assess the relevant outcomes appropriate?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Results and conclusions												
Was follow-up long enough for important events and outcomes to occur?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Quality domain	Shields 2015	Hill 2016	Heyer 2020	Rees 2022	Yeranosian 2014	Bjornsson 2010	Chin 2007	Hultenheim Klintberg 2011	Jaeger 2016	Norlin 2008	Odenbring 2008	Ranebo 2017
Were losses to follow- up reported?	U	U	U	U	U	Y	Y	Y	Р	Y	Y	Y
Did study provide estimates of random variability in the data analysis of relevant outcomes?	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Ρ
Were the adverse events reported?	Y	Y	Y	Y	Р	N	N	Р	N	N	P (of reops)	N
Were the conclusions supported by results?	Y	Y	Y	Y	Р	Y	Y	Y	Y	Y	Y	Y
Competing interest and sources of support												
Were both competing interests and sources of support for the study reported?	Y	P (no funding)	P (no funding)	Y	Y	N	N	Y	P (no funding)	N	Y	Y
TOTAL	5/19	5/19	5/19	5/19	10/19	10/20	7/20	6/20	7/20	9/20	3/20	7/20
Risk of bias	М	М	М	М	VH	VH	Н	н	н	VH	М	Н

Abbreviations

H = high, M = moderate, N = no, NA = not applicable, U = unclear, VH = very high, Y = yes.

Notes

* = data were only available after the intervention.

The overall quality of evidence was assessed using GRADE (Grading of Recommendations Assessment, Development and Evaluation) using the effects of risk of bias, indirectness, inconsistency, imprecision and publication bias.

The six major study outcomes (pain, shoulder function, health-related quality of life, adverse events and serious adverse events) were presented in the summary of findings table. The table summarises the certainty of evidence, the magnitude of effect of the intervention and the sum of the data available. Using the GRADE approach, the table includes an overall grading of the evidence related to the outcome of interest. Two tables are presented: SAD versus conservative therapy (Table 63) and SAD versus placebo (Table 64).

The certainty of evidence was assessed by the review authors as high, moderate, low or very low using the 5 GRADE considerations of study limitations, consistency of effect, imprecision, indirectness and publication bias). The table was prepared using the GRADEpro software.

According to the GRADE approach, the quality of evidence that supports each outcome is defined as follows:

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

	Anticipated effects*	absolute (95% Cl)				
Outcomes	Risk with conservative therapy	Risk with Shoulder decompression surgery	Relative effect (95% Cl)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Shoulder pain Scale from: 0 to 10 follow-up: mean 12 months	The mean shoulder pain was 6.09 points	MD 0.77 points lower (1.59 lower to 0.04 higher)	-	316 (3 RCTs)	⊕⊕⊖⊖ Low	Shoulder decompression surgery may have an effect on shoulder pain but evidence is uncertain
Shoulder function follow-up: mean 12 months	The mean shoulder function was 0 points	MD 3.6 points higher (9.16 lower to 16.37 higher)	-	259 (3 RCTs)	⊕⊖⊖⊖ Very low	No significant difference in shoulder function between shoulder decompression and conservative therapy
Health- related quality of life (HRQoL) follow-up: mean 12 months	The mean health-related quality of life (HRQoL) was 0	Not estimable	-	116 (1 RCT)	⊕⊕⊖⊖ Low	No significant difference in HRQoL between shoulder decompression and conservative therapy
Return-to- work follow-up: mean 60 months	669 per 1,000	736 per 1,000 (642 to 836)	RR 1.10 (0.96 to 1.25)	313 (3 RCTs)	⊕⊖⊖⊖ Very low	The evidence on the effect of subacromial decompression on the patients' return to work status is uncertain
Total adverse events follow-up: range 12 months to 24 months	37 per 1,000	34 per 1,000 (12 to 99)	RR 0.91 (0.31 to 2.65)	406 (2 RCTs)	⊕⊕⊕⊖ Moderate	Subacromial decompression does not increase the probability of having adverse events

Table 63 GRADE summary of findings table, subacromial decompression compared to conservative therapy

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Abbreviations

CI = confidence interval, MD = mean difference, RR = risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Table 64 GRADE summary of findings table, subacromial decompression compared to placebo

	Anticipated effects*	absolute (95% Cl)				
Outcomes	Risk with Placebo	Risk with Shoulder decompression surgery	Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Shoulder pain Scale from: 0 to 10 follow-up: mean 12 months	The mean shoulder pain was 0 points	MD 0.27 points lower (0.85 lower to 0.31 higher)	-	281 (2 RCTs)	⊕⊕⊕⊕ High	The probability of the subacromial decompression surgery decreasing pain is not significantly different with placebo
Shoulder function follow-up: mean 12 months	The mean shoulder function was 0 points	MD 1.3 points higher (4.57 lower to 7.13 higher)	-	157 (1 RCT)	⊕⊕⊕⊕ High	The subacromial shoulder decompression does not significantly improve shoulder function based on available evidence
HRQoL follow-up: mean 12 months	-	SMD 0.05 SD lower (0.28 lower to 0.18 higher)	-	285 (2 RCTs)	⊕⊕⊕⊕ High	Subacromial decompression has little to no effect on the HRQoL
Return to work follow-up: mean 24 months	797 per 1,000	828 per 1,000 (693 to 980)	RR 1.04 (0.87 to 1.23)	116 (1 RCT)	⊕⊕⊕⊜ Moderate	Subacromial decompression has little to no effect on the patients' ability to return to work

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Abbreviations

CI = confidence interval, HRQoL = health-related quality of life, MD = mean difference, RCT = randomised controlled trial, RR = risk ratio, SMD = standardised mean difference.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

The GRADE certainty of evidence varied across outcomes according to the risk of bias and number of available RCTs, as well as the precision of estimates and consistency of results.

Appendix E Other relevant information

Clinical practice guidelines

A review of clinical practice guidelines (CPGs) has been provided as a separate component of a review of subacromial decompression as Terms of reference 1: *Review clinical guidelines on the management of rotator cuff disease*¹³.

Thirteen clinical guidelines (including two specialty society statements) provide recommendations regarding the use of surgery, including rotator cuff repair and subacromial decompression (AIM, 2021, BOA, 2014, Colorado Department of Labor and Employment, 2015, Washington State Department of Labor and Industries, 2018, New York Workers Compensation Board, 2021, Diercks et al., 2014, Hohmann et al., 2020, NICE, 2018, AAOS, 2019, Hopman et al., 2013, Vandvik et al., 2019, Oliva et al., 2015, AMRC, 2018b). All were evidence-based, and 3 guidelines were appraised to be of better quality.

The identified guidelines were of varying quality and detail. The guidelines were consistent in recommending a stepped approach to care and a targeted selection of patients for surgical management, only when patients had tried and failed to respond to appropriate conservative therapy.

For care prior to surgery, guidelines were broadly consistent in their recommendations. Patients should undergo a review of history and physical examination. Where reported, all guidelines recommended physiotherapy or structured exercise as the initial therapy (for 6 to 12 weeks), often with some kind of simple analgesic or anti-inflammatory medication to help control symptoms. The judicious use of subacromial injection of steroid or local anaesthetic is recommended to reduce pain in the short term, if required. For patients with acute full-thickness rotator cuff tears (FTT), a trial of non-surgical therapy was not always needed.

However, guidelines were more varied in terms of their recommendations pertaining to X-ray, US or MRI. This may be related to the focus of each document. Documents with a particular focus on therapies generally provided less detail on diagnostic imaging, and did not distinguish between the use of specific tests in the care pathway. Guidelines that provided more detail on these tests were consistent in that diagnostic imaging early in the clinical pathway is not needed unless there is a concern of a serious pathology. The initial test should be X-ray. US or MRI were recommended later in the care pathway, only after patients had failed the initial conservative therapy, and to assess soft tissues before patients are considered for surgery.

For surgery, the detail provided in guidelines also varied in terms of how, when and to whom certain services should be provided. For FTT, guidelines were consistent in recommending repair. For partial-thickness rotator cuff tears (PTT), guidelines were generally consistent in recommending repair for patients who had persistent symptoms despite a specified duration of conservative therapy (6 weeks). Debridement was an option for PTT in 3 guidelines.

The use of **subacromial decompression during rotator cuff surgery** was recommended as an option in one guideline. Specific patient criteria were not provided. Subacromial decompression was specified as 'not for routine use' in 3 guidelines, and explicitly excluded in 2 guidelines.

¹³ <u>https://www1.health.gov.au/internet/msac/publishing.nsf/Content/1711-public</u>

Subacromial decompression as a standalone procedure is explicitly excluded in two guidelines, for the indications of subacromial impingement syndrome, and for subacromial pain syndrome or rotator cuff disease. Nine guidelines recommended the procedure in a restricted population. The detail for patient selection varied across guidelines. However, in all cases patients had to have ongoing symptoms despite a period (6 weeks to 6 months) of conservative therapy, and in most cases were required to have been diagnosed with subacromial impingement.

