

BMJ Open Clinical course of pain and disability in patients with subacromial shoulder pain: a systematic review protocol

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ABSTRACT

Introduction Previous systematic reviews have identified the multiple factors impacting on the prognosis of shoulder pain. However, the typical clinical course of subacromial shoulder pain remains unclear. The aim of this systematic review is to assess the clinical course of pain and disability in patients with subacromial shoulder pain.

Method and analysis We will systematically search electronic databases (Medline, Embase and AMED (via Ovid), Web of Science, Cochrane Library and Scopus) from the date of inception to 28 February 2018 for randomised controlled trials (RCTs) and observational studies with patients with subacromial shoulder pain. We will follow patient groups measured with pain and disabilities with no intervention or usual care treatment. Two reviewers will extract the data, and assess the risk of bias within included studies. We will use the Cochrane Risk of Bias tool for RCTs, and a methodological quality assessment tool for observational studies. We will perform meta-analyses for changes in pain and disability scores for each group (usual care and no intervention) at different time categories (up to 6 weeks, 6–12 weeks, 12–26 weeks or more). If there are 10 or more studies, we will perform a meta-regression for each planned analysis. The outcomes of the included studies will be described individually if the above statistical methods are not possible. Findings from this review will be of interest to clinicians and researchers, and will describe the expected clinical course of subacromial shoulder pain. This study may indicate the potential differences between the clinical courses of pain and disability over time.

Ethics and dissemination This review will not gather original data, hence ethical approval is not required. The results of this systematic review will be published in a peer-reviewed journal and presented at a scientific conference.

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INTRODUCTION

Shoulder pain is the third most common musculoskeletal disorder.¹ The annual prevalence of shoulder complaints, including trauma, frozen shoulder and subacromial shoulder pain, has been estimated to be 51%.² Among shoulder complaints, subacromial shoulder pain is the most common

Strengths and limitations of this study

- This study will be the first systematic review of observational and randomised controlled trials studies that followed patients with subacromial shoulder pain who received no intervention or usual care.
- This study may synthesise the outcomes of pain and disability of a large population of patients with subacromial shoulder pain at multiple time points.
- Studies included in this review may present diverse forms of 'usual care interventions' and clinical presentation (eg, duration of shoulder symptoms). Such heterogeneity may limit conclusions that can be drawn from this review.
- Depending on the number of articles included in this review, we may not be able to conduct meta-regression. This may limit the conclusions that can be drawn from this review.

disorder,³ representing 89% of total shoulder complaints referred to general practitioners (GPs) and physiotherapists.⁴ Subacromial shoulder pain is defined as pain at the shoulder joint radiating in the area between the neck and elbow that worsens with arm movements, especially during overhead activities.^{5,6} The annual prevalence of subacromial shoulder pain has been estimated as 7%.⁷

The clinical course of subacromial shoulder pain is currently unclear. Previous systematic reviews and studies described the stage of the disorder (eg, acute or chronic),⁸ personal (age) and shoulder pain disease characteristics (ie, the duration and amount of disability)^{9,10} and the type of primary care treatment impact the clinical course recovery in patients with subacromial shoulder pain.^{2,11} For example, 50% of patients presenting with acute subacromial shoulder pain may improve after 6 months, and 40% after 1 year.² These findings suggest that 10% of patients with acute subacromial shoulder pain do not recover. In addition, 50% of patients with chronic subacromial shoulder pain recover after 10¹² or 18 months of onset

of symptoms.¹³ Observational studies estimating the clinical course of subacromial shoulder pain are either scarce,⁸ or have only presented the percentage of patients who have fully recovered.^{12 14} The wide range of recovery rates reported by previous studies suggests the clinical course for these patients is challenging and unclear.

Thus, the aim of this review will be to systematically assess the clinical course of pain and disability of patients with subacromial shoulder pain in usual care and no treatment conditions. The second aim will be to investigate whether pain and disability have similar clinical courses.

METHODS

Search strategy

We will search Medline, Embase and AMED (via Ovid), Web of Science, Cochrane Library and Scopus from the date of inception. The following search terms will be used for the studies' inclusion population: "Shoulder pain", "Shoulder impingement syndrome", "Shoulder problems", "rotator cuff", "Subacromial pain syndrome", "Subacromial impingement", "Painful arc", "Shoulder complaints", "Musculoskeletal disorders", "Subacromial injection", "shoulder disorders", "non-specific shoulder", "painful arc". Search terms to identify the type of intervention include: "No intervention", "no treatment", "standard care", "usual care", "waiting list", "wait and see", "wait-and-see", "no exercise", "ergonomics", "usual therapeutic approach". Terms we will use to identify prognosis include: prognosis, "clinical course", "natural course", inception, follow-up, recovery, "course of pain" and "course of shoulder". The completed search strategy used for all databases is summarised in online supplementary appendix 1. In addition, the reference lists of included studies for relevant studies will be searched.

