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Health Technology Assessment (HTA)

Scoping Report

Title	Subacromial decompression for rotator cuff disease
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Technology	Subacromial decompression (e.g. acromioplasty and/or bursectomy)
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Type of Technology	Surgical procedure

Executive Summary

Rotator cuff disease encompasses a range of conditions that can cause disabling shoulder pain (e.g. subacromial impingement syndrome, tendinitis, bursitis, etc.). Subacromial decompression is a surgical procedure that is used to treat subacromial pain. The surgical procedure widens the subacromial space and decreases compressive forces on the rotator cuff. The Swiss Federal Office of Public Health is re-evaluating subacromial decompression due to recently published evidence that suggests the procedure has limited efficacy. This report aims to identify literature pertaining to the safety, efficacy, effectiveness, cost-effectiveness and budgetary impact of subacromial decompression in patients with subacromial pain, to establish the feasibility of conducting a health technology assessment of subacromial decompression.

Literature searches were conducted in eight biomedical, ethical and economic databases, as well as speciality websites and clinical trial registries. The searches retrieved 20 unique studies (k=31 publications) that met the PICO criteria for assessing efficacy/effectiveness (k=13) and safety (k=10). Eight randomised controlled trials (RCT) were included (3 placebo-controlled, 5 active-controlled). Additionally, 12 observational studies were included (4 case-series, 5 cohort, 3 case-control). One existing trial-based economic evaluation on subacromial decompression was identified, which was based on the most recent RCT. Limited social, ethical, legal and organisational issues were identified.

There is sufficient evidence to conduct a full HTA on the clinical efficacy/effectiveness and safety of subacromial decompression to treat subacromial pain. If an economic analysis is required/appropriate, a de novo approach will likely be necessary owing to the absence of existing model-based evaluations in the literature.

Zusammenfassung

Eine Erkrankung der Rotatorenmanschette umfasst eine Reihe von Beschwerden, die

behindernde Schulterschmerzen verursachen können (z.B. subakromiales Impingement-Syndrom, Tendinitis, Bursitis usw.). Die subakromiale Dekompression ist ein chirurgischer Eingriff, der zur Behandlung subakromialer Schmerzen eingesetzt wird. Der chirurgische Eingriff erweitert den subakromialen Raum und verringert die Druckkräfte auf die Rotatorenmanschette. Das Bundesamt für Gesundheit reevaluiert die subakromiale Dekompression aufgrund kürzlich veröffentlichter Erkenntnisse, die auf eine begrenzte Wirksamkeit des Verfahrens hindeuten. Dieser Bericht soll die Literatur zu Sicherheit, Wirksamkeit, Effektivität, Wirtschaftlichkeit und budgetären Auswirkungen der subakromialen Dekompression bei Patientinnen und Patienten mit subakromialen Schmerzen identifizieren, um die Durchführbarkeit eines Health Technology Assessment (HTA) der subakromialen Dekompression zu ermitteln.

Die Literaturrecherche wurde in acht biomedizinischen, ethischen und wirtschaftlichen Datenbanken sowie auf Fachwebsites und in Registern für klinische Versuche durchgeführt. Die Recherchen ergaben 20 Studien (k=31 Publikationen), welche die PICO-Kriterien für die Bewertung von Wirksamkeit/Effektivität (k=13) und Sicherheit (k=10) erfüllten. Acht randomisierte kontrollierte Studien (RCT) waren darin eingeschlossen (3 placebokontrolliert, 5 aktiv-kontrolliert). Zusätzlich waren 12 Beobachtungsstudien darin enthalten (4 Fallserien, 5 Kohorten-, 3 Fall-Kontroll-Studien). Es wurde eine bestehende studienbasierte wirtschaftliche Evaluation zur subakromialen Dekompression gefunden, die sich auf die jüngste RCT stützte. Es wurden begrenzte soziale, ethische, rechtliche und organisatorische Probleme ermittelt.

Es gibt genügend Evidenz für die Durchführung eines vollständigen HTA zur klinischen Wirksamkeit/Effektivität und Sicherheit der subakromialen Dekompression zur Behandlung subakromialer Schmerzen. Wenn eine Wirtschaftlichkeitsanalyse erforderlich/angemessen ist, wird aufgrund des Fehlens vorhandener modellbasierter Evaluationen in der Literatur wahrscheinlich ein De-novo-Ansatz erforderlich sein.

Synthèse

La maladie de la coiffe des rotateurs englobe une série d'affections qui peuvent provoquer des douleurs invalidantes à l'épaule (par exemple, le syndrome de conflit sous-acromial, les tendinites, les bursites, etc.). La décompression sous-acromiale est une procédure chirurgicale utilisée pour traiter la douleur sous-acromiale. Elle élargit l'espace sous-acromial et diminue les forces de compression sur la coiffe des rotateurs. L'Office fédéral de la santé publique suisse réévalue actuellement la décompression sous-acromiale en raison de résultats récemment publiés qui suggèrent que cette procédure a une efficacité limitée. Ce rapport vise à identifier la littérature relative à la sécurité, à l'efficacité (dans des conditions idéales et réelles), au rapport coût-

efficacité et à l'impact budgétaire de la décompression sous-acromiale chez les patients souffrant de douleurs sous-acromiales, afin d'établir la faisabilité d'une évaluation des technologies de santé concernant la décompression sous-acromiale.

Des recherches documentaires ont été effectuées dans huit bases de données biomédicales, éthiques et économiques, ainsi que sur des sites internet spécialisés et des registres d'essais cliniques. Les recherches ont permis de trouver 20 études uniques (k=31 publications) qui répondaient aux critères PICO pour l'évaluation de l'efficacité en conditions idéales et réelles (k=13), et de la sécurité (k=10). Huit essais contrôlés randomisés (ECR) ont été inclus (3 contrôlés par placebo, 5 contrôlés par substance active). En outre, 12 études observationnelles ont été incluses (4 études de séries de cas, 5 études de cohorte, 3 études cas-témoins). Une évaluation économique existante sur la décompression subacromiale, basée sur l'essai clinique le plus récent, a été identifiée. Les questions sociales, éthiques, juridiques et organisationnelles identifiées sont limitées.

Il existe suffisamment de preuves pour effectuer une ETS complète sur l'efficacité (en conditions idéales et réelles) et la sécurité de la décompression sous-acromiale pour traiter la douleur sous-acromiale. Si une analyse économique est requise/appropriée, une approche de novo sera probablement nécessaire en raison de l'absence d'évaluations basées sur des modèles dans la littérature.

Sintesi

Una patologia della cuffia dei rotatori comprende una serie di disturbi che possono causare dolori debilitanti alla spalla (p. es. la sindrome d'attrito sottocromiale, tendinite, borsite). La decompressione sottocromiale è un intervento chirurgico eseguito per il trattamento dei dolori sottocromiali, mediante il quale viene ampliato lo spazio sottocromiale e ridotta la pressione sulla cuffia dei rotatori. Sulla base di risultati scientifici pubblicati recentemente, che indicano un'efficacia limitata dell'intervento, l'Ufficio federale della sanità pubblica (UFSP) sottopone a una nuova valutazione la decompressione sottocromiale. Nel relativo rapporto dovrà essere individuata la letteratura riguardante la sicurezza, l'efficacia, l'efficienza, l'economicità e le conseguenze finanziarie della decompressione sottocromiale nei pazienti che avvertono dolori sottocromiali, per indagare sulla fattibilità di un Health Technology Assessment (HTA) della decompressione sottocromiale.

La ricerca bibliografica si è svolta attingendo da otto banche dati biomediche, etiche ed economiche, nonché da siti web specialistici e registri di sperimentazioni cliniche. Dalle ricerche sono risultati 20 studi singoli (k=31 pubblicazioni), che adempiono i criteri del sistema PICO

(Paziente-Intervento-Comparazione-Outcome) per la valutazione di efficacia/efficienza (k=13) e sicurezza (k=10). Nella ricerca erano compresi otto studi controllati randomizzati (RCT) (3 studi placebo-controllati, 5 studi di controllo), nonché 12 studi di osservazione (4 serie di casi, 5 studi di coorte, 3 studi caso-controllo). Dalla ricerca è emersa una valutazione economica avvalorata da studi sulla decompressione sottocromiale e basata sui più recenti RCT, in cui sono stati identificati problemi di carattere sociale, etico, giuridico e organizzativo di portata limitata.

Vi sono sufficienti risultati scientifici per l'esecuzione di un HTA completo sull'efficacia/efficienza e la sicurezza della decompressione sottocromiale per il trattamento di dolori sottocromiali. Se è necessario/appropriato eseguire un'analisi economica, si dovrà probabilmente adottare un approccio de novo a causa dell'assenza di valutazioni basate su modelli nella letteratura.

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Abbreviations and acronyms

15D	15 dimensions
AE	Adverse events
A&E	Accident and emergency
ASES	American Shoulder and Elbow Surgeons Shoulder Score
CADTH	Canadian Agency for Drugs and Technologies in Health
CAL	Coracoacromial ligament
CEA	Cost-effectiveness analysis
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CMA	Cost-minimisation analysis
CSAW	Can Shoulder Arthroscopy Work?
CT	Computed tomography
CUA	Cost-utility analysis
DASH	Disability of the Arm Shoulder and Hand questionnaire
DRG	Diagnosis-related group
EAE	Effectiveness, appropriateness, economic efficiency
EQ VAS	EuroQol visual analogue scale
EQ-5D	EuroQol 5 dimensions
EUnetHTA	European Network for Health Technology Assessment
FABQ	Fear-Avoidance Belief Questionnaire
FOPH	Federal Office of Public Health
FTT	Full-thickness tear
GP	General practitioner
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health-related quality of life
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
IHE	Institute of Health Economics
LHBT	Long head of biceps brachii tendon
MRI	Magnetic resonance imaging
MSQ	Munich Shoulder Questionnaire
N/A	Not applicable
NHS	National Health Service
NR	Not reported
NSAID	Non-steroidal anti-inflammatory drug
OSS	Oxford Shoulder Score
PICO	Population, intervention, comparator, outcome

PRIM	Project on Research and Prevention in Monotonous work
PTT	Partial-thickness tear
QoL	Quality of life
RCT	Randomised controlled trial
ROM	Range of motion
SD	Subacromial decompression
SF-36	Short form-36
SIS	Subacromial impingement syndrome
SPADI	Shoulder Pain And Disability Index
SSRS	Subjective Shoulder Rating Scale
SST	Simple Shoulder Test
UK	United Kingdom
VAS	Visual analogue scale
WHO	World Health Organization
WORC	Western Ontario Rotator Cuff Index

Objective of the HTA scoping report

The objective of the scoping report is to conduct a scoping search and to synthesize the available evidence base addressing the main health technology assessment (HTA) domains, i.e. clinical effectiveness/safety, costs/budget impact/cost-effectiveness, legal/social/ethical and organisational issues. In the report the analytical methods that are to be used when an HTA is pursued are described. Based on quantity and quality of the extracted evidence the feasibility of pursuing an HTA is judged. Analysis of the individual study outcomes is not the objective of the scoping report.

Conflicts of Interest

The authors have no financial, academic, personal or any other conflicts of interest to declare in relation to this project.

1 Policy question and context

Rotator cuff disease is a term used to encapsulate a range of syndromes, including rotator cuff tendinopathy/tendinitis, partial-thickness tears (PTT), full-thickness tears (FTT), calcific tendinitis, subacromial impingement syndrome (SIS), and subacromial bursitis.[1] Subacromial decompression is a surgical procedure for the treatment of subacromial pain. In recent years, an increase of this procedure has been observed.[1] Historically, clinical studies on the effectiveness of this intervention have not been of very high quality, and the suggested benefits of the procedure have thus been questioned. Recently, studies with more robust designs have been published. The HTA report that should follow this scoping report aims to incorporate recent findings into the existing body of evidence and determine whether the EAE criteria ("effectiveness, appropriateness, economic efficiency") required for coverage via mandatory health insurance in Switzerland are met (see Article 32 of the Federal Law on Health Insurance: Bundesgesetz über die Krankenversicherung, KVG; SR 832.10). If the EAE criteria are shown not to be met, it is possible to impose limitations on these surgical treatments or remove them from coverage in Switzerland.

2 Research question

The planned HTA report will aim to address the following research questions:

1. What are the benefits and harms of subacromial decompression surgery compared to non-surgical interventions in patients with subacromial pain?
2. What is the yearly budget impact of subacromial decompression surgery in Switzerland?
3. How cost-effective is subacromial decompression compared to alternative therapies performed in Switzerland?
4. Are there any social, legal, ethical and organisational issues associated with subacromial decompression for the treatment of subacromial pain?

Research questions are operationalized in more detail in ***Section 5 PICO*** and ***Section 6 HTA key questions***

3 Medical background

3.1 Medical context, disease description, and natural course

Medical context

The rotator cuff is a group of tendons and muscles that encompass the shoulder (i.e. the glenohumeral joint). The muscles connect the upper portions of the arm (i.e. the head of the humerus) to the shallow socket of the shoulder joint (i.e. the glenoid cavity). The rotator cuff stabilises the joint, permitting dynamic movement.[1-4]

Rotator cuff disease is a common condition that affects the shoulder joint. The disease is common in people who are over 60 years of age and/or frequently repeat specific motions with their shoulder(s). The repetitive motions responsible for rotator cuff disease can occur during occupational or leisure activities.[2 3 5-8]

Rotator cuff disease is a term used to encapsulate all symptomatic disorders of the rotator cuff that can result in pain, weakness and instability in the shoulder joint.[1 3] This includes all symptomatic disorders of the rotator cuff, and can be caused by inflammation, acute injury (trauma), or degeneration. Conditions that are classified as rotator disease include, tendinopathy/tendinitis, PTT, FTT, rotator cuff tear arthropathy, calcific tendinitis, bursitis, and SIS.[1-6 8-13] This report focuses on rotator cuff disease related to SIS, that presents without FTT, acute traumatic injury, calcific tendinitis, or instability.

The main risk factors for SIS include, age (≥ 60 years of age), family history, occupation (e.g. painters, construction workers, carpenters), and certain sports (e.g. sports with repetitive shoulder strain such as swimming, tennis, baseball).[2-5 7 12]

Signs and symptoms

Common signs symptoms of ISS include shoulder pain, difficulty doing overhead activities due to pain (i.e. shoulder abduction between 60°-120°), shoulder weakness, pain in the deltoid and/or forearm, loss in the shoulder's active range of motion, and sleep disturbance (due to shoulder pain).[1 3-5 7 8] Other SIS symptoms include, but are not limited to night pain or pain when sleeping, and weakness and pain during the 'Gerber's test' (i.e. a test for tendonitis or tear in the subscapularis tendon), the belly-press test (i.e. a test for tear in the subscapularis tendon), Neer's test (i.e. a test to determine if shoulder pain is caused by shoulder impingement), and/or Hawkins impingement test (i.e. a test to determine if shoulder pain is caused by shoulder impingement).