Further detail is provided in <u>Clinical guidelines review</u>, Report to MSAC, Terms of reference 1.

Source	Description diagnostic imaging / physiotherapy program / conservative therapies (e.g. corticosteroid injections) (overall duration, number of supervised sessions, specified elements)			
Clinical practice guideline	•			
AMRC (AMRC, 2018a)	Physiotherapy effective and safe in many cases			
AIM 2021 (AIM, 2021)	Imaging report required Physiotherapy is a general requirement Injections may be considered			
ACR 2018 (atraumatic) (ACR, 2018)	X-ray recommended; US and MRI not recommended for initial imaging			
AOA 2017 (AOA, 2017)	Should only be performed when certain conditions are met: for symptoms that are significant and persistent and that have not responded to non-operative care, including injections and physiotherapy			
BESS 2014 (BOA, 2014)	X-ray helpful in primary care US and MRI rarely needed in primary care Education, rest, NSAIDs, simple analgesia 'Appropriate structured' physiotherapy for 6 weeks Corticosteroid injection – one injection, two possibly after 6 weeks A further 6 weeks of physiotherapy in intermediate care			
Colorado 2015 (Colorado Department of Labor and Employment, 2015)	X-ray accepted as an initial test for certain indications MRI or US may be used after 4-6 weeks if required NSAIDs and limited opioids. Rest, exercise therapy, manual therapy (12 sessions) Corticosteroid injections are recommended For impingement, when functional deficits interfere with activities of daily living and/or job duties after 3 to 6 months of active patient participation in an appropriate shoulder rehabilitation program, surgery may restore functional anatomy and reduce the potential for repeated impingement			
Diercks 2014 (Diercks et al., 2014)	Xray can be used to determine bone morphology US and MRI recommended if initial conservative therapy fails NSAIDs, rest, exercise Corticosteroid injections may be used for severe pain If the patient does not respond to exhaustive non-operative treatment and does not qualify for a rehabilitation treatment, bursectomy can be considered			
Eubank 2021 (Eubank et al., 2021)	All patients should be referred to X-ray MRI and US often unnecessary and should not be ordered at primary care NSAIDs may be considered to assist in exercises			

Table 65	Summary of guideline recommendations and programs for primary care

	At least 12 weeks of an active, strength- based home or supervised exercise therapy program as the primary treatment option.
	There is strong evidence to support manual therapy such as joint mobilisations, manipulations and soft tissue techniques
	Corticosteroid injections may be used to assist in exercises
Hohmann 2020 (Hohmann et al., 2020)	Suggestion: X-ray for mechanical impingement
	MRI may be considered for detection of rotator cuff tear
	At least 6 weeks physical therapy, including anti-inflammatories
	Corticosteroid injection can be considered
	To consider if certain conditions are met:
	Pain for at least 6 months; positive physical test; symptoms persist despite at least 6 weeks physical therapy including anti- inflammatory medication; radiologic evidence of mechanical impingent; no MRI evidence of a high-degree tear; possible use of a steroid injection as a diagnostic tool
Hopman 2013 (Hopman et al., 2013)	X-rays and imaging not indicated for 4-6 weeks in the absence of red flags
	Patients who have symptoms after 6 weeks should be referred for MRI and X-ray
	Paracetamol and NSAIDs
	Initially treated with exercise prescribed and reviewed by a suitably qualified healthcare provider. This may be combined with manual therapy.
	For pain reduction in injured workers with persistent pain or who fail to progress following initiation of an active, non-surgical treatment program, the clinician may consider subacromial corticosteroid injections combined with a local anaesthetic.
	May refer to a specialist if significant/persistent symptoms persist in 3 months.
IICAC 2014 (Industrial Insurance Chiropractic	X-ray for mechanical impingement
Advisory Committee, 2014)	MRI or US may be useful
	Fair evidence on the use of manual or manipulative therapy
	Suggested that corticosteroid injections are superior to physiotherapy interventions
Juel 2019 (Juel et al., 2019)	X-rays are recommended
	US or MRI are recommended in case of suspected full thickness rupture
	NSAIDs in the lowest dose over the shortest possible time for severe pain that impedes activity
	Instructed home exercises are recommended.
	Guided exercises 3 months is recommended
	Suggested steroid injection for severe pain that impedes movement. Repeated injection is not recommended.
Kauta 2021 (Kauta et al., 2021)	May include up to a 3-month course of anti-inflammatory and analgesic drugs
	May include physiotherapy with anti-inflammatory and analgesic drugs for 3 months
	Deterioration or no improvement during this initial course of treatment, physician may upscale to local anaesthetic and steroid injections
Kassolik 2018 (Kassolik et al., 2018)	MRI or US only to be used at a later stage of treatment if physical therapy is not effective

	Recommended massage for painful shoulder syndrome. For shoulder impingement syndrome, the main physiotherapeutic intervention is active motor therapy.
Klauser 2012 (Klauser et al., 2012)	US is recommended for suspected FTT or PTT
Lafrance 2022 (Lafrance et al., 2022b)	Diagnostic imaging used only after the failure of adequate non- surgical management. Acetaminophen, NSAIDs. Opioids may be considered with severe/persistent pain. If severe/persistent pain, up to 2
	corticosteroid injections (not as first-line therapy). Active rehabilitation program. The most effective exercise approach
	remains uncertain. Manual therapy may be used to reduce pain. Refer to specialist care e.g. musculoskeletal or rehabilitation
	specialist or orthopaedic surgeon after 12 weeks.
	Subacromial decompression with acromioplasty is not recommended.
NYSWCB 2021 (New York Workers	X-ray recommended where clinically indicated
Compensation Board, 2021)	US or MRI recommended when symptoms remain after 4–6 weeks non-operative treatment to show positive evidence of deficit in rotator cuff
	May include medications. Acute rotator cuff tear could indicate the need for limited narcotics use.
	Operative procedures for impingement syndrome should not be considered prior to an adequate trial of physical rehabilitation that includes direction and supervision by an appropriate, licensed professional and active patient participation. Such a trial should normally last for a minimum of 6 weeks.
	Subacromial space injection with steroids may be therapeutic if the patient responded positively to a diagnostic injection of an anaesthetic. Not more than 2–3 times annually, maximum of 3 injections to the same site. Not indicated for rotator cuff injury.
	Acromioplasty should not be considered until a minimum 6 weeks/3- 6 months of active patient participation in physical rehabilitation
NHS 2013 (NHS, 2013)	X-ray indicated to exclude or detect pathology
	If pain is the limiting factor then a review of analgesia or a therapeutic injection can be considered
	Exercise should be considered
	Injection can be considered provided there are no contraindications
NHS England 2018 (NICE, 2018)	Exercises are effective and safe in many cases
	Decompression for pure subacromial impingement (excluding other indications including rotator cuff tear) should only be offered For patients with persistent or progressive symptoms, in spite of adequate non-operative treatment
Oliva 2015 (Oliva et al., 2015)	X-ray, US or MRI 'can be used'
	It is possible that rehabilitation is effective
	Corticosteroids may reduce pain in the short term
Rees 2021 (Rees et al., 2021)	X-ray recommended in patients not improving with conservative management
	US and MRI not indicated in primary, community and intermediate care
	Analgesics may be used
	Recommended physiotherapy rehabilitation is usually for six weeks initially unless physiotherapists identify a reason for earlier referral to secondary care. If there is patient improvement in the first six

	weeks of physiotherapy, then at least another six weeks therapy is justified
	No more than two subacromial corticosteroid injections should be given.
	Image-guided subacromial injections should NOT be used
Sconfienza 2020 (Sconfienza et al., 2020)	Intra-articular ACJ local anaesthetic and/or steroid injections produce pain reduction, with imaging guidance improving the outcome compared to palpation
SRBMUS 2021 (Society of Radiographers, 2021)	US with certain clinical history including restricted range of movement, suspected tear or tendinopathy
Vandvik 2018 (Vandvik et al., 2019)	Surgery is not recommended for patients with subacromial pain syndrome, also labelled as rotator cuff disease
Washington 2018 (Washington State Department of Labor and Industries, 2018)	X-ray is recommended MRI, ultrasound or X-ray arthrogram for suspected rotator cuff tear Medications may be considered Brief rest, less than 4 days, therapeutic exercise and mobilisation Because corticosteroid use is associated with side effects such as weakening of connective tissue, no more than 3 injections are
	recommended under one claim for the shoulder, 4 injections per lifetime For subacromial impingement syndrome, subacromial decompression with or without acromioplasty may be considered after 12 weeks of conservative care. Requirements include pain, MRI or X-ray and further imaging; AND subacromial injection with local anaesthetic gives documented pain relief
Yu 2021 (Yu et al., 2021)	Manipulation, strengthening and stretching exercises, cervicothoracic spine manipulation and mobilisation
Randomised controlled trials – subacromial decompression	
Beard 2018 (Beard et al., 2018)	No specific protocol described. for arthroscopy, postoperative physiotherapy was 1-4 treatment sessions.
Brox 1993 (Brox et al., 1993)	Conservative unclear: The training continued for 3 to 6 months, with the supervision gradually being reduced. In addition, 3 lessons were given on the anatomy and function of the shoulder, pain management and ergonometrics. Analgesics, including anti-inflammatory drugs but not cortisone injections, were allowed.
Cederqvist 2021 (Cederqvist et al., 2021)	Structured rehabilitation program – 15 sessions, 3 months This was repeated for patients randomised to conservative therapy Post-surgery rehabilitation protocol – 3 visits to physiotherapist
Farfaras 2016 (Farfaras et al., 2016)	Formal training with standardised protocol, 1 hour per day (twice a week with a physio) for 3–6 months Unclear regarding the total number of sessions.
Haahr 2005 (Haahr et al., 2005)	Physiotherapy. 19 sessions each of up to 60 minutes given by two experienced therapists
Ketola 2009 (Ketola et al., 2009)	There were a minimum of 7 controlled visits to the therapist until patient was able to perform independently. NSAIDs were allowed as necessary. Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program.