Study selection

Two reviewers will screen the titles and abstracts of each citation retrieved from the electronic search (ZJT and DCR). Each citation will be selected based on the following eligibility criteria: (1) involved participants with shoulder pain; (2) published in all languages; (3) was a randomised controlled trial (RCT) and observational studies; (4) involved in usual care or no intervention; (5) we will include RCTs with >2 weeks of follow-up. We will exclude RCT studies if participants received any form of experimental intervention including placebo, sham or another preplanned specific treatment. Placebo and sham studies will be excluded as these interventions may have psychological effects that influence reported pain and disability scores.^{15 16}

Two reviewers will obtain the full-text of potentially relevant articles and assess whether articles meet the inclusion criteria. In the case of disagreement, the third reviewer (ASG) will be consulted and final decision will be made by consensus. Studies that recruited patients with neck and shoulder pain will be included when the study reports shoulder pain characteristics (sample size

and continuous data) separate from neck pain. In case of insufficient data, a reviewer will contact the authors and request additional information to assess whether the study meets the inclusion criteria.

Participants

We have defined subacromial shoulder pain as pain and discomfort in the shoulder joint with or without referred pain into the arm.^{5 6 17} We will include studies with participants with subacromial shoulder pain or other diagnostic terms including subacromial pain disorders, rotator cuff tendinopathy, rotator cuff syndrome or disease, rotator cuff-related pain syndrome, rupture or tears of rotator cuff muscles, subacromial bursitis, anterolateral shoulder pain or non-specific shoulder pain. We will exclude articles with participants who have shoulder pain due to neurological disorders, painful hemiplegia, capsulitis (frozen shoulder), severe trauma, shoulder fracture, instabilities (dislocation), shoulder surgery or if patients have shoulder pain concomitant with systematic disease (eg, diabetes, cancer and rheumatoid disorders). We will exclude articles if >5% of participants with reported shoulder pain are due to any of the conditions listed in the above exclusion criteria.¹⁸

Type of intervention

We will include observational studies and RCT studies that included groups of participants with subacromial shoulder pain receiving no intervention or usual care.

For the purpose of this review, we defined 'usual care' as any form of primary healthcare treatment routinely prescribed by GPs and physiotherapists for patients with subacromial shoulder pain.^{5 8 19} Usual care might include the following: education, advice, oral analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, corticosteroid injection, massage and exercise prescription, as long as the authors clearly stated that these were the part of usual care offered to patients in that respective healthcare system.⁵

Outcomes

We will extract mean and standard deviation (SD) scores for pain and disability over time.

Data extraction

For each eligible study, two reviewers (ZJT and ASG) will independently extract the following summary data: study design, country, sample size, participants' characteristics, symptom duration, group allocation (usual care and no intervention), follow-up time points and outcome measures (pain and disability). We will provide a summary of data in a table format. The authors may be contacted if reported data are not complete. We will wait for 1 month to receive an answer. If we do not receive a response from the authors then the study will be excluded.

Strategy for data synthesis

We will assess the course of pain and disability within no treatment and usual care groups. When possible, we

will assess the course of pain and disability in acute and persistent shoulder pain independently. Categorising the chronicity of shoulder pain will be performed based on participants' mean or median shoulder pain duration at baseline. When mean and median are not available, a reviewer will, whenever possible, establish the chronicity of subacromial shoulder pain according to the inclusion criteria used by the studies.²⁰ We will consider subacromial shoulder pain with duration <3 months as acute,^{8 21 22} and ≥3 months as persistent shoulder pain.⁸ In order to standardise the outcome measures in the studies, we will convert the dependent outcome (pain and disability) to a common 0–100 scale.

Risk of bias within included studies

Two reviewers will independently assess the risk of bias within included studies. Disagreements will be resolved by discussion and, if needed, through consulting with a third reviewer. The overall risk of bias for RCT and observational studies will be reported individually for each domain and will be considered when interpreting the data.