Under specific circumstances, when a clinician is diagnosing SIS they may order medical imaging on the affected shoulder in order to identify any signs of pathology.[14] The imaging may include an X-ray, ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI). X-ray imaging is ordered to visualise bone spurs (i.e. osteophytes) or arthritis, while ultrasound imaging is used to visualise the soft tissue structures (e.g. muscle, tendons, bursa) in the affected shoulder. Finally, MRI and CT enable all structures of the shoulder to be visualised.[2 14]

Natural course of the disease

SIS is thought to be the result of interactions between intrinsic (i.e. biological) and extrinsic (i.e. mechanistic) influences that can cause narrowing of the subacromial space.[1 15 16] The intrinsic factors of SIS can result in attritional tears and concurrent joint degeneration when there is a thickening of the subacromial bursa and oedema. This can advance into inflammatory changes and the development of fibrosis.[1-4 7] Continued disease progression can result in a PTT or FTT of the rotator cuff tendons. Furthermore, histological studies have associated extracellular and cellular changes that affect the structure and integrity of rotator cuff tendons.[1 13]

The extrinsic theory behind SIS relates to contact between the section of the shoulder blade (i.e. scapula) that extends over the edge of the shoulder joint (i.e. acromion) and the surrounding rotator cuff tendons.[16 17] Other theories suggest that impingement can also be caused by bone spurs (i.e. osteophytes) on the under-surface of the acromion and/or distal part of clavicle being in contact with the overlapping rotator cuff tendons.[16-19] When narrowing of subacromial space results in discomfort and pain during shoulder abduction between 60^{o} -120^{o} it is referred to as the ‘painful arc’.[16-18 20] The coracoacromial ligament (CAL), which connects two protruding sections of bone (i.e. acromion and coracoid) in the scapula to one another, is thought to be a contributor to pain felt by people who suffer from SIS. This is because CAL stiffening increases its contact pressure with the nearby rotator cuff tendons. Various rotator cuff tendon pathologies, such as tears, can contribute to the CAL stiffening. This contact pressure can cause the degeneration of both the rotator cuff and the CAL.[19 21 22]

SIS can cause significant disability due to chronic pain, extensive weakness and loss of motion in the shoulder.[1 2 4 7 9] The weakness and loss of motion is generally the result of stiffness of the joint due to pain and/or tears. Shoulder stiffness occurring over prolonged periods of time can result in the severe contraction of the surrounding tissue.[2 4 7] Joint stiffness can still occur post-surgery, due to the patients’ failure to move the shoulder.[2 4 7 9]

3.2 Prevalence and burden of disease

There is limited information on the prevalence and burden of disease related to SIS in Switzerland; however, there are statistics on shoulder, neck, and arm pain, which currently represent the third most common cause of physical discomfort in the Swiss population, affecting around 32% (2018) of men and 44.8% (2018) of women.[23-25] In 2012, 6 out of 10 people who suffer from shoulder, neck and arm pain in Switzerland stated that the discomfort was associated with their current or previous employment.[23]

3.3 Treatment pathway

Most accepted guidelines on rotator cuff disease (including SIS) focus on the treatment of rotator cuff tears (i.e. PTT or FTT), and do not provide a treatment pathway specific to the management of SIS. Two different guidelines by *Cheshire and Wirral Partnership - National Health Service (NHS) Trust (2016)* in the United Kingdom (UK) and Diercks 2014 from *the Dutch Orthopaedic Society* provide a treatment pathway for SIS.[26 27] Both guidelines include surgical and non-surgical interventions.[26 27] The difference between the guidelines is that *Cheshire and Wirral Partnership - NHS Trust (2016)* suggests a non-surgical intervention as an alternative to surgical interventions.[26] In contrast, Diercks 2014 recommend that a surgical intervention follows non-surgical interventions, as the final step in the treatment pathway for SIS.[27]

Figure 1 provides a treatment pathway for SIS based on these two guidelines. A treatment pathway for SIS is dependent on a variety of factors (e.g. age, occupation, level of activity, co-morbidities). In general, the first step in the treatment pathway is the prescription of non-steroidal anti-inflammatory drugs (NSAIDs) for a period of up to two to four weeks.[15 16 21 26-29] Then, if the pain does not subside, the patient will undergo physiotherapy. If the patient does not improve and symptoms persist (i.e. greater than six weeks) the patient can receive a subacromial corticosteroid injection. If the symptoms do not subside after this injection, the patient may receive a surgical intervention and undergo a subacromial decompression.[1 15 16 21 26-31] Clinical experts have suggested that some orthopaedic surgeons may choose to repeat corticosteroid injections if the first attempt was unsuccessful, instead of proceeding to surgery systematically. To be eligible for subacromial decompression a patient generally has to have suspected SIS (i.e. with a positive Neer and Hawkins impingement test), experienced a minimum of three months of subacromial pain, and experienced no relief from conservative therapy.[1 15 16 26-28] The surgery is usually followed up with post-operative physiotherapy and exercises, before the patients can be discharged from the treatment pathway.[1 15 16 21 26-31]

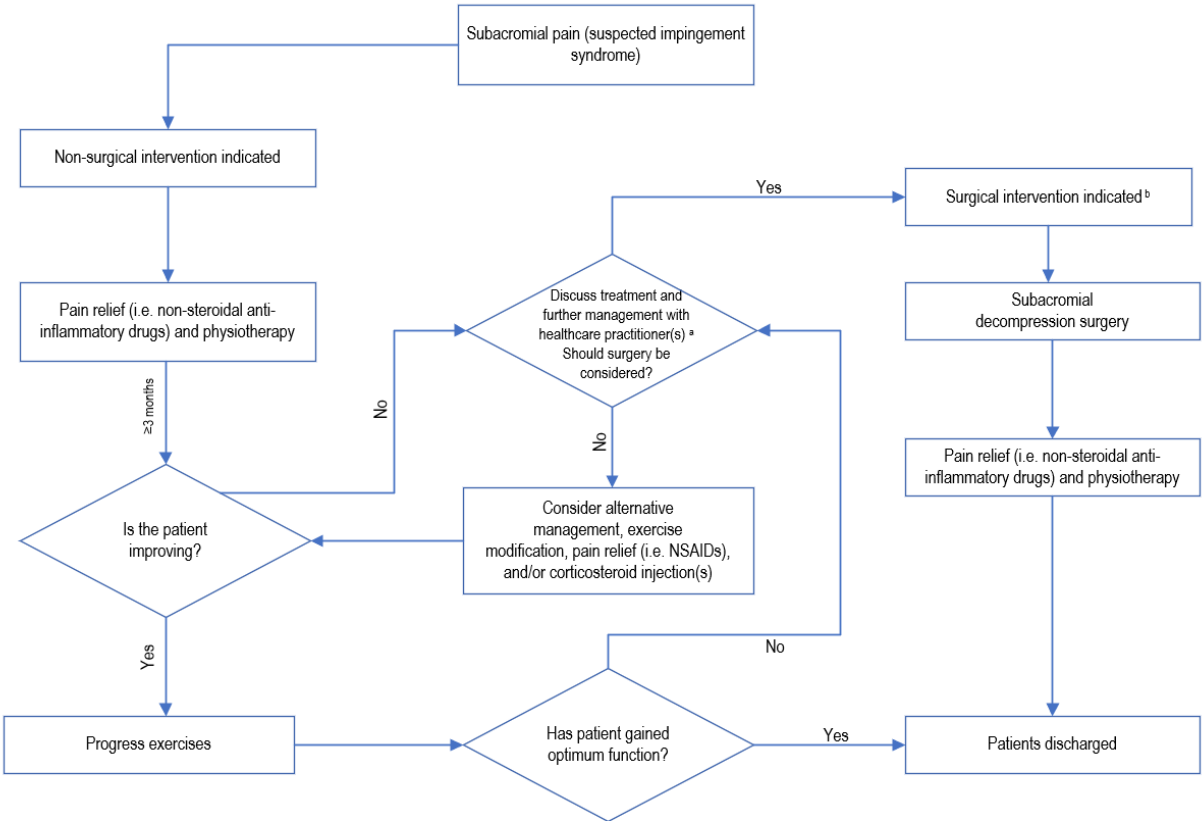

Figure 1 Treatment pathway for shoulder impingement syndrome

Note(s)

[a] If a patient is not improving while undergoing non-surgical treatment then a review of treatment with a physiotherapists and/or clinicians is considered.

[b] Surgical intervention is only considered after 3 months of conservative treatment without symptom relief.

Source: Based on treatment pathways outlined by Cheshire and Wirral Partnership-NHS Foundation Trust and Diercks 2014[26 27]

4 Technology

4.1 Technology description

4.1.1 Overview of subacromial decompression

Subacromial decompression was first described by Neer in 1972.[32] Subacromial decompression is a term used to describe a variety of surgical procedures conducted on the shoulder joint that aim to widen the subacromial space.[21 33 34] A subacromial decompression can include acromioplasty, and/or bursectomy, and/or CAL resection. Additionally, under specific circumstances the procedure can also include coplaning. The surgeries can be done as standalone procedures or in combination with one another. For example, if a patient undergoes an acromioplasty and bursectomy with a CAL arthroscopy and coplaning, it is considered a subacromial decompression.[1 16 19 21 33 34] While, if a patient just has an arthroscopic acromioplasty, it is still by definition a subacromial decompression. The individual procedures are described below.

- **Acromioplasty** is the resection of the undersurface of the section of the scapula that extends over the edge of the shoulder joint (i.e. the anterior acromion).[19 32]
- **Bursectomy** is the resection or debridement (i.e. removal of injured or damaged tissue) from the subacromial bursa.[17 19 21 35-37]
- **CAL release** involves the release (cutting) or resection of the CAL.[17 19 21 32 34 38]
- **Coplaning** involves the resection and/or smoothing of bone spurs (i.e. osteophytes) that occur on the underside of the acromion and/ or the distal section of the clavicle.[17 19 39]

4.1.2 Duration of treatment

The duration of treatment for subacromial pain can depend greatly on each individual patient's experience with the condition.[1 19 26 27] Subacromial decompression is generally completed in a single session of surgery. Under these conditions, the dressings covering the incisions can be removed 3 days post-surgery, while sutures are generally removed after 5 to 14 days. Typically, if the procedure was conducted without other surgical steps, such as biceps tenodesis or rotator cuff repair, a patient will be able to move their arm to shoulder height, or above, 2 to 4 weeks post-surgery. Full movement of the shoulder joint can be gained within 3 to 8 weeks post-surgery. The complete benefits of surgery can be realised anywhere between a few months to a year.[30 33 40 41]

Post-surgery, it is common for patients to undergo physiotherapy. How long the patient undergoes physiotherapy, and when the full benefit of the surgical intervention is realised, is highly dependent on their compliance with their treatment plan.[30 33 41]

4.1.3 Risks/ Safety concerns related to subacromial decompression

Subacromial decompression surgery has a low risk of adverse events (AEs), with a reported occurrence of around 3%.[1 17] The prominent reported AE associated with subacromial decompression is frozen shoulder (adhesive capsulitis). Frozen shoulder can result in further surgery, and/or corticosteroid injections. Other temporary minor complications include transient swelling from post brachial plexus block, and infection.[1 42 43] Severe AEs observed within 30 days post-surgery are rare (0.6%). Severe AEs include pulmonary embolism, nerve injury, deep infection, venous thromboembolism, and death.[1 40] It is unclear pulmonary embolism and venous thrombo-embolism are related to the procedure or anesthesia.

4.2 Alternative technologies

For this HTA, conservative therapy will be used as the alternative technology. Traditionally, conservative therapy is the first line of treatment for subacromial pain, with subacromial decompression only being considered if conservative therapy fails. Should subacromial decompression be disinvested, conservative therapy will remain the next-best alternative for patients with subacromial pain. For the purposes of the HTA, conservative therapy will be used as an alternative technology.

Conservative therapy for subacromial pain includes a variety of stages which are detailed in ***Figure 1***. To summarise, the first stages include pain relief (e.g. NSAIDs) for a period of two to four weeks. This is followed by physiotherapy and exercises. If the patient's symptoms do not improve they can receive a subacromial corticosteroid injection followed by further physiotherapy and exercises.[15 21 26 28 29]

5 PICO

5.1 PICO-Box

The inclusion criteria used to identify eligible studies are described in ***Table 1*****.**

Table 1 PICO criteria

P:	Patients with subacromial pain (sometimes diagnosed as "subacromial impingement syndrome") *Subgroups* • *Older patients (≥60 years of age), manual labourers, smokers,[44 45] athletes* *Exclusion criteria:* • *Patients undergoing surgery for benign/malignant tumours, adhesive capsulitis, shoulder instability/dislocation, joint replacement, fracture, or full thickness rotator cuff tear*
I:	Surgical intervention to widen the subacromial space surrounding the tendon, i.e. subacromial decompression, acromioplasty, bursectomy, coracoacromial ligament resection
C:	Placebo / sham procedures, conservative therapy (e.g. physiotherapy, injections) **†**, no intervention
O:	**Efficacy/effectiveness:** – Shoulder pain (e.g. mean change measured by a numerical/categorical scale) – Shoulder function (e.g. mean change measured via SPADI, OSS, DASH, etc.) – Health-related quality of life (QoL) (e.g. mean change measured with SF-36, EQ-5D-3L, etc.) – Ability/return to work (e.g. patient-reported ability to do their usual occupation) – Return to leisure activities – Further progression of SIS (i.e. treatment failure) **Safety:** – AEs – Serious AEs (i.e. mortality, life threatening, requiring intervention or author-defined)

Abbreviations: AE = adverse events, **DASH** = Disabilities of the Arm Shoulder and Hand, **EQ-5D-3L** = EuroQol 5 dimensions 3 level index, **OSS** = Oxford Shoulder Score, **QoL** = Quality of life, **SF-36** = Short form - 36, **SPADI** = Shoulder Pain and Disability Index,
† Non-operative treatments may include, non-steroidal anti-inflammatory drugs, intra-articular or subacromial glucocorticosteroid injections, physiotherapy.

5.2 Population

The study population of interest is patients with subacromial shoulder pain, which is also known as SIS. Patients are excluded if they had benign or malignant tumours, adhesive capsulitis, shoulder instability or dislocation, joint replacement, fracture, or full thickness rotator cuff tear. There are no limitations being placed on how long patients have had to experience subacromial pain.

5.3 Intervention

The intervention under investigation is a surgical procedure called subacromial decompression. The intervention can consist of three different procedures. These procedures include acromioplasty and bursectomy, and CAL resection. A subacromial decompression can include acromioplasty alone, or in combination with bursectomy and/or CAL resection. Furthermore, a subacromial decompression under specific circumstances can include a procedure called coplaning. When used as part of a subacromial decompression, coplaning is always done alongside acromioplasty, bursectomy, or CAL release and never as a standalone procedure.

5.4 Comparator

The comparators to subacromial decompression include placebo/sham procedures (e.g. diagnostic and/or therapeutic arthroscopy), conservative therapy (e.g. oral NSAIDs, steroid injections, physiotherapy), and no intervention. Additional details about the proposed comparators are presented in ***Section 4.2***. It is noted that placebo/sham procedures are not used in clinical practice, but rather represent relevant comparators to determine the efficacy of subacromial decompression under trial conditions.

5.5 Outcomes

Efficacy and effectiveness outcomes

Shoulder pain and **shoulder function** are critical outcomes. Pain and function are important indicators used to diagnose and assess the severity of subacromial pain and SIS. Shoulder pain can be estimated using numerical and/or categorical scales, such as the ‘Constant-Murley score’. Similarly, shoulder function can be measured using a variety of numerical and/or categorical scales such as the Shoulder Pain And Disability Index (SPADI), the Oxford Shoulder Score (OSS), the Disability of the Arm Shoulder and Hand questionnaire (DASH), and the University of California Los Angeles shoulder score and the visual analogue scale (VAS). The degree to which pain increases or

decreases indicates whether the treatment improved the patient's condition, or if the **treatment has failed**.