NSW	
	Costs not disclosed on the website
Shoulder Clinic SA, Keswick/Elizabeth Vale https://shoulderclinic.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Costs not disclosed on the website
Wakefield Shoulder Clinic Adelaide https://www.wakefieldshoulderclinic.com.au/	It can take 6 weeks to 3 months to notice good improvement in shoulder symptoms and require ongoing maintenance exercises to keep that improvement.
	Cost \$99.50 initial consultation \$78.50 standard consultation
Unley Physio, Unley https://www.unleyphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost \$125-135 initial consultation \$93 – 103 subsequent consultations
Physiofit - Adelaide https://physiofitadelaide.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website Most shoulder pain to have resolved (short term) within 12 weeks
	Cost \$82 initial consultation \$68 subsequent consultation
Core Physiotherapy and Pilates Studio - Adelaide https://corephysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
SA	
clinics Clinic name, city, website	Summary of advice
Local information – websites of physiotherapy	
Daghiani 2022 (Daghiani et al., 2022)	 1 corticosteroid injection was planned; a second injection (for the unguided group) was permitted at the clinician's discretion 12 sessions over 4 weeks
Roddy 2021 (Roddy et al., 2021)	their first injection. 6-8 physiotherapy sessions over 12-16 weeks
	A second injection could be given after 6 weeks in accordance with the trial protocol for patients who received good initial benefit from
Hopewell 2021 (Hopewell et al., 2021)	See also Keene 2020 Up to 6 physiotherapy sessions over 16 weeks (1h for initial, then 20-30 minutes each)
Randomised controlled trials – conservative interventions	
Rahme 1998 (Rahme et al., 1998)	Patients were seen 2-3 times per week. The intervals between treatments were successively increased as the patient became more familiar with the object of the exercises
Peters 1997 (Peters and Kohn, 1997)	Intense treatment program not described. Up to 3 corticosteroid injections were allowed.
Paavola 2018 (Paavola et al., 2018)	Postoperative care: One visit to physiotherapist, guidance for home exercises, then standardised rehabilitation program from each centre. 15 supervised physiotherapy visits

Sydney Hills Dhysic, Sydney	Advice on the number of physiotherapy appoints not montioned on
Sydney Hills Physio, Sydney http://www.sydneyhillsphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost
	\$130 initial consultation(40 mins)
	\$110 standard consultation (30 mins)
	\$160 extended consultation (50 mins)
Sydney Physio clinic, Sydney https://www.sydneyphysio.com.au/	Advice on the number of sessions
nups.//www.syuneyphysio.com.au/	This varies between individual conditions, but the physio will be able to give you an idea of a timeline for problem resolution on the initial
	visit.
	Cost
	\$110 initial consultation
Discrimina Marth Duda	\$80 standard consultation
Physiowise, North Ryde https://physiowise.com.au/?page_id=668	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost
	\$90 physiotherapist
	\$180 physiotherapist for complex conditions
	\$105 for senior physiotherapist
Total Physiotherapy Sydney, Sydney	\$210 for senior physiotherapist for complex conditions Advice on the number of physiotherapy sessions not mentioned on
https://www.totalphysiosydney.com.au	the website
	Cost
	\$125 Initial consultation (45 minutes)
	\$150 Initial consultation senior physiotherapist
	\$170 Extended initial consultation (60 minutes):
	\$205 Senior physiotherapist extended initial consultation
	\$98 Subsequent consultation (30 minutes)
	\$105 Senior physiotherapist subsequent consultation
	\$170 Extended subsequent consultation \$205 Senior physiotherapist extended subsequent consultation
Physio for all, North Sydney	Advice on the number of physiotherapy sessions not mentioned on
https://physio4all.com.au/	the website
	Cost
	\$130 initial consultation principal physiotherapist
	\$125 initial consultation practice physiotherapist
	\$110 standard consultation principal physiotherapist \$105 standard consultation practice physiotherapist
WA	
Modern Physiotherapy, South Perth	
https://modernphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost
	\$165 specialist initial consult
	\$115 standard consult
	\$145 long follow up consult
	\$115 title physiotherapist initial consult
	\$95 standard follow up \$105 long follow up
Inflow Physiotherapy, Subiaco	
https://inflowphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost

	\$140 initial consult
	\$117 standard consult
Perth Physiotherapy https://www.perthphysiotherapy.net.au/	Number of physiotherapy sessions Some patients enjoy results quickly while some may take slightly longer. We monitor your progress and modify our recommendations as needed
	Cost \$88 initial assessment \$79 standard session \$88 extended session
Perth Physiotherapy and Pilates https://www.perthphysiotherapyandpilates.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost \$90 (\$100 with Senior Physiotherapist) initial consultation \$84 (\$95 with Senior Physiotherapist) follow-up consultation
Perth Shoulder Physio, Sorrento https://perthshoulderphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost \$199 initial consultation \$129 follow up consultation
Victoria	
Richmond Physiotherapy, Richmond <u>https://www.richmondphysiotherapyclinic.com.au/</u>	Advice on the number of physiotherapy sessions Each individual is unique and it may take several visits before you return to normal.
	Cost For assessment and treatment \$119 advanced sports physiotherapist \$104 Senior physiotherapist \$99 associate physiotherapist
Physio Melbourne, St. Kilda/Fairfield/Coburg https://www.physiomelbourne.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost \$98 initial consult \$88 physio review
Melbourne CBD physio, Melbourne https://melbournecbdphysio.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost \$130 initial consult \$120 review consult
South Melbourne Physio https://www.smpc.com.au/	Advice on the number of physiotherapy sessions not mentioned on the website
	Cost 30 minutes (short initial or review consultation) \$140 principal physiotherapist \$130 senior physiotherapist \$115 associate physiotherapist
	40 minutes (initial long consult/long review/ initial exercise rehab)

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Non-randomised comparative studies

Two non-randomised comparative studies were identified and are summarised here for information only (Köhler et al., 2020, Biberthaler et al., 2013).

Study details Country Funding source Conflicts of interest	Study design/ NHMRC level of evidence	Study population	Inclusion criteria Exclusion criteria	Intervention Comparator	Follow-up times Outcomes
Biberthaler 2013 (Biberthaler et al., 2013) Trial number not reported Germany (1 clinic, 3 surgeons) Funding source not reported No competing interests declared	Retrospective non-randomised comparative study III-2 (method of patient selection not described)	Patients with subacromial impingement Patients with full- thickness tears excluded SAD: n=142 Conservative therapy: n=165	Inclusion: Patients were identified according to an age range between 20 and 82 years, presence of shoulder pain for more than three and less than six months and meeting the following criteria: -pain on abduction of the shoulder with a painful arc -positive Neer and Hawkins testing -positive impingement test (relief of pain after injection of local anaesthetics into the subacromial space) Exclusion: Patients with any other pathology such as rotator cuff tear, gleno- humeral instability, cartilage damage (>Outerbridge II), clinically verified acromioclavicular joint osteoarthritis, calcifying tendinitis, biceps pathology or signs of cervical root or	Intervention Arthroscopic SAD: Bursectomy, coraco-acromial ligament release, acromioplasty and coplaning. Patients started physiotherapy on the day after surgery and performed a standard rehabilitation protocol starting with active assisted range of motion on day 1. With decreasing pain, this training was progressed with strengthening exercises of the rotator cuff and shoulder muscles. Comparator Standardised physiotherapy protocol heat, cold pack or/and soft issue treatment (16 sessions with 60 min each for 12 weeks). Then, active training of the periscapular muscles and	Follow-up 55 (interquartile range 25%–75%: 25–87) months Primary: Munich Shoulder Questionnaire (MSQ) Secondary: Constant Shoulder Pain and Disability Index (SPADI) \ Disabilities of the Arm, Shoulder and Hand (DASH) score Outcomes collected by questionnaire