We will use the Cochrane Risk of Bias tool for assessing the risk of bias of included RCT studies.²³ This tool has six domains (selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias), and each domain is rated as low, high and unclear risk of bias. For the purpose of this review, performance risk of bias will be regarded as low risk if blinding of participants is impossible or difficult to be implemented. Blinding is often not possible in non-pharmacological health behaviour or exercise trials,²⁴ therefore, categorising the performance bias in the non-pharmacological trials as high risk of bias does not necessarily imply that the trial was poorly designed.^{24 25} With regard to attrition, unbalanced dropout rates between groups is ranked as 'high' risk of bias.²⁶ For the purpose of this systematic review, we will extract pain and disability scores from participants allocated to 'no intervention' or 'usual care' groups between baseline and follow-up time points. Unbalanced dropouts are unlikely to influence our analyses. Hence, we will rate RCTs as having 'high' risk of attrition bias if the no intervention or usual care group present dropouts >20% at the final follow-up.²⁷

We will assess risk of bias within observational studies using a tool proposed by Altman.²⁸ This tool was successfully used in a previous systematic review with a similar design to ours.²⁰ This tool has two items related to sampling, two items related to follow-up and one item related to prognostic outcome. Each item is categorised with a 'yes' or 'no'.

Data and statistical analysis

We will present a narrative synthesis of findings from all included studies. We will categorise studies as 'usual care' or 'no intervention'. We will conduct meta-analysis followed by meta-regression if we identify a sufficient number of studies for each of these analyses. If

meta-analysis or meta-regression is not possible, a narrative discussion based on findings from individual studies will be presented.

We will conduct meta-analyses within each time category for pain and disability if <10 studies are identified. Time may be categorised in three or more sections including 0–6 weeks, 6–12 weeks and 12–26 weeks or more (depending on the common follow-up time points in studies). Within each time category, we will pool the estimates of change in pain or disability related to baseline scores. We will use RevMan V.5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) to conduct the meta-analysis. For each meta-analysis, we will first convert raw data (mean and SD) associated with pain and disability to 0–100 score so that higher scores represent higher levels of pain and disability. We will then calculate the mean and standard error (SE) of the difference between baseline and follow-up at each time category (e.g. between 6 and 12 months' time category). If studies do not report the mean and SE of the difference in pain or disability between baseline and follow-up time points, the mean and SE difference will be calculated through RevMan V.5.3. We will use generic inverse variance to calculate the mean and SE differences between baseline and follow-up for each outcome of interest (ie, pain and disability). Random effect model will be used to standardise the between-studies variance during meta-analyses, such as variance due to differences in participant's clinical characteristics or sequence of treatment in usual care intervention.²⁹ When conducting the meta-analysis, we will assess the heterogeneity in the usual care and no intervention groups using I^2 . As per the Cochrane Handbook, I^2 <30% will be considered as not important heterogeneity; between 30% and 60% as moderate; 60%–90% as substantial and 90%–100% as considerable heterogeneity.²⁶

A meta-regression will also be conducted using 'R' Statistical Software,³⁰ if we have a minimum of 10 studies for a specific outcome (ie, pain or disability scores), within a respective group (ie, 'usual care' or 'no intervention'). The association between time as independent variable and pain or disability scores as dependent variables will be assessed. In addition, we will assess whether pain and disability scores present similar clinical courses. We hypothesise that the clinical course of pain will improve faster over time when compared with disability.²⁰

We will conduct a subgroup analysis if sufficient data are available. Subgroup analysis will be based on the following: different types of subacromial pain syndrome as per definition used by authors from included studies (eg, full rotator cuff tear, partial rotator cuff tear and subacromial bursitis) and duration of symptoms (acute: 0 up to 3 months and persistent: >3 months). It is possible that the studies reporting usual care will comprise diverse forms of interventions. If that is the case, such studies may be subgrouped based on the type of the intervention (eg, GPs or physiotherapy).

In order to assess the bias in meta-analysis results, we will use funnel plots.²⁶ This analysis will be performed if we have at least 10 studies included in the meta-analysis.³¹

CONCLUSION

To our knowledge, this will be the first systematic review to assess the clinical course of subacromial shoulder pain. This review will provide estimates of the course of subacromial shoulder pain and disability (acute and persistent) over time, for patients who have not received treatment or usual care. Such information can be of value for future studies comparing the effect of an intervention with expected recovery rates for patients who received usual care or no intervention. In addition, this study will inform whether pain and disability have the same clinical course over time. In the case of heterogeneity due to study characteristics (populations, outcome measures and follow-up time points) and biases, findings from this systematic review will provide possible directions for standardisation of participants, outcome measures and follow-up time points in future observational studies.

Patient and public involvement

Patients and/or the public were not involved with the development of this research project.

Contributors ZJT and DCR conceived of the project. ZJT was responsible for the designing of the review. DCR is the guarantor. DCR, GS and ASG contributed to design of the review. All authors revised and approved the protocol for the study. All authors revised manuscript for important content and approved the final version.

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