The effect of subacromial pain on **quality of life** (QoL) is also a critical outcome. QoL can be measured using a self-reported assessment of patients' physical and mental health. Examples of tools that can be used to measured QoL include questionnaires such as the short form–36 (FS-36) and the EuroQoL 5 dimensions 6 level index form (EQ-5D-3L). In brief, these tools require patients to assess their current health status across multiple dimensions (e.g. mobility, self-care, usual activities, pain/discomfort, in the case of the EQ-5D questionnaire).

The ability to **return to work and/or leisure activities** (i.e. sport) is an important outcome. A patient's ability to return to specific work or leisure activities indicates whether the intervention under investigation is effective. This is because the main risk factors for subacromial pain include repetitive overhead movements during leisure activities or occupation.

Safety

Serious AEs are critical safety outcomes, whereas **total AEs** are important outcomes. These outcomes reflect if a patient has been harmed during or due to the surgical procedure. Potential AEs and serious AEs associated with subacromial decompression are described in ***Section 4.1.3.***

6 HTA key questions

For the evaluation of the technology the following key questions covering the central HTA domains, as designated by the European Network for Health Technology Assessment (EUnetHTA) Core Model (clinical effectiveness, safety, costs, cost-effectiveness, budget impact, legal, social, ethical and organisational aspects), are addressed:

1. Is subacromial decompression effective/efficacious compared to conservative therapy, placebo and no treatment?
2. Is subacromial decompression safe compared to conservative therapy, placebo and no treatment?
3. What are the costs associated with subacromial decompression?
4. How cost-effective is subacromial decompression compared to conservative therapy and no treatment?
5. What is the budget impact of subacromial decompression?
6. Are there legal, social or ethical issues related to subacromial decompression?
7. Are there organisational issues related to subacromial decompression?

6.1 Additional questions

1. Are there subpopulations (i.e. people over 60 years of age, manual labours, smoker status, athletes) that benefit from subacromial decompression?
2. Are there subpopulations (i.e. smokers) that do not benefit from subacromial decompression?

7 Methodology literature search

7.1 Databases and search strategy

A scoping search strategy was designed to identify literature addressing the research questions. In the first instance, a scoping literature search was established to identify relevant systematic reviews on subacromial decompression as well as non-randomised trials (observational studies), economic evaluations, and existing randomised controlled trials (RCTs). An additional scoping search was then designed to identify RCTs specifically published after the search date of most recent high-quality systematic review (October 2018) obtained in the previous search. In addition, individual searches were designed to highlight economic, social, ethical, legal and organisational issues related to subacromial decompression for subacromial pain. These additional searches were limited to studies published before January 9th, 2020.

The literature searches were conducted in 8 biomedical databases (PubMed, Embase, Cochrane Library, Cumulative Index of Nursing and Allied Health Literature (CINAHL), EconLit, and York Centre for Reviews and Dissemination, Ethicsweb, PsychInfo). Details about the bibliographic databases are available in ***Table 12*** (***Appendix A***: Sources of literature (databases)). Additionally, the websites of HTA agencies and clinical practice guideline databases were searched to identify relevant HTA reports that included cost-effectiveness analyses (***Section 8.3***). The search strategies for RCTs and systematic reviews were verified using known publications, identified through targeted searches.

The key search terms related to the population and intervention were combined with various methodological search filters (i.e. RCT, observational studies, systematic reviews and HTA, cost-effectiveness), depending on the database and research question being addressed. The full search strategy for each database and the filters are reported in ***Appendix A***: Sources of literature (databases). The search filters are presented for the PubMed database; the syntax for each filter was adapted for Embase and CINAHL (available upon request).

7.2 Other sources

Searches were conducted to identify ongoing clinical trials related to subacromial decompression. Additionally, grey literature searches were conducted on specialty websites (***Appendix A***: Sources of literature (databases)) to highlight any relevant literature that may not have been otherwise identified. Trials were searched for in five clinical trial databases (*ClinicalTrals.gov*, *Cochrane Central Register of Controlled Trials*, *EU Clinical Trials Registry*, *World Health Organization (WHO), International Clinical Trials Registry Platform, Current Controlled Trials MetaRegister*, and *Australian New Zealand Clinical*

Trials Registry). The electronic registry databases were searched using the keywords outlined in ***Table 23*** (***Appendix A***: Sources of literature (databases)).

7.3 Study selection

Results from the literature search were imported into *Rayyan* (bibliographic management software). *Rayyan* functions similarly to *Endnote* but allows for easy blinding of reviewers and management of study inclusion conflicts.[46] Study selection was limited to English, French, German and Italian language studies. French, German, and Italian are 3 of the 4 official languages of Switzerland. The fourth language of Romansh was not included as there are a limited amount of publications available in the language.[47] [48] Relevant studies in other languages were identified to estimate the likelihood of language bias in the search results. Only studies that met the population, intervention, comparator, and outcome (PICO) criteria were considered eligible for inclusion. Moreover, studies based outside of *WHO-Mortality-Stratum A*[1] countries were excluded, during the full-text screening as the cause of death and burden of disease are not comparable to Switzerland.[49] [50] There was no minimum period of follow-up for safety outcomes. Whereas, for effectiveness and efficacy studies, a minimum follow-up period of 3 months was required.

Study selection was conducted independently by two reviewers, in duplicate, in two phases. All records were screened by title and abstract. Conflicts between reviewers on study inclusion were settled via consensus. If consensus could not be reached, a third reviewer decided whether to include or exclude the citation. Articles deemed potentially relevant were then reviewed in full-text by both reviewers independently, with disagreements settled via the same procedure of consensus.

Study characteristics were extracted for the included studies (e.g. author details, country of publication, year, setting, length of follow-up, population, intervention, comparator, outcomes, sample size) using preformed extraction templates. All data extractions were completed by one reviewer, then checked by a second reviewer for accuracy.

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[1] *WHO-Mortality Stratum A* countries include: Andorra, Australia, Belgium, Brunei, Canada, Croatia, Cuba, Cyprus, Czech Republic (Czechia), Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Malta, Monaco, The Netherlands, New Zealand, Norway, Portugal, San Marino, Singapore, Slovenia, Spain, Sweden, Switzerland, UK, and USA.[48] For more information see the WHO website (https://www.who.int/choice/demography/mortality_strata/en/)

8 Synthesis of evidence base

8.1 Search results

The results of the literature searches are summarised in ***Figure 2***. In total, 16 existing systematic reviews on subacromial decompression were identified.[1 5 16 29 34 51-61] These systematic reviews included 8 unique RCTs (17 publications[17 62-77]). No new RCTs beyond those identified in the existing systematic reviews were found during the second specific search.

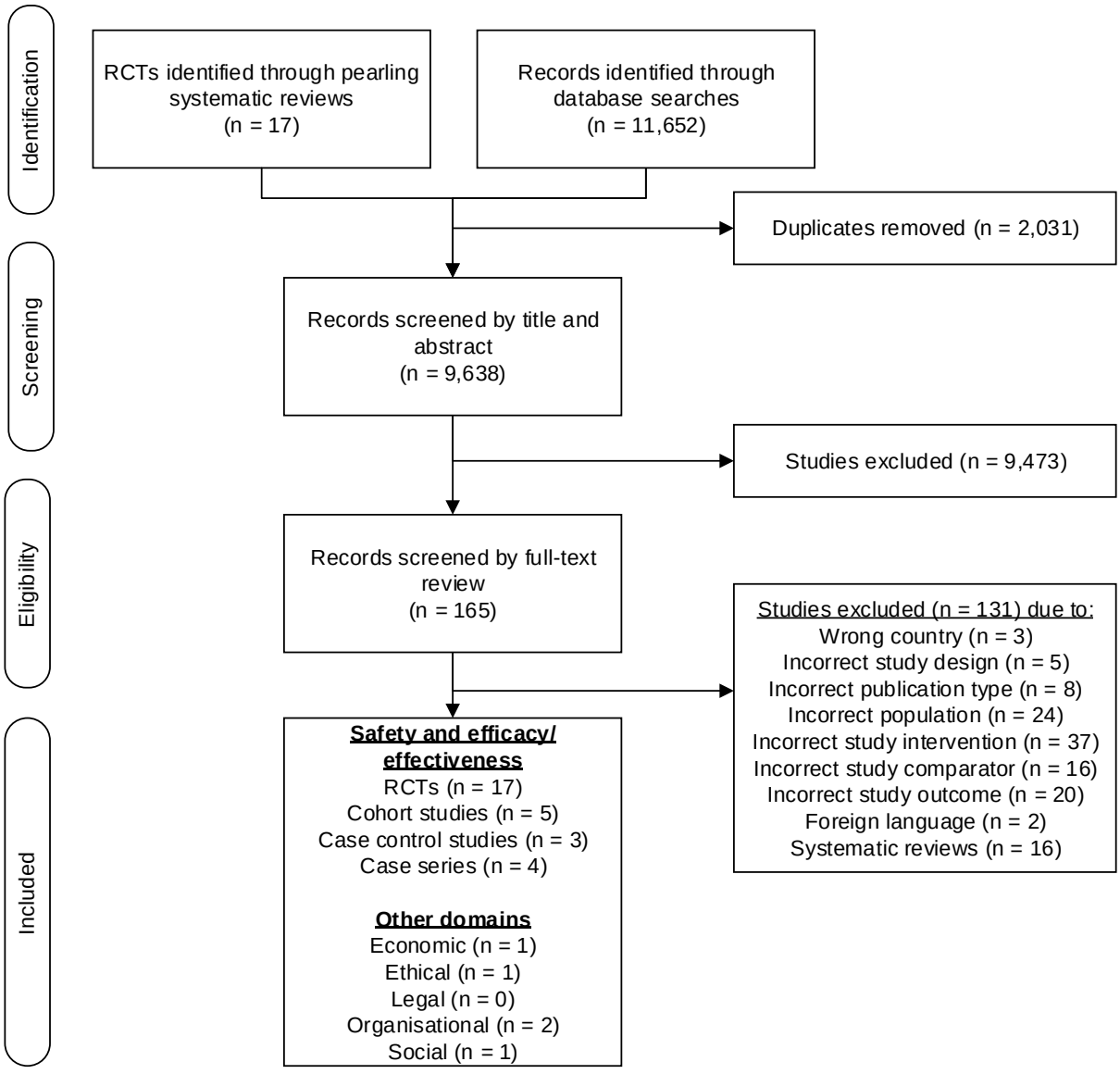

Figure 2 PRISMA flow chart

8.2 Evidence base pertaining to efficacy, effectiveness and safety

8.2.1 Search results

In total the searches identified 20 unique studies (31 publications) that reported the clinical efficacy, effectiveness, and safety of subacromial decompression. Of these studies, 8 were RCTs and 12 were observational studies (5 cohort, 3 case-control studies, 4 case-series).[17 62-88] It is important to note that 3 of the included RCTs had 2 comparators.[17 62-64 74 75] The identified studies, per outcome, include:

- **Efficacy/Effectiveness**
  - 3 placebo-controlled RCTs[17 62-64 74 75]
  - 5 active-controlled RCTs (compared decompression to physiotherapy or conservative therapy)[65-73 76 77]
  - 2 two-arm cohort studies (compared decompression to physiotherapy or conservative therapy)[78 82]
  - 1 case-control (compared decompression to no treatment)[79]
- **Safety**
  - 2 placebo-controlled RCTs (compared decompression to sham procedure, and an additional intervention, i.e. physiotherapy or no treatment)[17 62 74 75]
  - 3 cohort studies (compared one type of subacromial decompression to another, i.e. open vs arthroscopic or acromioplasty vs bursectomy, or conservative treatment)[86 87 89]
  - 3 case-control studies (compared decompression alone to decompression with rotator cuff repair or no treatment)[79 80 83]
  - 4 case-series[84 85 88 90]

The characteristics of each included study are summarised in ***Table 32*** and ***Table 33*** (***Appendix 2***).

8.2.2 Findings regarding efficacy, effectiveness and safety

None of the included studies were conducted in Switzerland; however, the majority were conducted in Western European countries (k=18).[17 42 62-90] The remaining 3 studies were located in North America (k=1) and Oceania (k=1).[85 88]

All the included RCTs (k=8) were conducted in Western Europe (Sweden, Norway, Finland, UK, Germany). The patients (some with PTT) included across the RCTs totalled 1,079, with 648 of these being included in the placebo-controlled trials.[17 62-77] Most studies were conducted at a single centre (k=4).[63 64 67 68 76 77] A third (k=3) of the studies had a follow-up period of 2 to 2.5 years.[63-66 74 75] The duration of follow-up ranged from immediate postoperative care up to 10 years.[17 62-77]

The observational studies (k=12) were conducted across Europe (Sweden, Norway, Germany, France, Belgium, the Netherlands), North America (Canada), and Oceania (Australia). There were 4,624 patients included across the observational studies. The centres where the studies were conducted were not recorded in the majority of the studies (k=10).[78-80 82-86 88 89] One study was a single centre and one was a multicentre study.[87 90] The follow-up period for the included observational studies ranged from immediate postoperative care up to 10 years.[79 80 82 84 85]

The patient indications varied between studies. All studies required patients to be diagnosed with SIS. Additionally, seven studies evaluated rotator cuff tears alongside SIS.[17 62 81 83 86-88] Most studies included patients with a diagnosis according to Neer and Hawkins-Kennedy (k=14).[63-77 79 80 82 83 85-88 90] The majority of the studies (k=12) also required patients to have experienced subacromial pain for a specific amount of time prior to allowing them to undergo subacromial decompression, as well as having failed conservative treatment (i.e. physiotherapy and/or NSAIDs) (k=11).[17 62-64 69-75 78 82 83 86] The amount of time patients were required to have experienced subacromial pain differed between studies (i.e. 6 weeks (k=1), 3 months (k=5), and 6 months (k=6)).[17 62-75 78 82 87]

Pain, function, and quality of life improvements are critical outcome measures of a subacromial decompression.[1 6 16] The outcome measures from the included RCTs are reported in ***Table 2***. While the outcome measures from the observational studies are reported in ***Table 3***.