Table 66 Study profiles, non-randomised comparative trials

			temporomandibular symptoms Patients were excluded if any additional surgical procedures other than subacromial decompression with or without acromioclavicular joint surgery were performed.	strengthening at least twice per week over a period of three months. Patients were encouraged to repeat the exercises at home on a daily basis. After 12 weeks, patients were instructed perform home exercises two to three times per week	
Köhler 2020 (Köhler et al., 2020) Trial number not reported Germany (number of centres and surgeons not provided) Competing interests not reported.	Prospective non- randomised comparative study	Patients with primary extrinsic shoulder impingement Patients with full- thickness tears excluded SAD: n=38 Conservative therapy: n=42	Inclusion: Clinical signs of impingement syndrome, diagnostic MRI scans demonstrating the absence of structural damage like lesions of the rotator cuff, patient age ≥ 18 ≤ 70 years Exclusion: Rheumatic diseases, osteoarthritis of the shoulder, shoulder instability, pathologies of the tendon of the long head of the biceps, injuries to the glenoid, and disruption of the rotator cuff tendon	Intervention: Arthroscopic SAD: Removal of bursal tissue, bone spurs, resection of the acromioclavicular joint where required. Comparator: Supervised exercises and additional therapies (ultrasound, Kinesio taping, electrotherapy). Three treatments per week during the first two weeks, followed by two treatments per week for approximately four weeks and, where appropriate, further episodic care until the patient was free of symptoms. Subacromial injections were allowed.	Follow-up at 3, 6 and 12 months Outcomes: Constant score Pain (numerical rating scale) Duration of inability to work

Abbreviations MRI = magnetic resonance imaging, NHMRC = National Health and Medical Research Council, SAD = subacromial decompression.

Study design

In both studies, it is unclear how patients were allocated to the intervention. Biberthaler appears to be a retrospective study of patients previously treated at a single clinic; patients received either conservative therapy or subacromial decompression (SAD). In all, 307 patients were enrolled to SAD or physiotherapy and exercise therapy. Köhler is a prospective study, with 80 patients included from a total pool of 106 patients (3 patients were identified with additional pathologies, and 23 withdrew).

Population

Neither study undertook a power calculation for the number of included patients.

In Biberthaler, patients were diagnosed following physical tests and an impingement test, with Xrays excluding other pathologies including rotator cuff tears, osteoarthritis, calcifying tendinitis and biceps pathology.

Biberthaler was not explicit on any previous therapies, only stating that included patients had shoulder pain for more than 3 and less than 6 months. Participants had a total median age of 57 years and a slightly higher proportion of females. Baseline demographics are not provided, and therefore it is unclear whether patient characteristics such as shoulder pain or function were similar between groups. Due to the retrospective nature of study design, patient selection to the intervention may have been biased.

Participants in Köhler had primary extrinsic (outlet) shoulder impingement. This study included a small number of patients with acromioclavicular joint osteoarthritis although patients with osteoarthritis of the shoulder were excluded.

Patients had received non-standard conservative care for at least 6 weeks, with no improvement in symptoms (Köhler). Further detail on this care is not provided. Patients in both groups were similar in BMI, but differed in age (physiotherapy 40.8 [SD 10.7] years; ASAD 50.3 [SD 12.1] years), and there were also differences in the proportion of female patients. It is unclear if these imbalances were due to study design and patient preferences as the method of selection is not reported.

Intervention

In Biberthaler and Köhler, arthroscopic SAD is provided in line with that provided in the RCTs. Any additional interventions such as pain medication or subacromial injections are not described. In both studies, surgical rehabilitation included physiotherapy and mobilisation or strengthening exercises.

Comparator

In Biberthaler, patients were provided with a comprehensive program of 12 weeks physiotherapy followed by 12 weeks exercise therapy, then home exercises.

In Köhler, patients were provided with supervised exercises and additional therapies (US, Kinesio Taping®, electrotherapy) for approximately 4 weeks and, where appropriate, further episodic care until the patient was free of symptoms. Subacromial injections were allowed.

Results

Biberthaler provides no primary analysis of results according to intervention and comparator. Results are instead provided only according to age, with outcomes for patients above and below the median age of 57 reported separately. It is unclear whether this analysis was intended prospectively.

In the younger population aged less than 57 years (median age 48 [interquartile range 42–53] years for ASAD and 50 [interquartile range 43–54] years for exercise therapy) the median MSQ score was the same in patients treated with ASAD (83 [interquartile range 66–91] points) and exercise therapy (84 [interquartile range 65–93] points), p = 0.37). In contrast, in older patients (median age 62 [interquartile range 59–68] years for ASAD and 64 [interquartile range 61–67] years for exercise therapy) there was a significantly improved MSQ score for patients treated with ASAD (89 [interquartile range 79–94] points) compared to patients who received exercise therapy (81 [interquartile range 60–90] points), p < 0.05. This nears, but does not exceed the MCID of 8.3 points (Hao 2019).

In Köhler, there were improvements for Constant score and pain in patients treated with surgery and exercise therapy but no difference between groups. Patients treated with exercise therapy were more likely to work at 3 (p < 0.001) and 6 months (p = 0.032) but not at 12 months (p = 0.990), compared to patients treated with ASAD. At 3 months, there was approximately 4 weeks mean difference between both groups in terms of duration of inability to work.

Predictive or prognostic factors for outcomes after SAD

Study ID Follow-up	Number of patients Patient population	Intervention	Outcomes related to radiological findings of the shoulder	
Erggelet 1999 (Erggelet et al., 1999)N = 131 (rotator cuff repair 106, acromioplasty n = 25 patients who had received and post-operative X-rays Patients who received rota cuff repair or acromioplastMinimum follow- up 2 yearsPatients who received rota 		Open rotator cuff repair or acromioplasty	All patients received pre- and post-operative X-rays. Heterotopic ossifications were found in 28 (26%) after rotator cuff reconstruction and 7 (28%) after acromioplasty. There was no significant difference in outcomes (questionnaire or Constant score) of patients with and without ossifications. The study provides no correlation of outcomes with the pre-operative ossifications.	
Singh 2014 (Singh et al., 2014) Mean follow-up 3.4 years Retrospective	(Singh et al., 2014)Patients with shoulder impingementMean follow-up 3.4 yearsAnteroposterior and lateral radiograph of the shoulder, US		 The authors present a scoring criteria to select patients likely to have prompt and sustained relief in symptoms after arthroscopic SAD: 1. Shoulder pain with overhead activities 2. Persistent pain for more than 6 months 3. Improvement for more than 1 week after subacromial steroid injection 4. Symptoms persist/recur despite at least 1 course of supervised targeted physiotherapy 5. Persistently positive Hawkins test 6. Radiological changes of impingement on both acromial and humeral region in subacromial space 	

 Table 67
 Case series studies which report on the predictive potential of radiology

Study ID Follow-up	Number of patients Patient population	Intervention	Outcomes related to radiological findings of the shoulder
	months of nonoperative treatment (physiotherapy and subacromial injection), they were then offered ASAD.		In this population: All patients had shoulder pain with overhead activities; all patients had symptoms for more than 6 months; 69% patients had a response of greater than 1 week to steroid injection; all patients had symptoms despite supervised targeted physiotherapy; 81% had a persistently positive Hawkins test; 55% patients had radiological changes of impingement on both acromial and humeral region. 62 (55%) patients met 5 or 6 of these predictive factors. Patient outcomes (OSS) were significantly improved in patients who had a compound had 5 or 6 of the above predictive factors at and 1 year after surgery (P not provided). On multivariate analysis, the presence of radiologic changes of impingement on both the acromion and humerus was the most consistent feature associated with good outcome (p < 0.001) after surgery
Magaji 2012 (Magaji et al., 2012) 1 year Prospective	N = 92 (consecutive) Symptoms for over six months due to subacromial impingement of the shoulder, who were being treated with physiotherapy for 6 months	Arthroscopic SAD	Patients were selected based on the following four clinical and radiological criteria: temporary benefit following steroid injection, pain in the mid-arc of abduction, a consistently positive Hawkins test and radiological evidence of impingement (sclerosis, cysts or osteophytes at the greater tuberosity and acromion) At 1 year, patients who met 3 or 4 of the above criteria had significantly improved OSS compared with patients who only met 2 of
			these criteria (p = 0.021) All patients who met 3 or 4 criteria had scuffing of the rotator cuff and the undersurface of the acromion.
Paulos 1990	N = 80 (consecutive)	SAD	Radiographic evaluation was at final follow-up.
(Paulos and Franklin, 1990) Mean 32 (range 12 to 54) months Retrospective	Patients with impingement syndrome (positive impingement sign, positive impingement test, near normal passive range of movement, greater than 12 months history of pain, failed a 6-month rehabilitation program.		The outlet view may be helpful in assessing preoperative acromial status i.e. primary impingement (data not provided).
Aydin 2011 (Aydin et al., 2011) Mean 28.6 (range 12-47) months Unclear if prospective	N = 45 (unclear if consecutive) Patients with chronic subacromial impingement syndrome	Arthroscopic SAD	Patients were distributed into 3 groups depending on the acromial Bigliani type 1 (flat), 2 (curved) or 3 (hooked), based on preoperative X-ray. There was a significant improvement from baseline Constant scores in all groups (p < 0.005). There was no difference between groups based on acromial anatomy (p = 0.668). The authors suggest that