Table 2 Number of RCTs identified for the relevant outcomes, per comparison

Outcome		Comparison			
		SD vs sham (placebo)	SD vs conservative treatment*	SD vs physiotherapy	SD vs no treatment
Pain and function[a]	OSS	1[17 62]	-	-	1[17 62]
	Constant-Murley score	2[17 62 74 75]	-	1[74 75]	1[65 66]
	Pain at activity/rest/night	1[63 64]	-	2[63 64 77]	-
	Neer shoulder score	1[63 64]	-	2[63-66]	-
	ROM	-	-	1[65 66]	-
	Watson & Sonnabend score	-	-	1[65 66]	-
	PRIM score (pain, activity)	-	-	1[67 68]	-
	Global change	-	-	1[67 68]	-
	Shoulder questionnaire score	-	-	1[69-73]	-
	VAS (Pain, disability, disability, working ability)	1[74 75]	-	3[74 75]	-
	Number of painful days	-	-	1[69-73]	-
	SST	1[74 75]	-	1[74 75]	-
	SSRS (pain, instability, activity, agility, overhead work)	-	1[76]	-	-
	Pain DETECT	1[17 62]	-	-	1[17 62]
QoL	EQ-5D	1[17 62]	-	-	1[17 62]
	EQ VAS	1[17 62]	-	-	1[17 62]
	Hopkins symptom checklist	1[63 64]	-	1[63 64]	-
	Sick leave	1[63 64]	-	1[63 64]	-
	SF-36	-	-	1[67 68]	-
	Sick leave index	-	-	1[67 68]	-
	Disability pension	-	-	1[67 68]	-
	Marginalisation index	-	-	1[67 68]	-
	15D	1[74 75]	-	1[74 75]	-
	HADS	1[17 62]	-	-	1[17 62]
Safety	AE	2[17 62]	-	1[74 75]	1[17 62]
	Serious AE	1[17 62]	-	-	1[17 62]

Explanatory Notes

***Conservative treatment:** Physiotherapy (including exercise therapy) ± nonsteroidal anti-inflammatory drugs (NSAIDs).

Abbreviations

AE = adverse events, **15D** = 15 dimensions, **EQ-5D** = EuroQol 5 dimensions, **EQ VAS** = EuroQol visual analogue scale, **HADS** = Hospital Anxiety and Depression Scale, **OSS** = Oxford Shoulder Score, **PRIM** = Project on Research and Intervention in Monotonous Work, **ROM** = range of motion, **SD** = subacromial decompression, **SST** = Simple Shoulder Test, **SSRS** = subjective shoulder rating scale, **VAS** = visual analogue scale.

Table 3 Number of observational studies identified for the relevant outcomes, per comparison

Outcome		Comparison				
		No comparator	**SD vs SD**	**SD vs conservative treatment***	**SD vs physiotherapy**	**SD vs no treatment**
Pain and function	DASH	N/A	-	-	1[78]	-
	Constant-Murley score	N/A	-	1[82]	1[78]	-
	MSQ	N/A	-	-	1[78]	-
	SPADI	N/A	-	-	1[78]	-
	ROM	N/A	-	-	-	2[79 80]
	Pain	N/A	-	-	-	1[79]
QoL	DASH	N/A	-	-	1[78]	-
	Return to work (rate and time)	N/A	-	1[82]	-	-
Safety	AE	4[84 85 88]	4[83 86 87]	-	-	-

Explanatory Notes
*** Conservative treatment:** Physiotherapy (including exercise therapy) ± nonsteroidal anti-inflammatory drugs (NSAIDs).
Abbreviations
AE = adverse events, **DASH** = Disability of the Arm Shoulder and Hand questionnaire, **MSQ** = Munich Shoulder Questionnaire, **N/A** = not applicable, **ROM** = range of motion, **SPADI** = Shoulder Pain And Disability Index, **SD** = subacromial decompression.

Ongoing and unpublished clinical trials (k=3) that met the PICO criteria are summarised in ***Table 4***. One of the included clinical trials is currently recruiting and is expected to be completed by March 2021. This trial aims to assess the efficacy of subacromial decompression in a single-arm trial. The two remaining clinical trials are RCTs that compare subacromial decompression with physiotherapy and usual care, respectively. These RCTs are not actively recruiting and were completed in 2008 and 2018, but the results of these trials are yet to be published.

Table 4 Identified ongoing clinical trials fitting the inclusion criteria

Trial registry ID	Indication Sample size	Intervention	Comparator	Primary outcomes	Recruitment status | Expected completion date
ClinicalTrials.gov					
NCT03815669	Subacromial impingement syndrome n=250	Arthroscopic subacromial decompression	NR	*Pain and function* • ROM • OSS • VAS *QoL* • EQ-5D • EQ VAS • HADS • FABQ • Return to work	Recruiting, March 2021
NCT00637013	Subacromial impingement syndrome n=100	Acromioplasty	Physiotherapy	*Pain and function* • VAS • Constant score	Active, not recruiting January 2017
International Clinical Trials Registry Platform, Current Controlled Trials MetaRegister (ISRCTN)					
ISRCTN58108023	Subacromial impingement syndrome n=70	Arthroscopic subacromial decompression	Usual care	*Pain and function* • Shoulder disability question-naire	Unknown November 1, 2008

Abbreviations

EQ-5D = EuroQol 5 dimensions, **EQ VAS** = EuroQol visual analogue scale, **FABQ** = Fear-Avoidance Beliefs Questionnaire, **HADS** = Hospital Anxiety and Depression Scale, **NR** = not reported, **NSAIDs** = nonsteroidal anti-inflammatory drugs, **OSS** = Oxford Shoulder Score, **ROM** = range of motion, **SST**= Simple Shoulder Test, **SSRS** = Subjective Shoulder Rating Scale, **VAS** = visual analogue scale.

8.2.3 Quality of evidence assessment

Due to the primary outcomes being patient-reported, and thus subjective, ensuring adequate blinding is critical in order to avoid performance bias. Most of the RCTs reported some form of blinding (k=5). A single study was double-blinded and four partially blinded (k=4). From the four partially blinded studies three blinded the practitioner who conducted the follow-up examinations; the patients were asked to wear a shirt in order to cover up any scars.[63-75] The remaining study only blinded the patients undergoing the two-treat arms with surgical procedures (subacromial decompression or sham), but not the third-arm of no treatment.[17 62] A detailed investigation of risk of bias will be conducted in the full HTA, using the Cochrane Collaboration's Risk of Bias tool for RCTs version 2.0.

Finally, the included observational studies did not report blinding. A full investigation of risk of bias in non-randomised and single-arm studies can be conducted in the full HTA, using the Cochrane Collaboration's ROBINS-I tool and the Institute of Health Economics (IHE) Quality Appraisal of Case Series Studies Checklist.[91]

8.3 Evidence base pertaining to costs, cost-effectiveness and budget impact

One relevant cost-utility analysis was identified, which took a UK NHS perspective.[92] The study conducted a trial-based economic evaluation utilising data from the Can Shoulder Arthroscopy Work (CSAW) trial.[17] The CSAW study, an RCT, was conducted to investigate the relative efficacy of subacromial decompression, arthroscopy or no treatment for SIS. The trial was conducted between 2012 and 2015, and costs relevant to the trial were later estimated based on available data in 2015 and 2016. The QoL measure used in the study was EQ-5D, which was collected during the trial period. Key information regarding this trial-based economic evaluation presented in ***Table 5***.

Table 5 Overview of the trial-based economic evaluation

Study (author, year)	Rombach 2019 [92]
Country/Region/Perspective	UK NHS perspective
Costing year	2015
Basis trial	The CSAW trial
Type of Economic Evaluation	CUA
Time Horizon	6 months, 12 months, and 24 months
Discount	3.5% for 12 and 24 months
Sensitivity	Deterministic and probabilistic sensitivity analyses
Evaluation outcome	ICER, where QoL was measured by EQ-5D by the CSAW trial

Abbreviations

CSAW = Can Shoulder Arthroscopy Work, **CUA** = cost-utility analysis, **EQ-5D** = EuroQol 5 dimensions, **ICER** = incremental cost-effectiveness ratio, **NHS** = National Health Service, **UK** = United Kingdom.

8.3.1 Resources and costing of the economic evaluation

The costs included in the study can be categorised into three groups: direct costs related to surgical procedure and equipment, costs for health services associated with the intervention, and administrative costs associated with service provision. These resources were costed via information obtained from publicly available sources, as well as private sources. Detailed information on the costs are presented in ***Table 6***.

Table 6 Resource costs incorporated in the Rombach 2019 study

Cost	Item	Source
Surgical equipment	Subacromial decompression Arthroscopy	Scotland National Statistics, NHS, Personal Social Services Research Unit
Health-service	Operating theatre duration GP and nurse visits Attendance to A&E departments Physiotherapy appointments Overnight inpatient stay	NHS, Information Science Division Scotland National Statistics
Administration	Daily administrative processing cost Work-up cost Recovery costs	National Schedule of Reference Costs

Abbreviations
A&E = Accident and Emergency, **GP** = General Practitioner, **NHS** = National Health Service

8.3.2 Outcomes of the economic analysis

The outcome of the study was the incremental cost-effectiveness ratio (ICER), where the quality of life was measured using the EQ-5D instrument. The outcome was analysed in three different time horizons: at 6 months, 12 months and 24 months. The 6-month outcome used data entirely from the trial. Clinical effectiveness data and resources were collected directly from patients in the trial to ensure maximum reliability. The 12-month outcome was estimated based on the trial follow-up, where assumptions and missing value imputations were undertaken. The 24-month outcome was estimated via an extrapolation, since it was beyond the trial period. The cost and effectiveness outcome beyond 12 months were discounted at 3.5% as recommended in the UK.

8.3.3 Addressing the issues of missing data

The study imputed missing data on some patients over the follow-up period, based on the EQ-5D responses. The imputation was conducted as follows:

- If a patient did not provide information about the use of a resource or EQ-5D data at baseline or after a follow- up, such information was imputed.
- Also, where a patient did not provide QoL measures or resource data, a linear regression model was used to impute the values.

The study made certain assumptions when extrapolating data to 24 months after the trial. The first assumption was that differences in QoL between the treatment arms were the same after 12 months. The second was that costs were the same for each treatment arm within a 12-month period.

8.3.4 Uncertainty and limitations

The study undertook both deterministic and probabilistic sensitivity analyses to examine how uncertainties in the costs and trial data might affect the results. Deterministic sensitivity analyses targeted variations in the costs of surgical devices (different price inflators), population sampling (intention-to-treat versus per-protocol for 12 months and beyond) as well as the three-time horizons. The probabilistic sensitivity analyses were undertaken using a non-parametric bootstrapping technique. The bootstrapped ICERs were then plotted against a cost-effectiveness plane, leading to the generation of a cost-effectiveness probability.

There are some major limitations in the Rombach 2019 study,[92] which limit the applicability of the results to Swiss context. Although published recently, the costing of the study was from 2015, and costs used in the study could potentially be out of date. Additionally, the study was conducted under the UK NHS perspective (funded by the UK government), which is different to the Swiss health system. Therefore, outcomes of the UK economic evaluations may not be directly applicable due to potential differences in how health services are included and costed. This may be a significant limitation of the study. Furthermore, assumptions, imputation procedures and extrapolations were based on six-month trial data, which is a relatively short timeline. Therefore, the long-term economic outcome of SIS requires the construction of a health economic model that incorporates disease progression and long-term resource usage.

8.3.5 The cost-effectiveness outcome in the Swiss context

The study by Rombach 2019[92] reported the cost-effectiveness of SIS in the short-term (up to 24 months); however, this study alone may not be sufficient to inform a decision on whether the intervention should continue to be publicly funded. On the other hand, to conduct a model-based health economic evaluation requires reasonable clinical inputs and an adequate understanding of how the condition progresses and is managed in the long-term. The feasibility of performing a de novo health economic evaluation is discussed in more detail in ***Section 9***.

8.4 Evidence base pertaining to legal, social and ethical issues

8.4.1 Legal issues

The searches did not identify any literature related to the legal implications of disinvesting subacromial decompression.

8.4.2 Social issues

There is limited evidence on social issues related to the use of subacromial decompression and the comparators for treating subacromial pain. A single qualitative study from the UK explored the social issues related to subacromial pain.[93] A key finding was that the language used by doctors to explain subacromial pain and treatment options can affect patients' engagement and opinion towards non-surgical interventions such as conservative therapy.[93] Additional studies have investigated patients' experience of shoulder pain, expectations of treatments, and the impact of shoulder pain on quality of life.

8.4.3 Ethical issues

The searches identified a single study that addressed ethical concerns related to a subacromial decompression. The study described the authors experience with informed consent and shoulder surgery in an Italian healthcare context;[94] however, informed consent is not a consideration for disinvestment and thus would not be included in an HTA analysis. Ethical issues that will be investigated in the HTA relate to the benefit-harm balance of subacromial decompression relative to the comparators, which will be informed by the clinical evaluation.

8.5 Evidence base pertaining to organisational issues

Two studies, from Norway and the UK, investigated potential organisational issues related to subacromial decompression.[28] [93] One study was a rapid recommendation that detailed a clinical practice guideline for the treatment of SIS.[28] The other study was a qualitative study that investigated the effect that the language doctors used to explain SIS had on patients' opinions toward treatment options.[93] These studies highlighted that when patients pursue conservative therapy instead of subacromial decompression to treat SIS, more patient education to assist with their understanding of the condition and treatment may be needed. Similarly, clinicians would need to be educated on the new clinical pathway for patients with SIS, as well as how to best assist these patients with improving their understanding of this condition and the importance of maintaining their treatment regimen.[28] [93]

9 Feasibility HTA

The scoping report has identified an evidence base of moderate size that could be used to assess the clinical efficacy, effectiveness, and safety of using subacromial decompression to treat subacromial pain. There is enough evidence to conduct meta-analysis on the clinical efficacy outcomes of QoL, pain and function. There is RCT data comparing subacromial decompression to placebo (sham procedure) (k=3), and non-surgical treatment (k=5). The meta-analysis will not include subgroup analysis of the separate types of subacromial decompression (i.e. acromioplasty and/or bursectomy) due to the surgical procedures usually being conducted in combination in practice. However, the possibility of subgroup analysis on sub-populations such as older patients, manual laborers, smoking status, and athletes will be explored.

A single existing economic evaluation of subacromial decompression was identified.[92] As the existing economic evaluation was trial-based, the generalisability of the study to Switzerland is limited. The study explored short-term cost-effectiveness outcomes (up to 24 months) and did not provide information on how a model-based health economic evaluation could be structured or populated for long-term outcomes. A de novo model-based economic evaluation may be performed in the HTA, depending on the findings of the clinical evaluation regarding clinical events and disease pathways. The review of the clinical evidence found a moderate body of primary clinical studies including 8 RCTs and 12 observational studies. This body of evidence indicates that it is likely feasible to conduct a de novo economic model. Nevertheless, the best approach to be taken for the economic evaluation will be determined at the HTA stage. A budget impact analysis will investigate the effect of restricting the reimbursed indications for subacromial decompression. Both the epidemiological and the market share approaches will be considered to estimate the financial impact on the Swiss health system, and the utilisation of these methods will depend on the availability of data. Cost data will be sourced from TARMED (Swiss tariff system), Swiss diagnostic related groups (DRG) Codes and SASIS (company hosting costings for the Swiss health care system) billing information. However, information on the number of patients with SIS in Switzerland appears to be limited.

Limited evidence was identified that addressed legal, social, ethical and organisational issues related to subacromial decompression. As such, an evidence-based review of these sections is likely to be limited. Potential areas for investigation are outlined in ***Section 10.***

10 Outlook

10.1 Clinical evaluation

The clinical evaluation of efficacy will include a meta-analysis of published RCTs that compare subacromial decompression to placebo (sham procedure) or conservative therapy (physiotherapy ± NSAIDs). Non-randomised studies evaluating the effectiveness of subacromial decompression relative to the comparators will be meta-analysed where appropriate, depending on the risk of confounding. Where there is insufficient data to perform a meta-analysis for any relevant outcomes, a narrative synthesis of the studies will be performed.

10.2 Economic evaluation

There are no established models to inform the general modelling approach. If an economic evaluation were to be done, a de novo model would be required. Where necessary, literature from similar indications (e.g. rotator cuff tear) may be used to inform the modelling approach.[95] A classification matrix covering the outcomes of clinical safety and effectiveness will be used to determine the type of economic evaluation to be conducted (***Table 7***). To allow the economic evaluation to proceed, it requires both the comparative safety and effectiveness to be at least non-inferior, or at least one of the clinical outcomes to be superior. This approach prioritises the clinical evidence over economic benefits, to prevent the reimbursement of health technologies from being driven solely by cost advantages.

Table 7 Classification of economic evaluation types

		Comparative effectiveness			
Comparative safety		**Inferior**	**Uncertain[a]**	**Non-inferior[b]**	**Superior**
	Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
	Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
	Non-inferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
	Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

Abbreviations
CEA = cost-effectiveness analysis, **CMA** = cost-minimisation analysis, **CUA** = cost-utility analysis.
Notes
? = reflects uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis.

[a] = Uncertainty covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations.
[b] = An adequate assessment of 'non-inferiority' is the preferred basis for demonstrating equivalence.

Inputs for the economic evaluation will be obtained through a range of sources. The most up-to-date clinical data would be ideal to populate the de novo model. Relevant costs will be sourced from TARMED for outpatient care, DRGs for inpatient care, and the Speciality List (Spezialitätenliste) for pharmaceutical interventions. Clinical expert advice will be sought if information cannot be identified through published sources. Key assumptions, particularly those sought from clinical advice, will be investigated via sensitivity analysis. To suit the Swiss context, EQ-5D is likely to be used to quantify HRQoL (if CUA is warranted) where Swiss mapping would be sought with priority.

10.3 Social, legal, ethical and organisational issues

The scoping searches identified few relevant issues relating to these HTA domains. Ethical issues will largely be informed by the benefit-harm balance estimated from the clinical evaluation. Organisational issues relating to the estimated uptake of comparators if subacromial decompression is disinvested will be informed by Swiss hospital procedure rates for decompression (i.e. TARMED and SwissDRG Codes, and SASIS billing data). Social issues related to the potential disinvestment of subacromial decompression will necessarily be limited to the available literature on patient preferences and expectations of surgery, which are limited.

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12 Appendix A: Sources of literature (databases)

12.1 Literature sources

Table 8 Biomedical bibliographic databases

Source	Results
PubMed	https://www.ncbi.nlm.nih.gov/pubmed/
Embase	https://www.embase.com/
The Cochrane Library (inc. CENTRAL)	https://www.cochranelibrary.com/
CINAHL	https://www.ebscohost.com/nursing/products/cinahl-databases/cinahl-complete
York CRD	https://www.crd.york.ac.uk/CRDWeb/
Econlit	https://www.aeaweb.org/econlit/
PsychInfo	https://www.apa.org/pubs/databases/psycinfo/
EthicsWeb	http://www.ethicsweb.eu/search_ets

Table 9 HTA agency websites

HTA Websites	
International	
National Information Centre of Health Services Research and Health Care Technology (NICHSR)	https://www.nlm.nih.gov/hsrph.html
National Library of Medicine Health Services/Technology Assessment Texts (HSTAT)	https://www.ncbi.nlm.nih.gov/books/NBK16710/
International Information Network on New and Emerging Health Technologies (EuroScan International Network)	https://www.euroscan-network.global/index.php/en/47-public-features/761-database-home
Australia	
Adelaide Health Technology Assessment (AHTA)	https://www.adelaide.edu.au/ahta/pubs/
Centre for Clinical Effectiveness, Monash University	http://monashhealth.org/health-professionals/cce/
Centre for Health Economics, Monash University	https://www.monash.edu/business/che
National Health and Medical Research Council	https://www.nhmrc.gov.au/
Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S)	https://www.surgeons.org/research-audit/research-evaluation-inc-asernips
Australia & New Zealand	
Health Technology Reference Group (HTRG)	https://www.coaghealthcouncil.gov.au/AHMAC/Health-Technology-Reference-Group
Austria	

Institute of Technology Assessment / HTA unit	https://www.oeaw.ac.at/ita/publikationen/
Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	https://hta.lbg.ac.at/page/publikationen/en
Gesundheit Österreich GmbH (GOG)	http://www.goeg.at
Hauptverband der Österreichischen Sozialversicherungsträger (HVB)	http://www.sozialversicherung.at
University for Health Sciences, Medical Informatics and Technology	https://www.umit.at
Argentina	
Institute for Clinical Effectiveness and Health Policy (IECS)	http://www.iecs.org.ar
Belgium	
Scientific Institute of Public Health (IPH)	https://www.wiv-isp.be/en
Belgian Health Care Knowledge Centre (KCE)	http://kce.fgov.be
Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (RIZIV-INAMI)	https://www.inami.fgov.be/
Bulgaria	
National Center of Public Health Analyses (NCPHA)	http://ncpha.government.bg/index.php?lang=en
Brazil	
National Committee for Technology Incorporation (CONITEC)	http://conitec.gov.br/en/
Canada	
Institute of Health Economics (IHE)	http://www.ihe.ca
Institut National d'Excellence en Santé et en Services (INESSS)	https://www.inesss.qc.ca/en/home.html
The Canadian Agency for Drugs And Technologies in Health (CADTH)	http://www.cadth.ca/
The Canadian Association for Health Services and Policy Research (CAHSPR)	https://www.cahspr.ca/
Centre for Health Economics and Policy Analysis (CHEPA), McMaster University	http://www.chepa.org/
Centre for Health Services and Policy Research (CAHSPR), University of British Columbia	http://www.chspr.ubc.ca/
Institute for Clinical and Evaluative Studies (ICES)	http://www.ices.on.ca/
Saskatchewan Health Quality Council (Canada)	http://www.hqc.sk.ca/
Evidence Development and Standards Branch (HQO)	http://www.hqontario.ca
Croatia	
Ministry of Health of the Republic of Croatia (MIZ)	https://www.miz.hr
Croatian Health Insurance Fund (CHIF)	https://www.hzzo.hr
Croatian Institute of Public Health (CIPH)	https://www.hzjz.hr/english/
Colombia	
Instituto de Evaluación Tecnológica en Salud (IETS)	http://www.iets.org.co

Cyprus	
Ministry of Health Cyprus (MoH Cyprus)	https://www.eunethta.eu/moh-cyprus
Republic of Cyprus Pharmaceutical Services	https://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument
Czech Republic	
Ministry of Health Czech Republic (MoH Czech)	https://www.mzcr.cz/en
State Institute for Drug Control (SUKL)	https://www.sukl.eu
Denmark	
Danish National Institute of Public Health	https://www.sdu.dk/en/sif/forskning
Social & Health Services and Labour Market (DEFACTUM)	http://www.defactum.net
Estonia	
Institute of Family Medicine and Public Health (UTA)	https://www.tervis.ut.ee
Finland	
National Institute for Health and Welfare (THL)	https://www.thl.fi
Finnish Coordinating Center for Health Technology Assessment (FinCCHTA)	https://www.ppshp.fi/Tutkimus-ja-opetus/FinCCHTA/Sivut/HTA-julkaisuja.aspx
Finnish Medicines Agency (FIMEA)	http://www.fimea.fi
France	
French National Authority for Health (Haute Autorité de Santé; HAS)	http://www.has-sante.fr/
Comité d'Evaluation et de Diffusion des Innovations Technologiques (CEDIT)	http://cedit.aphp.fr/
Germany	
German Institute for Medical Documentation and Information (DIMDI)	https://www.dimdi.de/
Institute for Quality and Efficiency in Health Care (IQWiG)	http://www.iqwig.de
Federal Joint Committee (Gemeinsamer Bundesausschuss; G-BA)	https://www.g-ba.de/english/
Greece	
Institute of Pharmaceutical Research and Technology (IFET)	http://www.ifet.gr/english_site/
National and Kapodistrian University of Athens (EKAPTY-NKUA)	http://en.phs.uoa.gr/
National Evaluation Centre of Quality and Technology in S.A-EKAPTY	http://www.ekapty.gr/
National Organization for Medicines (EOF)	http://www.eof.gr
National Organisation for Healthcare Provision (EOPYY)	http://www.eopyy.gov.gr
Onassis Cardiac Surgery Centre (OCSC)	http://www.onasseio.gr/
Hungary	
Health Services Management Training Center (SU)	http://www.semmelweis.hu/emk/en/

National Institute of Pharmacy and Nutrition (NIPN)	http://www.ogyei.gov.hu/main_page/
Ireland	
Health Information and Quality Authority (HIQA)	http://www.hiqa.ie
National Centre for Pharmacoeconomics, St James Hospital (NCPE)	http://www.ncpe.ie
Italy	
Agenzia Sanitaria e Sociale Regionale (ASSR)	http://www.inahta.org/members/assr/
Centro Regionale Unico sul Farmaca del Veneta (CRUF/AOUIVR)	http://www.ospedaleuniverona.it/ecm/home
HTA Unit in A. Gemelli Teaching Hospital (UVT)	https://www.policlinicogemelli.it/
Italian Medicines Agency (AIFA)	http://www.agenziafarmaco.gov.it
National Agency for Regional Health services (Agenas)	http://www.agenas.it
Regione Del Veneto – Area Sanita E' Sociale (Veneto/CRUF)	http://www.ospedaleuniverona.it/ecm/home
Regione Emilia-Romagna (RER)	http://www.regione.emilia-romagna.it/
Sede del Ministro – Ministero della salute (DGFDM IT)	http://www.salute.gov.it
University Hospital A. Gemelli (UCSC GEMELLI)	http://www.roma.unicatt.it/
Unita di Valutazione Technology Assessment (UVTA/AOP)	http://www.sanita.padova.it
Kazakhstan	
Ministry of Public Health of the Republic of Kazakhstan, Republican Centre for Health Development (RCHD)	http://www.rcrz.kz
Korea	
National Evidence-based healthcare Collaborating Agency (NECA)	www.neca.re.kr/eng
Latvia	
National Health Service (NVD)	http://www.vmnvd.gov.lv/
Lithuania	
The Institute of Hygiene (HI)	http://www.hi.lt
State Health Care Accreditation Agency (VASPVT)	http://www.vaspvt.gov.lt
Luxembourg	
Inspection Générale de la Sécurité Sociale (IGSS), Cellule d'Expertise Médicale (CEM)	http://www.mss.public.lu/publications/index.html
Malaysia	
Health Technology Assessment Section, Ministry of Health Malaysia (MaHTAS)	http://www.moh.gov.my
Malta	
Directorate for Pharmaceutical Affairs (DPA/MoH Malta)	http://www.health.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
Mexico	
Centro Nacional de Excelencia Tecnológica en Salud (CENETEC)	www.cenetec.gob.mx
The Netherlands	

Erasmus Universiteit Rotterdam (EUR)	http://www.eur.nl/
Health Council of the Netherlands (Gezondheidsraad)	https://www.gezondheidsraad.nl/
The Netherlands Organisation for Health Research and Development (ZonMw)	http://www.zonmw.nl
Zorginstituut Nederland (ZIN)	https://www.zorginstituutnederland.nl/
Utrecht University (UU)	http://www.uu.nl
Norway	
The Norwegian Institute of Public Health (NIPHNO)	http://www.fhi.no/
Norwegian Directorate of Health (Hdir)	http://helsedirektoratet.no/english
Norwegian Medicines Agency (NOMA)	http://www.legemiddelverket.no
Poland	
Agency for Health Technology Assessment and Tariff System (AOTMiT)	http://www.aotm.gov.pl
Portugal	
Administração Central do Sistema de Saúde, I.P. (ACSS IP)	http://www.acss.min-saude.pt
National Authority of Medicines and Health Products (INFARMED)	http://www.infarmed.pt
Republic of China, Taiwan	
Center for Drug Evaluation (CDE)	http://www.cde.org.tw
Romania	
Babes-bolayi University, Cluj School of Public Health (UBB)	http://publichealth.ro/
Institutu National De Sanatate Publica (INSP/NIPHB)	https://www.insp.gov.ro/
National School of Public Health, Management and Professional Development (NSPHMPDB)	http://www.snspms.ro
Singapore	
Agency for Care Effectiveness (ACE)	
Slovakia	
Comenius University in Bratslava (UniBA FOF)	https://uniba.sk/en/
Ministry of Health of the Slovak Republic (MoH Slovak Republic)	http://www.health.gov.sk
Slovenia	
Ministry of Health of the Republic of Slovenia (MoH Slovenia)	http://www.mz.gov.si/en/
National institute of Public Health (NIJZ)	http://www.nijz.si
Public Agency of the Republic of Slovenia for Medical Products and Medical Devices (JAZMP)	http://www.jazmp.si/en/
South Africa	
Charlotte Maxeke Research Consortium (CMeRC)	http://www.cmerc.org
Spain	
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	http://www.aemps.gob.es

Agencia de Evaluación de Tecnologias Sanitarias, Instituto de Salud “Carlos III”I / Health Technology Assessment Agency (AETS)	http://publicaciones.isciii.es/
Agency for Health Quality and Assessment of Catalonia (AQuAS)	http://aquas.gencat.cat
Andalusian HTA Agency	http://www.aetsa.org/
Basque Foundation for Health Innovation and Research (BIOEF)	http://www.bioef.org/
Basque Office for Health Technology Assessment (OSTEBA)	http://www.euskadi.eus/web01-a2ikeost/en/
Directorate General for Pharmacy and Health Care Products (DGFPS MSPSI)	website not provided
Evaluation AND Planning Unit – Directorate of the Canary Islands Health Service (SESCS)	https://funcanis.es/
Fundación Canaria de Investigación Sanitaria (Funcanis)	http://www.funcanis.org/
Fundacion Profesor Novoa Santos (AVALIA FNS)	http://www.fundacionprofesornovoasantos.org/es/
Fundación Pública Andaluza Progreso y Salud (FPS)	http://www.juntadeandalucia.es/fundacionprogresoysalud/
Galician Agency for Health Technology Assessment (AVALIA-T)	http://acis.sergas.es
Health Sciences Institute in Aragon (IACS)	http://www.iacs.es/
The Instituto De Salud Carlos III (AETS-ISCIIIS)	https://eng.isciii.es/eng.isciii.es/Paginas/Inicio.html
Sweden	
Center for Medical Health Technology Assessment	http://www.cmt.liu.se/?l=en&sc=true
Dental and Pharmaceutical Benefits Agency (TLV)	http://www.tlv.se
Medical Products Agency (MPA)	http://www.lakemedelsverket.se
Swedish Council on Technology Assessment in Health Care (SBU)	http://www.sbu.se/en/
Switzerland	
Swiss Federal Office of Public Health (SFOPH)	http://www.bag.admin.ch/hta
Swiss Network on Health Technology Assessment (SNHTA)	http://www.snhta.ch/
Tunisia	
INEAS – National Authority for Assessment and Accreditation in Healthcare, TUNISIA	http://www.ineas.tn/fr
United Kingdom	
All Wales Therapeutics and Toxicity Centre (AWTTC)	http://awttc.org
Healthcare Improvement Scotland (HIS)	http://www.healthcareimprovementscotland.org
National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA)	https://www.nihr.ac.uk/