Study ID Follow-up	Number of patients Patient population	Intervention	Outcomes related to radiological findings of the shoulder
			acromioplasty is not necessary in the treatment of subacromial impingement.
Chui 1997 (Chui et al., 1997) Mean 4.7 (range 3 to 8) months Retrospective	N = 22 (unclear if consecutive) Patients with shoulder impingement with a positive impingement sign after failed conservative treatment	Open acromioplasty	Preoperative X-rays were taken to determine the acromiohumeral distance. There was a trend to improved results for patients with acromiohumeral distance of 1cm or less compared with patients with a larger distance; however, this was not significant.
Benson 2009 (Benson et al., 2009) 6 months Unclear if prospective	N = 20 (consecutive) Subacromial impingement in the absence of full-thickness tears of the rotator cuff Minimum duration of symptoms 6 months, failure of conservative care, a failed home exercise programme and the presence of pain at rest and moderate to severe pain at night	SAD	Pre-operatively, the shape of the acromion was determined by radiography. Based on OSS outcomes, at 6 months patients with flat or curved acromia did significantly better than those with a hooked acromion (t-test, p = 0.046).

Abbreviations MRI = magnetic resonance imaging, OSS = Oxford Shoulder Score, SAD = subacromial decompression, US = ultrasound.

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
Arroll 2005 (Arroll and Goodyear-Smith, 2005)	Patients with rotator cuff tendonitis and frozen shoulder	Intra-articular and subacromial corticosteroid injections, with or without local anaesthetic	Placebo, NSAIDs, local anaesthetic	RCTs k=5	Subacromial injections of corticosteroids are effective for improvement for rotator cuff tendonitis up to a 9-month period. They are also probably more effective than NSAID medication. Higher doses may be better than lower doses for subacromial corticosteroid injection for rotator cuff tendonitis.
Babatunde 2021 (Babatunde et al., 2021) Systematic review and network meta- analysis	Patients with subacromial shoulder conditions	Non-surgical (e.g. corticosteroid injections, therapeutic exercise, shockwave therapy) and surgical treatment	All possible comparisons e.g. any other intervention, placebo, usual care or no treatment	RCTs k=99	The results show small to moderate estimates of effect for most treatment options and no strong evidence for any one individual treatment being clearly superior to another. The results of this large NMA including 54 RCTs showed small to moderate effect sizes for most treatment options for SSCs. Six treatments had a high probability of being effective, in the short term, for pain and function (acupuncture, manual therapy, exercise, exercise plus manual therapy, laser therapy and TENS), but with very low certainty for most treatment options. After accounting for risk of bias, there is evidence of moderate certainty that exercise is an effective treatment option for both pain and function outcomes in patients with SSCs, up to 3 months follow-up. Further NMA focusing specifically on exercise interventions may be conducted to determine the comparative effectiveness of different types of, or approaches to, exercise for patients with SSC.
Buchbinder 2003 (Buchbinder et al., 2003)	Adults with shoulder pain (excluded rheumatoid arthritis, polymyalgia rheumatica and fracture)	Corticosteroid injections	Placebo or another intervention	RCTs k=26	Despite many RCTs of corticosteroid injections for shoulder pain, their small sample sizes, variable methodological quality and heterogeneity means that there is little overall evidence to guide treatment. Subacromial corticosteroid injection for rotator cuff disease and intra- articular injection for adhesive capsulitis may be beneficial although their effect may be small and not well-maintained.

Table 68 Systematic reviews of conservative therapies

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
Bury 2016 (Bury et al., 2016)	Rotator cuff related shoulder pain (including rotator cuff tendinopathy, shoulder impingement syndrome)	Scapula focused approaches including exercise therapy, stretches and/or manual therapy	Any comparison that adopts a general or non- scapula approach, such as usual care or an alternative exercise therapy	RCTs k=4	A scapula-focused approach for rotator cuff related shoulder pain confers benefit over generalised approaches up to six weeks but this benefit is not apparent by 3 months. Early changes in pain are not clinically significant. With regards to scapula position/ movement, the evidence is conflicting. These preliminary conclusions should be treated with significant caution due to limitations of the evidence base.
Cook 2018 (Cook et al., 2018)	Adults with rotator cuff-related shoulder pain	Subacromial injections of corticosteroid	Local anaesthetic injections	RCT k=13	Corticosteroid injections may have a short-term benefit (up to 8 weeks) over local anaesthetic injections alone in the management of rotator cuff-related shoulder pain. Beyond 8 weeks, there was no evidence to suggest a benefit of corticosteroid over local anaesthetic injections. It is unknown if improvement over time is due to placebo, natural history or a therapeutic effect of the medicines used in the published research
Coombes 2010 (Coombes et al., 2010)	Tendinopathy	Corticosteroid and other injections	Placebo or non- surgical intervention for tendinopathy	RCTs k=41 (k=16, rotator cuff tendinopathy)	 Pooled data for three studies comparing corticosteroid injections with placebo injection showed a medium effect of corticosteroid injection for reduction of pain. A large effect of corticosteroid injection for overall improvement was noted in one study compared with injection of tenoxicam (an NSAID). By contrast, no difference in effect was shown in all studies in which oral NSAIDs were prescribed. Trials comparing corticosteroid injection with physiotherapy reported no differences in pain or function although more patients reported overall improvement after corticosteroid injection at 6 weeks in one study. Efficacy did not differ in all studies of intermediate and long-term outcomes after treatment for rotator-cuff tendinopathy.

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
Desmeules 2016 (Desmeules et al., 2016)	Rotator cuff-related tendinopathy (including impingement syndrome, subacromial bursitis, or bicipital tendinitis); adult workers, or work-related measures were reported	Therapeutic exercises for the shoulder	Any alternative intervention (different exercise programs, surgery or placebo)	RCTs k=10 trials	There is low to moderate-grade evidence that therapeutic exercises provided in a clinical setting are an effective modality to treat workers suffering from RC tendinopathy and to promote return-to-work. However, the optimal intensity and context in which the therapeutic exercise program is provided remain unclear, as does whether other interventions would be useful.
Goldgrub 2016 (Goldgrub et al., 2016)	Adults and children with soft tissue injuries of the shoulder (grade I-II sprains/strains, nonspecific musculoskeletal shoulder pain, bursitis, subacromial impingement syndrome, shoulder tendinitis, rotator cuff tendinosis, tendinopathy)	Multimodal care (a conservative program of care that involves at least 2 distinct therapeutic modalities provided by 1 or more health care disciplines)	Other interventions, placebo/sham interventions, no intervention, or invasive interventions	RCTs k=10 trials	Two RCTs suggest that multimodal care may be associated with greater benefits than corticosteroid injection(s) for subacromial impingement syndrome of variable duration. However, the effect sizes were small and were non-clinically important in long-term follow-up. The current evidence suggests that combining multiple interventions into one program of care does not lead to superior outcomes for patients with subacromial impingement syndrome or nonspecific shoulder pain.
Haik 2016 (Haik et al., 2016)	Patients with subacromial pain syndrome	Active or passive physical therapy modalities (including physical resources, exercise therapy and manual therapy)	Alternative therapies No intervention, placebo or sham treatment	RCTs k=64	 Exercise therapy is the best conservative therapy to reduce pain, improve function and increase range of motion in individuals with subacromial pain in all stages of treatment. Exercise therapy based on stretching and strengthening of rotator cuff and scapular muscles is as effective as surgery intervention. Exercise therapy associated with manual therapy based on joint and soft tissue techniques is more effective than exercises alone to reduce pain in the short term in patients with subacromial pain. Low-level laser therapy and pulsed electromagnetic field are no better than placebo treatment or exercise therapy to improve pain or function in patients with subacromial pain.