NHS Quality Improvement Scotland	http://www.nhshealthquality.org/
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/
Health Technology Wales (HTW)	http://www.healthtechnology.wales
National Institute for Health Research (NIHR), including HTA programme	http://www.nets.nihr.ac.uk/programmes/hta
United States	
Agency for Healthcare Research and Quality (AHRQ)	https://www.ahrq.gov/research/findings/index.html
Harvard School of Public Health	http://www.hsph.harvard.edu/
Institute for Clinical and Economic Review (ICER)	http://www.icer-review.org/
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
Minnesota Department of Health (US)	http://www.health.state.mn.us/
Office of Health Technology Assessment Archive (US)	http://ota.fas.org/
U.S. Blue Cross / Blue Shield Association Technology Evaluation Center (Tec)	https://www.bcbs.com/news/press-releases/blue-cross-blue-shield-association-launches-evidence-street-website-streamline
Veteran's Affairs Research and Development Technology Assessment Program (US)	http://www.research.va.gov/default.cfm
Uruguay	
Health Assessment Division, Ministry of Public Health, (HAD)	http://www.msp.gub.uy

Source: Based on the INAHTA members list [96]

Table 10 Specialty websites

Specialty websites	
Geneva Medical Association	https://www.amge.ch/
American Association for Surgery of Trauma	aast.org/Default.aspx
American Association of Orthopaedic Surgeons	http://www.aaos.org/
American College of Sports Medicine	https://www.acsm.org/
American College of Surgeons	http://www.facs.org/
American Orthopaedic Association	https://www.aoassn.org/aoaimis/aoanew
American Orthopaedic Society for Sports Medicine	https://www.sportsmed.org/aossmimis
American Shoulder and Elbow Surgeons	https://www.ases-assn.org/
American Sports Medicine Institute	http://www.asmi.org/
Arbeitsgemeinschaft fur Osteosynthesefragen	http://www.aofoundation.org/wps/portal/
Association of Orthopaedic and Trauma surgeons of Russian Federation	http://www.rniito.org/
Association of Surgeons of Great Britain and Ireland	http://www.asgbi.org.uk/
Australian Orthopaedic Association	https://www.aoa.org.au/

Australian Specialty Orthopaedic Meetings	http://www.aoa.org.au/Content/NavigationMenu/Events/Subspecialties/default.htm
Austrian Orthopaedic Association	http://www.orthopaedics.or.at/
Austrian Orthopaedic Society	http://www.unfallchirurgen.at/index.php
Arbeitsgemeinschaft wissenschaflicher Fachgesellschaften (AWMF)	https://www.awmf.org
Belgian Orthopaedic and Trauma Society	http://www.bvot.be/index.php
British Association of Sports and Exercise Medicine	http://www.basem.co.uk/
British Elbow and Shoulder Society	http://www.bess.org.uk/
British Orthopaedic Association	http://www.boa.ac.uk/
British Orthopaedic Research Society	http://www.borsoc.org.uk/
British Orthopaedic Specialists Association	https://www.bosa.org.uk/
British Orthopaedic Sports Trauma Association	http://www.bosta.ac.uk/
British Trauma Society	http://www.bts-org.co.uk/
Bulgarian Orthopaedics and Traumatology Association (BOTA)	http://www.bulortho.org/ENG/index.htm
Canadian Orthopaedic Association	http://www.coa-aco.org/
Combined meeting of Orthopaedic Research Societies	http://www.eors.eu/
Dansk Ortopaedisk Selskab (DOS) - Denmark	http://barneortopaedi.dk/
Dutch Orthopaedic Association	http://www.orthopeden.org/m_home
Dutch Orthopaedic Society	http://www.trauma.nl/
Eastern Orthopaedic Association	http://eoa-assn.org/
European Federation of National Associations of Orthopaedics and Traumatology	https://www.efort.org/
European Federation of Societies for Microsurgery	http://www.efsm.eu/
European Orthopaedic Research Society	https://www.eors.info/
European Society for Movement Analysis in Adults and Children	http://www.esmac.org/
European Society for Surgery of Shoulder and Elbow	https://www.eusser.org/
European Society for Trauma and Emergency Surgery	http://www.estesonline.org/
Finnish Orthopaedic Association	http://www.soy.fi/
German Society for Orthopaedic and Trauma	https://dgou.de/en/home/
German Orthopaedic Society	http://www.bvou.net/fe/index.php
Greek Orthopaedic Association	http://www.eexot.gr/
Hungarian Orthopaedic Association	http://www.ortopedtarsasag.hu/info.aspx?sp=100
Icelandic Orthopaedic Association	http://www.lis.is/
International Congress of Shoulder and Elbow Surgery	http://www.icses.org/
International Federation of Sports Medicine	https://www.fims.org/
International Society of Orthopaedic Surgery and Traumatology (Belgian)	http://www.sicot.org/

International Society of Physical and Rehabilitation Medicine	http://www.isprm.org/
International Sports Medicine Science and Performance	http://www.leedsmet.ac.uk/conferences/sportsmedicine/index_conference_details.htm
Internet Society of Orthopaedic Surgery and Trauma	http://www.isost.net/
International combined meeting of orthopedic research societies	https://i-cors.org/
Irish Orthopaedic Association	http://www.ioa.ie/
Mid-American Orthopaedic Association	http://www.maoa.org/
National Association of Orthopaedic Technologists	http://www.naot.org/
Nederlandse Orthopaedische Vereniging	https://www.orthopeden.org/
New Zealand Orthopaedic Association	http://www.nzoa.org.nz/
Nordic Orthopaedic Federation	http://www.norf.org/?Home
Norwegian Orthopaedic Association Norwegian Medical Association	https://beta.legeforeningen.no/om-oss/english/
Orthopaedic Research and Education Foundation	https://www.oref.org/
Orthopaedic Research Society	https://www.ors.org/
Orthopaedic Trauma Association	https://ota.org/
Polish Orthopaedic Association	http://www.ptoitr.org.pl/
Polish Orthopaedic Society	http://www.ortopedia.biz.pl/
Romanian Orthopaedic Association	http://www.sorot.ro/
Russian Orthopaedic Society	http://www.rniito.org/
Ruth Jackson Orthopaedic Society	http://www.rjos.org/web/index.html
Societa Italiana di Ortopedia e Traumatologia	http://www.siot.it/pagine/index.html
Society of Orthopaedics and Traumatology of the East	http://www.sotest.org/
Société Française de Chirurgie Orthopédique et Traumatologique	http://www.sofcot.fr/
Society of Military Orthopaedic Surgeons	https://www.somos.org/
Southern Orthopaedic Association	http://soaassn.org/
Spanish Orthopaedic Society	http://www.secot.es/
Sports and Exercise Medicine UK	http://www.uksem.org/
Faculty of sports and exercise medicine UK	https://www.fsem.ac.uk/
Swedish Orthopaedic Association	http://www.ortopedi.se/index1.asp?siteid=1&pageid=1
Swiss Orthopaedic Association	http://www.swissorthopaedics.ch/de/
Turkish Orthopaedic Association	http://www.totbid.org.tr/
Vereinigung Süddeutscher Orthopäden und Unfallchirurgen Association of South German Orthopaedic Surgeons	https://www.vsou.de/home/
Washington State Orthopaedic Association	https://wsoa.org/
Wenckebach Instituut (Netherlands)	http://www.wenckebachinstituut.nl/docu

	menten/algemeen/International%20conferences.htm
Western Orthopaedic Association	http://woa-assn.org/index.cfm
World Orthopaedic Concern (United Kingdom)	http://www.wocuk.org/
IOC world conference on prevention of injury & illness in sport	https://ioc-preventionconference.org/

Table 11 Clinical practice guidelines

Clinical practice guidelines	
Guidelines International Network (GIN)	https://www.g-i-n.net/library/international-guidelines-library
Association of Scientific Medical Societies (AWMF)	https://www.awmf.org/awmf-online-das-portal-der-wissenschaftlichen-medizin/awmf-aktuell.html
National Guideline Clearinghouse	https://www.ahrq.gov/gam/index.html
Scottish Intercollegiate Guidelines Network	https://www.sign.ac.uk/
Swiss Medical Weekly	https://smw.ch/en/
TRIP Database	http://www.tripdatabase.com/

12.2 Search results

Table 12 Summary of biomedical bibliographic database search results

Source	Results
PubMed	5,808
Embase	2,751
The Cochrane Library (inc. CENTRAL)	333
CINAHL	1,789
York CRD	20
Econlit	430
PsychInfo	520
EthicsWeb	1
Total	**11,652**

Table 13 Search strategy – PubMed [Inception to 9th January 2020]

No.	Query	Results
1	Rotator cuff [tw]	12,467
2	Shoulder [tw]	74,317
3	Subacromial [tw]	2,679
4	Glenohumeral [tw]	6,109
5	**1 OR 2 OR 3 OR 4**	**78,140**
6	Shoulder impingement syndrome [mh]	1,713
7	Shoulder pain [tw]	8,656
8	Pain [tw]	686,674
9	Subacromial bursitis [tw]	116
10	Bursitis [mh]	4,653
11	Bursit* [tw]	4,594
12	Impingemen* [tw]	10,252
13	Rotator cuff disease [tw]	477
14	Rotator cuff injuries [mh]	5,301
15	Rotator cuff injur* [tw]	5,522
16	Tendinopathy [mh]	11,752
17	Tendin* [tw]	18,150
18	Degenerati* [tw]	213,967
19	Calci* [tw]	175,548
20	**6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19**	**1,081,516**
21	General Surgery [mh]	38,242
22	Surger* [tw]	2,573,051
23	Surgi* [tw]	1,355,129
24	Operati*[tw]	92,1574
25	Bursectom* [tw]	667
26	Arthroplast* [tw]	82,550
27	Acromioplast* [tw]	577
28	Decompress* [tw]	50,112
29	Arthroscopy [mh]	22,773
30	Arthroscop* [tw]	34,544
31	Repair [tw]	318,086
32	Debridement [tw]	31,422
33	(calci*[tw] + remov* [tw])	7,371
34	**21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33**	**3,630,153**
35	**5 AND 20 AND 34**	**15,586**

Filtered		
36	**35 AND systematic review filter[1] AND time filter (∞ to December 2019)**	**647**
37	**35 AND randomised control trial AND observational studies filter AND time filter (from September 2018 to December 2019)**	**398**
38	**35 AND cost-effectiveness filter[1] AND time filter (∞ to December 2019)**	**488**
39	**35 AND observational filter[1] (∞ to September 2018)**	**2,831**
40	**35 AND ethical considerations search string**	**249**
41	**35 AND social considerations search string**	**474**
42	**35 AND legal considerations search string**	**191**
43	**35 AND organisational considerations search string**	**530**

Explanatory Notes

[1]**Source**: CADTH[97]

Table 14 Search strategy – Embase (OVID) [Inception to 9th January 2020]

No.	Query	Results
1	exp Rotator cuff/	7,611
2	exp Shoulder/	55,123
3	Subacromial.ti,ab,kw.	2,884
4	glenohumeral.ti,ab,kw.	7,079
5	**Or/1-5**	**68,209**
6	exp Shoulder impingement syndrome/	2,727
7	Shoulder pain.ti,ab,kw.	8,063
8	Exp Pain/	1,134,609
9	Subacromial bursitis.ti,ab,kw.	127
10	exp Bursitis/	3,709
11	Bursit*.ti,ab,kw.	2,673
12	Impingemen*.ti,ab,kw.	11,153
13	Rotator cuff disease.ti,ab,kw.	532
14	exp Rotator cuff injuries/	10,392
15	Rotator cuff injur*.ti,ab,kw.	502
16	exp Tendinopathy/	14,198
17	Tendin*.ti,ab,kw.	14,930
18	Degenerati*.ti,ab,kw.	198,133
19	Calci*.ti,ab,kw.	451,952
20	**Or /5-18**	**1,764,143**
21	exp General Surgery/	14,213
22	Surger*.ti,ab,kw.	1,376,990
23	Surgi*.ti,ab,kw.	1,093,789
24	Operati*.ti,ab,kw.	945,583

25	Bursectom*.ti,ab,kw.	290
26	Arthroplast*.ti,ab,kw.	67,852
27	Acromioplast*.ti,ab,kw.	537
28	Decompress*.ti,ab,kw.	46,594
29	exp Arthroscopy/	26,254
30	Arthroscop*.ti,ab,kw.	32,855
31	Repair.ti,ab,kw.	351,350
32	Debridement.ti,ab,kw.	25,991
33	(calci* AND remov).ti,ab,kw.	0
34	**Or/20-32**	**2,794,722**
35	**5 AND 20 AND 34**	**8,105**
Filtered		
36	**35 AND systematic review filter[1] (CADTH) AND time filter (∞ to December 2019)**	**279**
37	**35 AND randomised control trial[1] AND observational studies filter[1] (CADTH) AND time filter (from September 2018 to December 2019)**	**208**
38	**35 AND cost-effectiveness filter[1] (CADTH) AND time filter (∞ to December 2019)**	**164**
39	**35 AND observational studies[1] AND time filter (∞ to September 2018)**	**1,042**
40	**35 AND ethical considerations search string**	**665**
41	**35 AND social considerations search string**	**747**
42	**35 AND legal considerations search string**	**379**
43	**35 AND organisational considerations search string**	**309**

Explanatory Notes

[1]**Source**: CADTH[97]

Table 15 Search Strategy – Cochrane Library [Inception to 8th January 2020]

No.	Query	Results
1	(rotator cuff):ti,ab,kw (Word variations have been searched)	1,552
2	(Shoulder):ti,ab,kw	10,220
3	(Subacromial):ti,ab,kw	748
4	**#1 OR #2 OR #3**	**10,641**
5	(pain):ti,ab,kw	165,847
6	(bursit*):ti,ab,kw	472
7	(impingemen*):ti,ab,kw	986
8	(injur*):ti,ab,kw	56,390
9	(tendinopathy):ti,ab,kw	906
10	(tendin*):ti,ab,kw	1,711

11	(degenerat*):ti,ab,kw	9,257
12	(calci*):ti,ab,kw	35,250
13	**#5 #6 OR #7 #8 OR #9 OR #10 OR #11 OR #12**	**46,142**
14	(surgery):ti,ab,kw	201,700
15	(surgi*):ti,ab,kw	96,418
16	(operati*):ti,ab,kw	84,221
17	(bursectom*):ti,ab,kw	34
18	(arthroplast*):ti,ab,kw	11,252
19	(acromioplast*):ti,ab,kw	113
20	(decompress*)	3,413
21	(arthroscop*)	5,021
22	(repair)	15,339
23	(debridement)	2,949
24	(calci* AND remov*):ti,ab,kw	796
25	**#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24**	**268,045**
Filtered		
26	**#4 AND #13 AND #25 in Cochrane Reviews**	**13**
27	**#4 AND #13 AND #25 in Trials**	**320**

Table 16 Search strategy – CINAHL [Inception to 9th January 2020]

No.	Query	Results
1	MH ”Rotator cuff+”	2,731
2	MH “Shoulder+”	5,865
3	TX “Subacromial”	1,712
4	TX “Glenohumeral”	3,627
5	**1 OR 2 OR 3 OR 4**	**11,781**
6	MH “Shoulder impingement syndrome+”	1,234
7	TX “Shoulder pain”	7,803
8	MH “Pain+”	185,836
9	TX “Subacromial bursitis”	89
10	MH “Bursitis+”	1,526
11	TX “Bursit*”	1,884
12	TX “Impingemen*”	6,475
13	TX “Rotator cuff disease”	351
14	MH “Rotator cuff injuries+”	2,650
15	TX “Rotator cuff injur*”	2,840
16	MH “Tendinopathy+”	4,103

17	TX “Tendin*”	10,845
18	TX “Degenerati*”	41,104
19	TX “Calci*”	81,696
20	**5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19**	**317,205**
21	TX “Surger*”	779,842
22	TX “Surgi*”	348,148
23	TX “Operati*”	316,846
24	TX “Bursectom*”	85
25	TX “Arthroplast*”	44,034
26	TX “Acromioplast*”	235
27	TX “Decompress*”	12,199
28	MH “Arthroscopy+”	10,509
29	TX “Arthroscop*”	23,418
30	TX “Repair”	68,234
31	TX “Debridement”	13,596
32	(TX “calci*” AND TX “remov*”)	11,034
33	**20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32**	**1,100,374**
34	**5 AND 20 AND 33**	**2,916**
Filtered		
35	**34 AND systematic review filter (CADTH) AND time filter (∞ to December 2019)**	**205**
36	**34 AND randomised control trial filter (CADTH) AND time filter (from September 2018 to December 2019)**	**11**
37	**34 AND cost-effectiveness filter (CADTH) AND time filter (∞ to December 2019)**	**8**
38	**34 AND observational studies AND time filter (∞ to September 2018)**	**1,552**

Table 17 Search Strategy – York CRD (including DARE, NHS EED, HTA) [Inception to 9 January 2020]

Number	Query	Results
1	Subacromial impingement	12
2	Subacromial decompression	11
3	**1 OR 2**	**20**

Table 18 Search strategy – Econlit [Inception to 9 January 2020]

Number	Query	Results
1	TX shoulder OR TX rotator cuff OR TX subacromial	4,674
2	TX impingement OR TX pain OR TX bursitis OR TX tendin* OR TX degenerate* OR TX calci*	22,494
3	TX surgery OR TX surgical OR TX operati* OR TX arthroplasty* OR TX decompress* OR TX arthoscop* OR TX repair OR TX debridement	241,481
4	**1 AND 2 AND 3**	**430**

Table 19 Ethical considerations search strategy - PsycINFO[Inception to 9 January 2020]

No.	Query	Results
1	Glenohumeral.af	201
2	Subacromial.af	161
3	Shoulder.af	9,940
4	Rotator cuff.af	432
5	**1 OR 2 OR 3 OR 4**	**10,111**
6	Decompression.af	2,112
7	Impingement.af	568
8	Pain.af	230,082
9	**6 OR 7 OR 8**	**231,638**
10	Ethics.af	162,964
11	Morality.af	51,494
12	Principlism.af	218
13	**10 OR 11 OR 12**	**196,972**
14	**5 AND 10 AND 13**	**119**

Table 20 Ethical considerations search strategy – Ethicsweb [Inception to 9 January 2020]

Query	Results
(Glenohumeral OR Subacromial OR Shoulder OR “Rotator cuff)” AND (Decompression OR impingement OR Pain) AND (Ethics OR Morality OR Principlism)	**1**

Table 21 Social considerations search strategy – PsycINFO [Inception to 9 January 2020]

No.	Query	Results
1	Glenohumeral.af	201
2	Subacromial.af	161
3	Shoulder.af	9,940
4	Rotator cuff.af	432
5	**1 OR 2 OR 3 OR 4**	**10,111**
6	Decompression.af	2,112
7	Impingement.af	568
8	Pain.af	230,082
9	**6 OR 7 OR 8**	**231,638**
10	patient experience.af	1,199
11	QoL.af	3,224
12	social aspects.af	131,690
13	medical decision-making process.af	9,774
14	patient education.af	99
15	psychological aspects.af	30,312
16	patient expectations.af	19,791
17	patient attitude.af	1,835
18	**10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17**	**75,358**
19	**5 AND 9 AND 18**	**401**

Table 22 Social considerations search strategy – EthicsWeb [Inception to 9 January 2020]

Query	Results
(Glenohumeral OR Subacromial OR Shoulder OR “Rotator cuff”) AND (Decompression OR Impingement OR Pain OR Pain*) AND (“patient experience” OR “Quality of life” OR “social aspects” OR “medical decision-making process” OR “patient education” OR “psychological aspects” OR “patient expectations” OR “Patient attitude”)	**0**

Table 23 Clinical trials registry keyword searches

Joint	Intervention	Pathology
• Glenohumeral • Subacromial • Rotator cuff • Shoulder	• Subacromial decompression • Decompression	• Subacromial impingement • Shoulder pain • Subacromial impingement syndrome • Rotator cuff disease

12.3 Search strings and filters

Table 24 Systematic review and HTA filter - PubMED (CADTH)

No.	Query
1	systematic[sb]
2	meta-analysis[pt]
3	meta-analysis as topic[mh]
4	meta-analysis[mh]
5	meta analy*[tw]
6	integrative review*[tiab]
7	integrative overview*[tiab]
8	research integration*[tiab]
9	research overview*[tiab]
10	collaborative review*[tiab]
11	collaborative overview*[tiab]
12	systematic review*[tiab]
13	technology assessment*[tiab]
14	technology overview*[tiab]
15	"Technology Assessment, Biomedical"[mh]
16	HTA[tiab]
17	HTAs[tiab]
18	comparative efficacy[tiab]
19	comparative effectiveness[tiab]
20	outcomes research[tiab]
21	indirect comparison*[tiab]
22	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22**
23	indirect treatment[tiab]
24	mixed-treatment[tiab]
25	**23 OR 24**
26	comparison*[tiab]
27	**25 AND 26**
28	Embase*[tiab]
29	Cinahl*[tiab]
30	systematic overview*[tiab]
31	methodological overview*[tiab]

32	methodologic overview*[tiab]
33	methodological review*[tiab]
34	methodologic review*[tiab]
35	quantitative review*[tiab]
36	quantitative overview*[tiab]
37	quantitative synthes*[tiab]
38	pooled analy*[tiab]
39	Cochrane[tiab]
40	Medline[tiab]
41	Pubmed[tiab]
42	Medlars[tiab]
43	handsearch*[tiab]
44	hand search*[tiab]
45	meta-regression*[tiab]
46	metaregression*[tiab]
47	data synthes*[tiab]
48	data extraction[tiab]
49	data abstraction*[tiab]
50	mantel haenszel[tiab]
51	peto[tiab]
52	der-simonian[tiab]
53	dersimonian[tiab]
54	fixed effect*[tiab]
55	"Cochrane Database Syst Rev"[Journal]
56	"health technology assessment winchester, england"[Journal]
57	"Evid Rep Technol Assess (Full Rep)"[Journal]
54	"Evid Rep Technol Assess (Summ)"[Journal]
55	"Int J Technol Assess Health Care"[Journal]
56	"GMS Health Technol Assess"[Journal]
57	"Health Technol Assess (Rockv)"[Journal]
58	"Health Technol Assess Rep"[Journal]
59	**28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50 OR 51 OR 52 OR 53 OR 55 OR 56 OR 57 OR 58**
60	**22 OR 27 OR 59**

Source: CADTH[97]

Table 25 Cost-effectiveness filter – PubMED (CADTH)

No.	Query
1	Economics[Mesh:NoExp]
2	"Costs and Cost Analysis"[mh]
3	Economics, Nursing[mh]
4	Economics, Medical[mh]
5	Economics, Pharmaceutical[mh]
6	Economics, Hospital[mh]
7	Economics, Dental[mh]
8	"Fees and Charges"[mh]
9	Budgets[mh]
10	budget*[tiab]
11	economic*[tiab]
12	cost[tiab]
13	costs[tiab]
14	costly[tiab]
15	costing[tiab]
16	price[tiab]
17	prices[tiab]
18	pricing[tiab]
19	pharmacoeconomic*[tiab]
20	pharmaco-economic*[tiab]
21	expenditure[tiab]
22	expenditures[tiab]
23	expense[tiab]
24	expenses[tiab]
25	financial[tiab]
26	finance[tiab]
27	finances[tiab]
28	financed[tiab]
29	value for money[tiab]
30	monetary value*[tiab]
31	models, economic[mh]
32	economic model*[tiab]
33	markov chains[mh]

34	markov[tiab]
35	monte carlo method[mh]
36	monte carlo[tiab]
37	Decision Theory[mh]
38	decision tree*[tiab]
39	decision analy*[tiab]
40	decision model*[tiab]
41	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39**

Source: CADTH[97]

Table 26 RCT and observational studies filter – PubMed (CADTH)

No.	Query
1	Randomized Controlled Trial [pt]
2	Controlled Clinical Trial [pt]
3	Pragmatic Clinical Trial [pt]
4	Equivalence Trial [pt]
5	Clinical Trial, Phase III [pt]
6	Randomized Controlled Trial [mh]
7	Randomized Controlled Trials as Topic [mh]
8	Controlled Clinical Trial [pt]
9	Controlled Clinical Trials as Topic [mh]
10	Randomization [tw]
11	Random Allocation [mh]
12	Double-Blind Method [mh]
13	Double Blind Procedure [tw]
14	Double-Blind Studies [tw]
15	Single-Blind Method [mh]
16	Single Blind Procedure [tw]
17	Single-Blind Studies [tw]
18	Placebos [mh]
19	Placebo Effect [mh]
20	Control Groups [mh]
21	Control Group* [tiab]

22	Allocated [tw]
23	(Nonrandom* [tw] OR quasirandom* [tw] OR quasi-random* [tw] OR non-random* [tw])
24	(pragmatic study [tw] OR pragmatic studies [tw])
25	(random* [tw] OR Sham* [tw] OR Placebo* [tw])
26	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25**
27	(singl* [tw] OR doubl* [tw])
28	(blind* [tw] OR dumm* [tw] OR mask* [tw])
29	**27 AND 28**
30	(tripl* [tw] OR trebl* [tw])
31	**30 AND 28**
32	(Study [tw] OR studies [tw] OR trial* [tw] OR group* [tw])
33	control* [tw]
34	**32 AND 33**
35	(open label [tw] OR open-label [tw])
36	**32 AND 35**
37	(Equivalence [tw] OR superiority[tw] OR non-inferiority[tw] OR noninferiority [tw])
38	**32 AND 37**
39	(Phase III [tw] OR Phase 3 [tw])
40	**32 AND 39**
41	(Pragmatic [tw] OR practical [tw])
42	trial* [tw]
43	**41 AND 42**
44	(Quasiexperimental [tw] OR quasi-experimental [tw])
45	**42 AND 44**
46	**26 OR 29 OR 31 OR 34 OR 36 OR 38 OR 38 OR 40 OR 43 OR 45**

Source: CADTH[97]

Table 27 Observational studies filter – PubMed (CADTH)

No.	Query
1	Controlled Clinical Trial [pt]
2	Pragmatic Clinical Trial [pt]
3	Equivalence Trial [pt]
4	Controlled Clinical Trial [pt]
5	Controlled Clinical Trials as Topic [mh]
6	Double-Blind Method [mh]
7	Double Blind Procedure [tw]
8	Double-Blind Studies [tw]
9	Single-Blind Method [mh]
10	Single Blind Procedure [tw]
11	Single-Blind Studies [tw]
12	Control Groups [mh]
13	Control Group* [tiab]
14	(Nonrandom* [tw] OR non-random* [tw])
15	(pragmatic study [tw] OR pragmatic studies [tw])
16	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15**
17	(singl* [tw] OR doubl* [tw])
18	(blind* [tw] OR dumm* [tw] OR mask* [tw])
19	**17 AND 18**
20	(tripl* [tw] OR trebl* [tw])
21	**20 AND 18**
22	(Study [tw] OR studies [tw] OR trial* [tw] OR group* [tw])
23	control* [tw]
24	**22 AND 23**
25	(open label [tw] OR open-label [tw])
26	**22 AND 25**
27	(Equivalence [tw] OR superiority[tw] OR non-inferiority[tw] OR noninferiority [tw])
28	**22 AND 27**
29	(Pragmatic [tw] OR practical [tw])
30	trial* [tw]
31	**30 AND 29**
32	**16 OR 19 OR 21 OR 24 OR 26 OR 28 OR 31**

Source: CADTH[97]

Table 28 Social considerations search string - PubMed

No.	Query
1	patient experien* [tiab]
2	quality of life [mh])
3	social aspects of [tiab]
4	medical decision-making process [mh]
5	patent education as topic [mh]
6	patient educati* [tiab]
7	patient attitude* [tiab]
8	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7**

Table 29 Ethical considerations search string - PubMed

No.	Query
1	Ethics[mh]
2	Ethic*[tiab]
3	Ethical theory [mh]
4	bioethics[mh]
5	Bioethic*[tiab]
6	Morals[mh]
7	Moral*[tiab]
8	Principle-Based Ethics[mh]
9	principl*[tiab]
10	patient rights [mh]
11	patient autonomy[tiab]
12	personal autonomy [mh]
13	autonom*[tiab]
14	social justice [mh]
15	patient rights[mh]
16	ethical issues [tiab]
17	Normative [tiab]
18	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17**

Table 30 Legal considerations search string - PubMed

No.	Query
1	Jurisprudence [mh]
2	Law enforcement [mh]
3	Law[tiab]
4	Laws[tiab]
5	Legislation, drug [mh]
6	Legislation, pharmacy [mh]
7	Legislation, food [mh]
8	Legislation as Topic [mh]
9	Legislat*[tiab]
10	Legal.case [pt]
11	Legal Guardians [mh]
12	Legal [tiab]
13	Liability, legal [mh]
14	Legal services [mh]
15	Liability [tiab]
16	Legislat* [tiab]
17	Medical device legislation [mh]
18	Legislation, nursing [mh]
19	Legislation, medical [mh]
20	Legislation, hospital [mh]
21	Legislation, food [mh]
22	Legislation, drug [mh]
23	Conflict of interest [mh]
24	Guarant* [tiab]
25	Regulat* [tiab]
26	Acquisition [tiab]
27	CoI [tiab]
28	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27**

Table 31 Organisational considerations search string - PubMed

No.	Query
1	Health information systems [mh]
2	Health information management [mh]
3	Health information exchange [mh]
4	'Work process' [tiab]
5	'Work flow' [tiab]
6	Communication [mh]
7	Health communication [mh]
8	quality assurance, health care [mh]
9	Implementation science [mh]
10	Organization culture [mh]
11	'Human skills' [tiab]
12	Sustainability [tiab]
13	'system structure' [tiab]
14	Accep*[tiab]
15	**1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14**

13 Appendix B: Characteristics of included trials

Table 32 Characteristics of included RCTs for the efficacy of subacromial decompression