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
Lavoie-Gagne 2022 (Lavoie-Gagne et al., 2022) Systematic review and network meta- analysis	Patients with subacromial impingement	Any intervention	Any intervention	RCTs k=35	Arthroscopic decompression with acromioplasty and physiotherapy demonstrated superior outcomes whereas CSI demonstrated poor outcomes in all 3 domains (pain, patient-relevant outcomes, and range of movement). For patients with significant symptoms, the authors recommend physiotherapy with corticosteroid injection as a first-line treatment, followed by acromioplasty and physiotherapy if conservative treatment fails. For patients with symptoms limited to 1 to 2 domains, the authors recommend a shared decision-making approach focusing on treatment rankings within domains pertinent to individual patient symptomatology
Page 2016 (Page et al., 2016a)	Adults with rotator cuff disease (e.g. subacromial impingement syndrome, rotator cuff tendonitis or tendinopathy, supraspinatus, infraspinatus or subscapularis tendonitis, subacromial bursitis, or rotator cuff tears)	Manual therapy or exercise (mobilisation, manipulation and supervised or home exercises)	Placebo, no intervention, a different type of manual therapy or exercise or any other intervention (e.g. glucocorticoid injection, surgery, electrotherapy, oral anti- inflammatories)	RCTs k=60	Only one trial compared a combination of manual therapy and exercise reflective of common current practice to placebo. We judged it to be of high quality and found no clinically important differences between groups in any outcome. Effects of manual therapy and exercise may be similar to those of glucocorticoid injection and arthroscopic subacromial decompression, but this is based on low quality evidence. Adverse events associated with manual therapy and exercise are relatively more frequent than placebo but mild in nature.
Page 2016 (Page et al., 2016b)	Adults with rotator cuff disease (e.g. subacromial impingement syndrome, rotator cuff tendinitis, calcific tendinitis)	Any electrotherapy modality (therapeutic ultrasound, low- level laser therapy (LLLT), transcutaneous electrical nerve stimulation (TENS)	Placebo, no treatment, or electrotherapy modality to another physical therapy combination	RCTs k=47	Based on low quality evidence, therapeutic ultrasound may have short-term benefits over placebo in people with calcific tendinitis, and low-level laser therapy may have short-term benefits over placebo in people with rotator cuff disease. Therapeutic ultrasound, low-level laser therapy and pulsed electromagnetic field therapy may not provide additional benefits when combined with other physical therapy interventions.

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
Pieters 2020 (Pieters et al., 2020) Umbrella review	Subacromial shoulder pain (rotator cuff tendinopathy, painful arc syndrome, subacromial bursitis, rotator cuff tendinosis, supraspinatus tendinitis, and contractile dysfunction)	Non-surgical treatments (exercise, exercise combined with manual therapy, multimodal physical therapy, corticosteroid injection, laser, ultrasound, extracorporeal shockwave therapy, or pulsed electromagnetic energy)	Non-surgical treatments	Systematic reviews k=16	There is a growing body of evidence to support exercise therapy as an intervention for subacromial shoulder pain. Ongoing research is required to provide guidance on exercise type, dose, duration, and expected outcomes. A strong recommendation may be made regarding the inclusion of manual therapy in the initial treatment phase. Conflicting evidence on the effectiveness of multimodal therapy and corticosteroid injection. Other commonly prescribed non-surgical interventions, such as ultrasound, low-level laser, and extracorporeal shockwave therapy, lack evidence of effectiveness.
Puzzitiello 2020 (Puzzitiello et al., 2020)	Patients with rotator cuff disease, especially prior to rotator cuff repair – reporting of adverse events	Corticosteroid injections	Nil	Observational studies k=8	Several recent clinical trials have demonstrated that CSIs are correlated with increased risk of revision surgery after rotator cuff repair in a temporal and dose dependent matter. Caution should be taken when deciding to inject a patient, and this treatment should be withheld if a rotator cuff repair is to be performed within the following 6 months.
Saito 2018 (Saito et al., 2018)	Adults with subacromial pain	Physical therapy intervention that focused on addressing scapular components	Alternative physical therapy (i.e., glenohumeral mobilisation and stretching, cervical intervention) or no intervention	RCTs k=6	Scapular focused interventions significantly improved pain with activities and shoulder function in the short term. No between-group difference in shoulder pain and function were found at follow up (4 weeks). A between-group difference in shoulder abduction range of movement in the short term only was found. No between-group difference in flexion range of movement, supraspinatus muscle strength, pectoralis minor length or forward shoulder posture were found. In conclusion, in adults with SAPS, scapular focused interventions can improve short-term shoulder pain and function.

Systematic review [Study ID]			Comparator	Included studies (k)	Conclusions
Saracoglu 2018 (Saracoglu et al., 2018)	Patients with subacromial impingement syndrome	Taping in addition to physiotherapy	Physiotherapy alone	RCTs k=3 NRCT k=1	Clinical taping, in addition to any physiotherapy interventions (e.g. exercise, electrotherapy, and manual therapy), might be an optional modality for managing patients with shoulder impingement syndrome, especially for the initial stage of the treatment. However, further robust, placebo-controlled and consistent studies are needed in order to prove whether it is more effective than physiotherapy interventions without taping.
Steuri 2017 (Steuri et al., 2017)	Adults with shoulder impingement	Conservative (non- surgical) interventions including exercise, manual therapy and medical management	Any other kind of intervention (including surgery)	RCTs k=200 (184 trials in the meta-analyses)	Exercise therapy was effective in improving pain, function and active range of motion. Specific exercises were more effective than general shoulder exercises. NSAIDS, corticosteroid injections (with an advantage for ultrasound guided injections), manual therapy, tape in combination with exercise, extracorporeal shockwave therapy and laser were also effective. NSAIDS and corticosteroids are superior to placebo, but it is unclear how these treatments compare to exercise. The quality of evidence was very low, therefore clinicians should apply this evidence cautiously when making clinical decisions.
Shire 2017 (Shire et al., 2017)	Patients with subacromial impingement syndrome	Specific exercise strategies involving resistive exercises	General resistance exercise	RCTs k=6 (k=4, specific scapular exercises, k=2, specific proprioceptive strategy)	No consistent statistically significant differences in outcomes between treatment groups were reported in the studies. There is insufficient evidence to support or refute the effectiveness of specific resistive exercise strategies in the rehabilitation of subacromial impingement syndrome.
Zadro 2021 (Zadro et al., 2021b)	Patients with shoulder pain (rotator cuff disease, adhesive capsulitis or mixed or undefined shoulder pain).	Image-guided glucocorticoid injection	Non-image-guided injection	RCTs k=19	Moderate-certainty evidence indicates that ultrasound- guided injection in the treatment of shoulder pain probably provides little or no benefit over injection without imaging in terms of pain or function and low-certainty evidence indicates there may be no difference in quality of life. We

Systematic review [Study ID]	Population	Intervention	Comparator	Included studies (k)	Conclusions
					are uncertain if ultrasound guided injection improves participant-rated treatment success, due to very low- certainty evidence. Low-certainty evidence also suggests ultrasound-guided injection may not reduce the risk of adverse events compared with non-image-guided injection. No serious adverse events were reported in any trial.

Abbreviations NRCT = non-randomised comparative trial; RCT = randomised controlled trial

Appendix F MBS items related to shoulder surgery

Item number	Descriptor						
47417	Treatment of fracture of tuberosity of humerus and associated dislocation of shoulder, by closed reduction Multiple Operation Rule (Anaes.) (Assist.) Fee: \$274.25 Benefit: 75% = \$205.70 85% = \$233.15						
47420	Treatment of fracture of tuberosity of humerus and associated dislocation of shoulder, by open reduction (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$538.80 Benefit: 75% = \$404.10						
47438	Humerus, proximal, treatment of fracture of, and associated dislocation of shoulder, by open reduction (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$685.85 Benefit: 75% = \$514.40						
47540	Hip spica or shoulder spica, application of, as an independent procedure Multiple Operation Rule (Anaes.) Fee: \$225.25 Benefit: 75% = \$168.95 85% = \$191.50						
47966	Item not currently available: general tendon and ligament transfer						
47967	Restoration of shoulder function by major muscle tendon transfer, including associated dissection of neurovascular pedicle, excluding micro-anastomosis and biceps tenodesis—one transfer (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$450.50 Benefit: 75% = \$337.90						
48239	Item not currently available: bone grafting						
48406	Osteotomy of fibula, radius, ulna, clavicle, scapula (other than acromion), rib, tarsus or carpus, for correction of deformity, including any of the following (if performed): (a) removal of bone; (b) excision of surrounding osteophytes; (c) synovectomy; (d) joint release; —one bone (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$348.40 Benefit: 75% = \$261.30						
48900	SHOULDER, excision of coraco-acromial ligament or removal of calcium deposit from cuff or both. (Anaes.) (Assist.) Fee: \$293.75						
48903	SHOULDER, decompression of subacromial space by acromioplasty, excision of coraco- acromial ligament and distal clavicle, or any combination. (Anaes.) (Assist.) Fee: \$587.75						
48906	SHOULDER, repair of rotator cuff, including excision of coraco-acromial ligament or removal of calcium deposit from cuff, or both – not being a service associated with a service to which item 48900 applies (Anaes.) (Assist.) Fee: \$587.75						
48909	SHOULDER, repair of rotator cuff, including decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination – not being a service associated with a service to which item 48903 applies. (Anaes.) (Assist.) Fee: \$783.80						

Table 69 MBS items related to shoulder interventions and other co-claimed surgical items

48915	Shoulder, hemi-arthroplasty of (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$783.80 Benefit: 75% = \$587.85
48918	Anatomic or reverse total shoulder replacement, including any of the following (if performed): (a) associated rotator cuff repair; (b) biceps tenodesis; (c) tuberosity osteotomy; other than a service associated with a service to which another item in this Schedule applies if the service described in the other item is for the purpose of performing a procedure on the shoulder region by open or arthroscopic means (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,567.50 Benefit: 75% = \$1,175.65
48921	Shoulder, total replacement arthroplasty, revision of (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,616.30 Benefit: 75% = \$1,212.25
49824	Revision of total shoulder replacement, including either or both of the following (if performed): (a) bone graft to humerus; (b) bone graft to scapula (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,861.30 Benefit: 75% = \$1,396.00
48927	Shoulder prosthesis, removal of (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$381.90 Benefit: 75% = \$286.45
48939	Shoulder, arthrodesis of, with synovectomy if performed (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,126.55 Benefit: 75% = \$844.95
48942	Arthrodesis of shoulder, with bone grafting or internal fixation, including either or both of the following (if performed): (a) removal of prosthesis; (b) synovectomy; other than a service associated with a service to which item 48245, 48248, 48251, 48254 or 48257 applies (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,469.40 Benefit: 75% = \$1,102.05
48945	SHOULDER, diagnostic arthroscopy of (including biopsy) – not being a service associated with any other arthroscopic procedure of the shoulder region (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$284.00 Benefit: 75% = \$213.00
48948	 SHOULDER, arthroscopic surgery of, involving any 1 or more of: removal of loose bodies; decompression of calcium deposit; debridement of labrum, synovium or rotator cuff; or chondroplasty – not being a service associated with any other arthroscopic procedure of the shoulder region (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$636.75 Benefit: 75% = \$477.60
48951	SHOULDER, arthroscopic division of coraco-acromial ligament including acromioplasty – not being a service associated with any other arthroscopic procedure of the shoulder region. (Anaes.) (Assist.) Fee: \$930.65
48954	Synovectomy of shoulder, performed as an independent procedure, including release of contracture (if performed), other than a service associated with a service to which another item in this Schedule applies if the service described in the other item is for the purpose of performing a procedure on the shoulder region by arthroscopic means (H) (Anaes.) (Assist.) Fee: \$979.60 Benefit: 75% = \$734.70
48958	Joint stabilisation procedure for multidirectional instability of shoulder, anterior or posterior repair, by open or arthroscopic means, including labral repair or reattachment (if performed), excluding bone grafting and removal of hardware, other than a service associated with a service

	to which another item in this Schedule applies if the service described in the other item is for the purpose of performing a procedure on the shoulder region by arthroscopic means (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$1,126.55 Benefit: 75% = \$844.95
48960	SHOULDER, reconstruction or repair of, including repair of rotator cuff by arthroscopic, arthroscopic assisted or mini open means; arthroscopic acromioplasty; or resection of acromioclavicular joint by separate approach when performed – not being a service associated with any other procedure of the shoulder region (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$979.60 Benefit: 75% = \$734.70
48972	Tenodesis of biceps, by open or arthroscopic means, performed as an independent procedure (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$450.50 Benefit: 75% = \$337.90
48980	Excision of heterotopic ossification, myositis ossificans or post-traumatic ossification in the shoulder girdle (H) Multiple Operation Rule (Anaes.) (Assist.) Fee: \$832.65 Benefit: 75% = \$624.50
49590	Excision of ganglion, cyst or bursa of knee, by open or arthroscopic means, performed as an independent procedure, other than a service associated with a service to which another item in this Group applies Multiple Operation Rule (Anaes.) (Assist.) Fee: \$386.55 Benefit: 75% = \$289.95 85% = \$328.60
50127	Item not currently available: JOINT OR JOINTS, arthroplasty of, by any technique not being a service to which another item applies
55054	Ultrasonic cross-sectional echography, in conjunction with a surgical procedure (other than a procedure to which item 55848 or 55850 applies) using interventional techniques, not being a service associated with a service to which any other item in this Group applies (R) GroupI1 - Ultrasound Subgroup1 - General Fee: \$111.75 Benefit: 75% = \$83.85 85% = \$95.00
55848	Musculoskeletal ultrasound, in conjunction with a surgical procedure using interventional techniques, not being a service associated with a service to which any other item in this group applies, and not performed in conjunction with a service mentioned in item 55054 (R) GroupI1 - Ultrasound Subgroup6 - Musculoskeletal [note, that is, exclusive of a diagnostic US at the same time] Fee: \$139.90 Benefit: 75% = \$104.95 85% = \$118.95
55850	Musculoskeletal ultrasound, in conjunction with a surgical procedure using interventional techniques, inclusive of a diagnostic musculoskeletal ultrasound service, if: (a) the medical practitioner or nurse practitioner has indicated on a request for a musculoskeletal ultrasound that an ultrasound guided intervention be performed if clinically indicated; and (b) the service is not performed in conjunction with a service mentioned in item 55054 or any other item in this Subgroup (R) GroupI1 - Ultrasound Subgroup6 – Musculoskeletal Fee: \$184.70 Benefit: 75% = \$138.55 85% = \$157.00

Appendix GCurrent and proposed MBS items

Proposed consolidation	Recommendation 74	Recommendation 75
Current item	48900 SHOULDER, excision of coraco-acromial ligament or removal of calcium deposit from cuff or both. (Anaes.) (Assist.)Fee: \$298.45 Benefit: 75% = \$223.85 85% = \$253.70	48906 SHOULDER, repair of rotator cuff, including excision of coraco-acromial ligament or removal of calcium deposit from cuff, or both – not being a service associated with a service to which item 48900 applies (Anaes.) (Assist.)
		Fee: \$597.15 Benefit: 75% = \$447.90
Current item	48903 SHOULDER, decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination. (Anaes.) (Assist.) Fee: \$597.15 Benefit: 75% = \$447.90	48909 SHOULDER, repair of rotator cuff, including decompression of subacromial space by acromioplasty, excision of coraco-acromial ligament and distal clavicle, or any combination – not being a service associated with a service to which item 48903 applies. (Anaes.) (Assist.)
		Fee: \$796.35 Benefit: 75% = \$597.30
Current item	 48951 SHOULDER, arthroscopic division of coraco-acromial ligament including acromioplasty – not being a service associated with any other arthroscopic procedure of the shoulder region. (Anaes.) (Assist.) Fee: \$945.55 Benefit: 75% = \$709.20 	48960 SHOULDER, reconstruction or repair of, including repair of rotator cuff by arthroscopic, arthroscopic assisted or mini open means; arthroscopic acromioplasty; or resection of acromioclavicular joint by separate approach when performed – not being a service associated with any other procedure of the shoulder region. (Anaes.) (Assist.)
		Fee: \$995.25 Benefit: 75% = \$746.45
Proposed new consolidated item	 489XX Open or arthroscopic subacromial decompression of Shoulder. Inclusive of, if performed: i) coraco-acromial ligament division ii) acromioplasty iii) excision of outer clavicle and acromioclavicular joint iv) removal of calcium deposit v) excision of bursa Not being a service associated with a service to which any open or arthroscopic shoulder region procedure applies. (Anaes.) (Assist.) 	 489XY Open, arthroscopic, arthroscopic assisted or mini open repair of rotator cuff of Shoulder. Inclusive of, if performed: i) decompression of subacromial space by acromioplasty ii) excision of coraco-acromial ligament, distal clavicle and acromioclavicular joint. iii) excision of the bursa iv) biceps tenodesis Not being a service associated with a service to which any open or arthroscopic shoulder region procedure applies (Anaes.) (Assist.)