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes [A]
Beard 2018 [17 62] UK NCT01623011	Subacromial pain ≥ 3 months (tendinopathy and PTT) Clinical diagnosis of tendinopathic pain or PTT (by radiography, MRI or ultrasound) Age up to 75 years Resistant to conservative treatment n=313	RCT, partial blinding, cross over Multicentre (32 hospital sites) 12 months	Arthroscopic subacromial decompression (acromioplasty) Investigational arthroscopy (placebo) No treatment	*Pain and function* • OSS • Constant-Murley score • Pain DETECT *Quality of life* • EQ-5D • EQ VAS • HADS (depression and anxiety scores) *Safety* • Serious AEs (death, life-threatening, requiring inpatient hospitalisation) • AEs
Brox 1999 [63 64] Norway NR	Shoulder pain ≥ 3 months Clinical diagnosis of rotator cuff disease (no imaging) Age up to 66 years Resistant to conservative treatment n=125	RCT, partial blinding Single centre 30 months	Arthroscopic subacromial decompression (bursectomy + acromioplasty + resection of the coracoacromial ligament) Detuned laser treatment (placebo) Physiotherapy (supervised)	*Pain and function* • Neer's shoulder score (pain, function, ROM, anatomical or radiological evaluation) • Pain on activity/at rest/at night *Quality of life* • Hopkins symptom checklist • Sick leave
Farfaras 2016 [65 66] Sweden NR	Subacromial pain ≥ 6 months, with intact rotator cuff (verified by ultrasound) n=87	RCT, partial blinding NR Mean 29.7 to 31.6 months, range 23.6 to 37.5 months	Arthroscopic acromioplasty + bursectomy Open acromioplasty Physiotherapy	*Pain and function* • Constant score • Watson & Sonnabend score • ROM *Quality of life* • SF-36

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes [A]
Haahr & Andersen 2006 [67 68] Denmark NR	Subacromial pain for 6 months to 3 years Clinical diagnosis of impingement syndrome (no imaging) ROM Age up to 55 years n=90	RCT, blinding NR Single centre Range 48 to 96 months	Arthroscopic subacromial decompression Physiotherapy	*Pain and function* • PRIM score (pain, activity) • Constant score *Quality of life* • Sick leave index • Disability pension index • Marginalisation index
Ketola 2009 [69-73] Finland NR	Shoulder impingement syndrome ≥ 3 months (diagnostic by radiography or MRI, Neer's test) Age up to 60 years Resistant to conservative treatment n=140	RCT, partial blinding Multicentre 24 months	Arthroscopic acromioplasty + Physiotherapy Physiotherapy	*Pain and function* • Shoulder disability questionnaire score • Pain (VAS) • Disability (VAS) • Working ability (VAS) • Number of painful days
Paavola 2018 [74 75] Finland NCT00428870	Subacromial pain ≥ 3 months Clinical diagnosis of impingement syndrome (MRI to exclude rotator cuff tear) Age up to 65 years Resistant to conservative treatment n=210	RCT, double blind Multicentre (n=3) 24 months	Arthroscopic subacromial decompression (bursectomy + acromioplasty) Diagnostic arthroscopy (placebo) Physiotherapy	*Pain and function* • Pain at rest and activity (VAS) • Constant-Murley score • SST *Quality of life* • 15D *Safety* • AEs

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes [A]
Peters 1997 [76] Germany NR	Subacromial impingement, duration Clinical diagnosis of impingement syndrome (radiography, ultrasound, Neer's test or Hawkins impingement test) Age up to 78 years n=72	RCT, blinding NR Single centre 48 months	Arthroscopic subacromial decompression or acromioplasty Open subacromial decompression (Surgeon preference) Conservative treatment (physiotherapy + NSAIDs)	*Pain and function* • SSRS (pain, instability, activity, agility, overhead work)
Rahme 1998 [77] Sweden NR	Subacromial impingement syndrome Age up to 63 years n=42	RCT, blinding NR Single centre 12 months	Acromioplasty Physiotherapy	*Pain and function* • Pain at rest • VAS

Explanatory note(s)

[A] All outcomes reported are relevant to the PICO described in ***Section 5 PICO***

Abbreviations

15D = 15 dimensions, **EQ-5D** = EuroQol 5 dimensions, **EQ VAS** = EuroQol visual analogue scale, **HADS** = Hospital Anxiety And Depression Scale, **MRI** = magnetic resonance imaging, **NR** = not reported, **NSAID** = non-steroidal anti-inflammatory drug, **OSS** = Oxford Shoulder Score, **PRIM** = Project on Research and Intervention in Monotonous work, **PTT** = partial thickness tear, **RCT** = randomised controlled trial, **ROM** = range of motion, **SF-36** = Short-form 36, **SST** = Simple Shoulder Test, **SSRS** = Subjective Shoulder Rating Scale, **UK** = United Kingdom, **VAS** = visual analogue scale.

Table 33 Characteristics of included observational studies for the effectiveness and safety of subacromial decompression

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
Biberthaler 2013 [78] Germany	Shoulder pain for 3 to 6 months Subacromial impingement syndrome (Neer's and Hawkins-Kennedy)—excluding PTT or FTT Pain on abduction of the shoulder with a painful arc Resistant to conservative treatment Age up to 82 years n=331	Cohort study NR 55 months (median)	Arthroscopic subacromial decompression Physiotherapy	*Pain and function* • MSQ • Constant-Murley score • DASH • SPADI *Quality of life* • DASH
Inderhaug 2018 [83] Norway	Subacromial pain ≥ 6 months Subacromial impingement syndrome (Neer's and Hawkins-Kennedy) ± PTT and FTT Normal passive ROM Reduced subacromial space (verified by imaging) Tendinopathy (verified by MRI) Resistant to conservative treatment (3-6 months) Maximum age NR n=360	Case-control NR Mean 90 months, minimum 84 months	Subacromial decompression Subacromial decompression ± rotator cuff repair	*Pain and function* • VAS (function, pain, satisfaction) • Quick DASH score *Safety* • AEs

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
Kronberg 1997 [79] Sweden	Subacromial impingement syndrome (Neer's and Hawkins-Kennedy) Age up to 66 years n=24	Case-control NR 9 months	Acromioplasty (open) ± rotator cuff repair No treatment	*Pain and function* • Pain (VAS) • ROM
Leroux 1994 [80] France	Subacromial impingement syndrome (Neer's stage II) Normal radiographs and opaque arthrograms Age up to 65 years n=60	Case-control NR 7 to 71 months	Arthroscopic acromioplasty Non-operated (with impingement) Control (no disease)	*Pain and function* • Torque (Biodex multi-joint system) • Average power • ROM (Biodex multi-joint system)
Luyckx 2011 [84] Belgium	Subacromial impingement syndrome Age up to 82 years n=272	Case-series NR Mean 15 months, minimum 12 months	Arthroscopic subacromial decompression	*Pain and function* • Time to resume work *Safety* • AEs
Machner 2000[90] Germany	Subacromial impingement syndrome (Neer's stage II or III) ≥ 6 months ± PTT or FTT Subacromial impingement clinical diagnostic (radiography) Resistant to conservative treatment Maximum age NR n=103	Case-series Single centre Mean 30 months, range 7 to 84 months	Arthroscopic subacromial decompression	*Pain and function* • Constant score *Safety* • AEs

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
McKee 2000[88] Canada	Subacromial impingement syndrome (Neer's and Hawkins-Kennedy) ≥ 6 months ± PTT Subacromial impingement clinical diagnosis (radiography) Resistant to conservative treatment Age up to 78 years n=71	Case-series NR 24 months	Open subacromial decompression ± rotator cuff repair	*Quality of life* • SF-36 (functional, physical, mental) • SPADI score *Safety* • AEs
Pillai 2012 [85] Australia	Subacromial impingement syndrome Unsuccessful arthroscopic subacromial decompression: 12-36 months (mean: 19 months) Imaging (MRI) Age NR n=96	Case-series NR Mean 16 months, range 12 to 26 months	Open subacromial decompression	*Safety* • AEs
Schröder 2001[86] The Netherlands	Subacromial impingement syndrome (pathology confirmed intraoperatively) ≥ 3 months – excluding PTT or FTT Detection of degenerative changes in joint or calcifications (MRI, arthrogram, ultrasound) Resistant to conservative treatment (6 months) Age up to 77 years n=272 (250 patients)	Cohort study NR Mean 30 months, range 12 to 120 months	Open acromioplasties (Highly experienced surgeons) Arthroscopic acromioplasties *Subgroups* - Novice surgeons - Surgeons with experience - Highly experienced arthroscopic surgeons	*Safety* • AEs

First author; year; country; trial ID	Inclusion criteria; Sample size	Design; Setting; Follow-up	Intervention; Comparator	Outcomes
Schulze 2017 [82] Germany	Pain ≥ 6 weeks Subacromial impingement syndrome (Neer's or Hawkins-Kennedy) Age: >18, <70 Resistant to conservative treatment Imaging (MRI) n=93	Cohort study NR 3 months 6 months	Subacromial decompression Conservative treatment	*Pain and function* • Constant-Murley score *Quality of life* • Return to work
Soyer 2003[89] France	Subacromial impingement syndrome (Neer's impingement test) ± PTT or FTT Resistant to conservative treatment Age up to 78 years n=39 (41 surgeries)	Cohort study NR Mean 37 months, range 12 to 48 months	Arthroscopic subacromial decompression (patients with no PTT or FTT) Arthroscopic subacromial decompression (patients with PTT or FTT) Control (contralateral shoulder without pathology)	*Safety* • AEs
Veen 2019[87] The Netherlands	Subacromial impingement syndrome ± PTT and FTT - Diagnosis of tendinitis supraspinatus/ biceps (DRG 1450) - Diagnosis of rotator cuff or biceps tear (DRG 1460) Maximum age NR n=2,910	Cohort study Multicentre 48 months	Acromioplasty Bursectomy	*Safety* • AEs

Abbreviations

AE = Adverse event, **ASES** = American Shoulder and Elbow Surgeons Shoulder Score, **DASH** = Disability of the Arm Shoulder and Hand questionnaire, **DRG** = diagnosis-related group, **FTT** = full thickness tear, **LHBT** = long head of biceps brachii tendon, **MRI** = magnetic resonance imaging, **MSQ** = Munich Shoulder Questionnaire, **NR** = not reported, **OSS** = Oxford Shoulder Score, **PTT** = partial thickness tear, **ROM** = range of motion, **SPADI** = Shoulder Pain And Disability Index, **SST** = Simple Shoulder Test, **SSRS** = Subjective Shoulder Rating Scale, **VAS** = visual analogue scale, **WORC** = Western Ontario Rotator Cuff Index.

14 Appendix C: List of excluded trials at full text

Wrong study design

1. Jacobsen JR, Jensen CM, Deutch SR. Acromioplasty in patients selected for operation by national guidelines. Journal of shoulder and elbow surgery. 2017;26(10):1854-61.
2. Garofalo R, Karlsson J, Nordenson U, Cesari E, Conti M, Castagna A. Anterior-superior internal impingement of the shoulder: an evidence-based review. Knee surgery, sports traumatology, arthroscopy: official journal of the ESSKA. 2010;18(12):1688-93.
3. Rahme H, Solem-Bertoft E, Westerberg CE, Lundberg E, Sorensen S, Hilding S. The subacromial impingement syndrome. A study of results of treatment with special emphasis on predictive factors and pain-generating mechanisms. J Scand J Rehabil Med. 1998;30(4):253-62.
4. Bazzocchi A, Pelotti P, Serraino S, Battaglia M, Bettelli G, Fusaro I, et al. Ultrasound imaging-guided percutaneous treatment of rotator cuff calcific tendinitis: success in short-term outcome. The British journal of radiology. 2016;89(1057):20150407.
5. Okifuji A, Turk DC. The influence of psychosocial environment in pain comorbidities. Pain comorbidities: Understanding and treating the complex patient. 2012:157-74.

Wrong population (includes country and patient demographics)

1. Catalano PA, Castagna A, Auliso M, Albisetti W, Facchini R. Subacromial impingement syndrome: Arthroscopic treatment. 1994;14(1):31-5.
2. Cormier S, Lavigne GL, Choiniere M, Rainville PL. Expectations predict chronic pain treatment outcomes. Pain. 2016;157(2):329-38.
3. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are Psychosocial Factors Associated With Patient-reported Outcome Measures in Patients With Rotator Cuff Tears? A Systematic Review. Clinical orthopaedics and related research. 2018;476(4):810-29.
4. Strauss EJ, Salata MJ, Kercher J, Barker JU, McGill K, Bach Jr BR, et al. The arthroscopic management of partial-thickness rotator cuff tears: A systematic review of the literature. Arthroscopy - Journal of Arthroscopic and Related Surgery. 2011;27(4):568-80.
5. Xiao J, Cui GQ, Wang JQ. [Arthroscopic treatment of bursal-side partial-thickness rotator cuff tears]. J Zhonghua Wai Ke Za Zhi. 2010;48(19):1492-5.
6. Abbot AE, Li X, Busconi BD. Arthroscopic treatment of concomitant superior labral anterior posterior (SLAP) lesions and rotator cuff tears in patients over the age of 45 years. J Am J Sports Med. 2009;37(7):1358-62.

7. Tillander BM, Norlin RO. Change of calcifications after arthroscopic subacromial decompression. J Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons. 1998;7(3):213-7.
8. Taylor SA, Ramkumar PN, Fabricant PD, Dines JS, Gausden E, White A, et al. The Clinical Impact of Bicipital Tunnel Decompression During Long Head of the Biceps Tendon Surgery: A Systematic Review and Meta-analysis. Arthroscopy: the journal of arthroscopic & related surgery : official publication of the Arthroscopy Association of North America and the International Arthroscopy Association. 2016;32(6):1155-64.
9. Shin SJ, Oh JH, Chung SW, Song MH, Shin S-J, Oh JH, et al. The efficacy of acromioplasty in the arthroscopic repair of small- to medium-sized rotator cuff tears without acromial spur: prospective comparative study. J Arthroscopy: The Journal of Arthroscopy & Related Surgery. 2012;28(5):628-35.
10. Steinbeck J, Halm H, Jerosch J, Wendt P. Endoscopic subacromial decompression in the management of tendinitis and significant partial thickness. Tears of the rotator cuff. J Zeitschrift fur Orthopadie und Ihre Grenzgebiete. 1998;136(1):8-12.
11. Hata Y, Saitoh S, Murakami N, Seki H, Nakatsuchi Y, Takaoka K. A less invasive surgery for rotator cuff tear: mini-open repair. J J Shoulder Elbow Surg. 2001;10(1):11-6.
12. Page MJ, Green S, McBain B, Surace SJ, Deitch J, Lyttle N, et al. Manual therapy and exercise for rotator cuff disease. The Cochrane database of systematic reviews. 2016(6):Cd012224.
13. Biberthaler P, Wiedemann E, Nerlich A, Kettler M, Mussack T, Deckelmann S, et al. Microcirculation associated with degenerative rotator cuff lesions. In vivo assessment with orthogonal polarization spectral imaging during arthroscopy of the shoulder. J J Bone Joint Surg Am. 2003;85(3):475-80.
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15. Gross CE, Chalmers PN, Chahal J, Van Thiel G, Bach Jr BR, Cole BJ, et al. Operative treatment of chondral defects in the glenohumeral joint. Arthroscopy - Journal of Arthroscopic and Related Surgery. 2012;28(12):1889-901.
16. Nadarajah V, Stevens KN, Henry L, Jauregui JJ, Smuda MP, Ventimiglia DJ, et al. Patients undergoing shoulder surgery have high preoperative expectations. Knee surgery, sports traumatology, arthroscopy: official journal of the ESSKA. 2020.

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