Appendix H Administrative data analysis

Trigger combination	Co-claimed combination ^A	Episodes (as % of the total number of episodes)
48900	US (w or w/o diagnosis) or echography with intervention (no consultation) ^B	69.88
	Echography with intervention with specialist consult ^c	3.39
	US (w or w/o diagnosis) with intervention with GP consult ^D	3.88
	US (w or w/o diagnosis) or echography with intervention, with or without consultation	77.90
	US (w or w/o diagnosis) with intervention with X-ray ^E	2.13
	With 48951 ^F	1.00
	With total shoulder replacement and bone grafting ^G	NR
	Total top 10 episodes 48900	81
8903	Synovectomy and ganglion/cyst ^H	7.30
	SAD and ganglion/cyst and arthroplasty	3.94
	Synovectomy and ganglion/cyst and arthroplasty ^J	2.16
	Joint stabilisation alone ^k	1.87
	All surgery with other shoulder pathology	15.27
	With 48951 ^F (all surgery with only SAD items)	NR
	Total top 10 episodes 49803	18.02
48951	No other surgical item (all surgery with only SAD items)	12.42
	Ganglion/cyst [⊥]	2.34
	Tendon and ligament transfer ^M	2.05
	Rotator cuff repair (w or w/o tendon transfer, w/w/o ganglion/cyst) ^N	4.85
	Osteotomy (w/wo ganglion/cyst) ^o	2.87
	Total top 10 episodes 48951	24.5

Table 70 Top 10 co-claimed combinations of trigger services 48900, 48903, 48951 for 2020–21

Notes

 $\mathbf{A} = \mathbf{C}$ o-claimed combinations also included MBS items relevant to anaesthesia, cannulation, nerve block and surgical assistance. For the purposes of the analysis these items are not reproduced here. $\mathbf{B} = 55848$, 55054, 55850. $\mathbf{C} = 104$, 55054. $\mathbf{D} = 23$ or 91809, 55848, 55850. $\mathbf{E} = 57703$, 55850, 55848. $\mathbf{F} = \mathbf{SHOULDER}$, arthroscopic division of coraco-acromial ligament including acromioplasty – not being a service associated with any other arthroscopic procedure of the shoulder region. $\mathbf{G} = 48239$, 48918. $\mathbf{H} = 48954$, 49590. $\mathbf{I} = 48951$, 49590, 50127. $\mathbf{J} = 48954$, 49590, 50127. $\mathbf{K} = 48958$. $\mathbf{L} = 49590$. $\mathbf{M} = 47966$. $\mathbf{N} = 49590$, 47966, 48906. $\mathbf{O} = 48406$, 49590.

Abbreviations

CAL = coraco-acromial ligament, GP = general practitioner, SAD = subacromial decompression, US = ultrasound, NR = Not released data value equal to <10 patients.

	X-ray	%	US	%	СТ	%	MRI	%	Total	%
Female	267		314		12		45		638	59.2%
0–54	152	56.9%	182	58.0%	<10	Omitted	27	60.0%	365	57.2%
55–74 and 75+	115	43.1%	132	42%	<10	Omitted	18	40%	273	42.8%
Male	188		215		11		25		439	40.8%
0–54	80	42.6%	101	47.0%	<10	Omitted	15	60.0%	198	45.1%
55–74 and 74+	108	57.4%	114	53.0%	<10	Omitted	10	40.0%	241	54.9%
Total	455	60.5%	529	70.3%	23	3.1%	70	9.3%	1077	
0–54	232	51.0%	283	53.5%	<10	Omitted	42	60.0%	563	52.3%
55–74 and 74+	223	49%	246	46.5%	<10	Omitted	28	40%	514	47.7%

 Table 71
 Diagnostic imaging by sex and age-group for MBS item 48900

Abbreviations

CT = computed tomography, MBS = Medicare Benefit Schedule, MRI = magnetic resonance imaging, US = ultrasound.

	X-ray	%	US	%	СТ	%	MRI	%	Total	%
Female	331	,,,	210		137	,,,	186	70	864	54.2%
0–54	58	17.5%	53	25.2%	14	10.2%	51	27.4%	176	20.4%
55–74	170	51.4%	114	54.3%	62	45.3%	97	52.2%	443	51.3%
75+	103	31.1%	43	20.5%	61	44.5%	38	20.4%	245	28.4%
Male	277		182		79		191		729	45.8%
0–54	87	31.4%	58	31.9%	11	13.9%	83	43.5%	239	32.8%
55–74	136	49.1%	93	51.1%	42	53.2%	90	47.1%	361	49.5%
75+	54	19.5%	31	17.0%	26	32.9%	18	9.4%	129	17.7%
Total	608	61.4%	392	39.6%	216	21.8%	377	38.0%	1593	100%
0–54	145	23.8%	111	28.3%	25	11.6%	134	35.5%	415	26.1%
55–74	306	50.3%	207	52.8%	104	48.1%	187	49.6%	804	50.5%
75+	157	25.8%	74	18.9%	87	40.3%	56	14.9%	374	23.5%

Table 72 Diagnostic imaging by sex and age-group for MBS item 48903

Abbreviations

CT = computed tomography, MBS = Medicare Benefit Schedule, MRI = magnetic resonance imaging, US = ultrasound.

	X-ray		US		СТ		MRI		Total	
Female	1439		1280		127		1207		4053	43.8%
0–54	427	29.7%	388	30.3%	33	26.0%	451	37.4%	1299	32.1%
55–74	863	60.0%	755	59.0%	71	55.9%	661	54.8%	2350	58.0%
75+	149	10.4%	137	10.7%	23	18.1%	95	7.9%	404	10.0%
Male	1830		1651		153		1572		5206	56.2%
0–54	572	31.3%	500	30%.3	52	34.0%	543	34.5%	1667	32.0%
55–74	1056	57.7%	973	58.9%	81	52.9%	888	56.5%	2998	57.6%
75+	202	11.0%	178	10.8%	20	13.1%	141	9.0%	541	10.4%
Total	3269	51.0%	2931	45.8%	280	4.4%	2779	43.4%	9259	100%
0–54	999	30.6%	888	30.3%	85	30.4%	994	35.8%	2966	32.0%
55–74	1919	58.7%	1728	59.0%	152	54.3%	1549	55.7%	5348	57.8%
75+	351	10.7%	315	10.7%	43	15.4%	236	8.5%	945	10.2%

 Table 73
 Diagnostic imaging by sex and age-group for MBS item 48951

Abbreviations

CT = computed tomography, MBS = Medicare Benefit Schedule, MRI = magnetic resonance imaging, US = ultrasound.

 Table 74
 Total number of patients by sex and age-group for MBS items 48900, 48903, 48951

	n	%
Female	5555	46.6%
0–54	1840	33.1%
55–74	3024	54.4%
75+	691	12.4%
Male	6374	53.4%
0–54	2104	33.0%
55–74	3560	55.9%
75+	710	11.1%
Total	11929	100%
0–54	3944	33.1%
55–74	6584	55.2%
75+	1401	11.7%

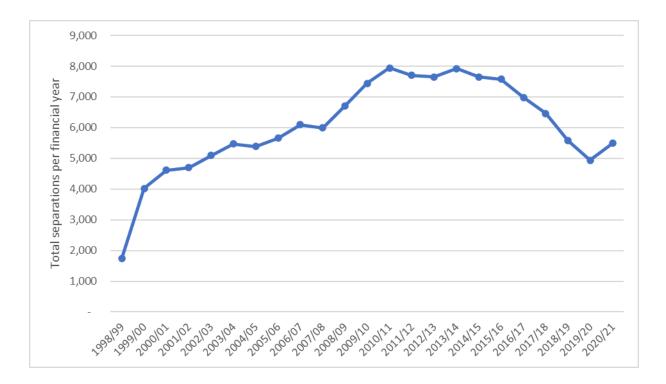


Figure 29 Number of hospital separations with a principal diagnosis of, M75.4, impingement syndrome of the shoulder, 1998-99 to 2020-21

<u>Notes</u>

Principal diagnosis codes according to ICD-10-AM classifications (various definitions).



Figure 30 Number of procedures performed in Australian hospitals for the exclusion of coraco-acromial ligament of calcium deposit from rotator cuff, or for decompression of the subacromial space; 2000-2001 to 2019-2020

Notes

Procedures are classified using the Australian Classification of Health Interventions (ACHI) codes. Where a procedure has an MBS equivalent, the first 5 digits of its ACHI code are the MBS item number (IHPA, 2022).

Code 48900-00: Excision of coraco-acromial ligament; 48900-01: Excision of calcium deposit from rotator cuff; 48903-00: Decompression of subacromial space; 48951-00: Arthroscopic decompression of subacromial space.

Source

AIHW Procedures Data Cubes (AIHW, 2022b)

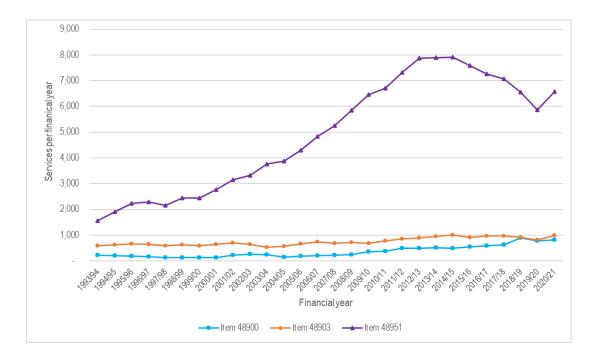


Figure 31 Utilisation of MBS items 48900, 48903 and 48951; 1993-1994 to 2020-2021

Notes

MBS item 48900 for excision of coraco-acromial ligament or removal of calcium deposit, or both; MBS item 48903 for shoulder subacromial decompression surgery; MBS item 48951 for arthroscopic division of coraco-acromial ligament, including acromioplasty. <u>Source</u>

Historic MBS utilisation data are available online via Services Australia (MBS, 2022b)