The effectiveness of interventions in the management of patients with primary frozen shoulder

There are many types of treatment used to manage the frozen shoulder, but there is no consensus on how best to manage patients with this painful and debilitating condition. We conducted a review of the evidence of the effectiveness of interventions used to manage primary frozen shoulder using the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the Physiotherapy Evidence Database Database, MEDLINE and EMBASE without language or date restrictions up to April 2009. Two authors independently applied selection criteria and assessed the quality of systematic reviews using the Assessment of Multiple Systematic Reviews (AMSTAR) tool. Data were synthesised narratively, with emphasis placed on assessing the quality of evidence.

In total, 758 titles and abstracts were identified and screened, which resulted in the inclusion of 11 systematic reviews. Although these met most of the AMSTAR quality criteria, there was insufficient evidence to draw firm conclusions about the effectiveness of treatments commonly used to manage a frozen shoulder. This was mostly due to poor methodological quality and small sample size in primary studies included in the reviews.

We found no reviews evaluating surgical interventions.

More rigorous randomised trials are needed to evaluate the treatments used for frozen shoulder.

Frozen shoulder is a painful and debilitating condition affecting 2% to 5% of the general population. Since it was first described by Duplay in 1872, the condition has been the subject of much research. The pathology of frozen shoulder has been examined more recently by Bunker and Anthony, who describe a ‘Dupuytren’s-like’ contracture of the coracohumeral ligament and capsule which prevents external rotation. It is characterised by severe pain and insidious shoulder stiffness, which can cause almost complete loss of passive and active forward elevation and external rotation of the glenohumeral joint.

The natural history of the condition follows a pattern of recovery which moves through three phases: the ‘painful phase’ lasting three to eight months, the ‘adhesive phase’ lasting four to six months, and the ‘resolution phase’ lasting five to 24 months. However, the literature suggests that for many patients the symptoms do not resolve completely, leaving them with prolonged pain or stiffness.

Frozen shoulder can be classified as primary, when patients display symptoms with no identifiable cause, and secondary when there is a known cause such as recent injury. A number of medical conditions, such as diabetes mellitus and upper limb trauma, have been associated with a frozen shoulder, and it is most common in the middle-aged and in women.

Many types of treatment have been described, but there is little consensus as to how to manage these patients. The interventions used are usually adapted to the phase of the condition and can include education/watchful waiting; physical therapy (including physiotherapy, cryotherapy and acupuncture); oral corticosteroids; non-steroidal anti-inflammatories (NSAIDs); injections (corticosteroid, local anaesthetic, sodium hyaluronate and calcitonin), articular or arthrographic distension; manipulation under anaesthetic; physical therapy; or a combination of these.

The aim of this study was to critically assess the quality and content of existing systematic reviews of the management of primary frozen shoulder and to identify deficiencies that might be corrected by further research.

Materials and Methods

Data sources. The Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), the...
Physiotherapy Evidence Database (PEDro), MEDLINE, MEDLINE in process and EMBASE were searched for systematic reviews on the frozen shoulder. No date limits were applied to the searches of CDSR, DARE and PEDro. For the searches of MEDLINE and EMBASE a date limit of 2007 to 2009 was applied to retrieve any recent reviews that might not yet have appeared on CDSR, DARE or PEDro. No language restrictions were applied. The Hedges best sensitivity filter was used to retrieve systematic reviews from MEDLINE12 and from EMBASE.13 The keywords used for the search included frozen shoulder, bursitis, adhesive capsulitis, shoulder bursitis or capsulitis, shoulder peri-arthritis, shoulder pain, shoulder impingement syndrome, subacromial impingement syndrome and stiff shoulder. The reference lists of identified relevant studies were also carefully studied.

Study selection, quality assessment and data extraction. Titles and abstracts were initially assessed independently by two authors (MR, LD), as was the assessment of quality. Any uncertainty or disagreement in study selection or of quality assessment was resolved by discussion. If no consensus could be reached, a specialist shoulder surgeon (AR) arbitrated. Inter-rater agreement was assessed using κ statistics.

Inclusion criteria. Reviews were included if they were systematic and considered the management of primary frozen shoulder in adults. Results pertaining to frozen shoulder had to be presented separately in studies that included shoulder pain. The following methods of management, singly or in combination, were considered for the management of a frozen shoulder: watchful waiting, non-steroidal anti-inflammatory medication, intra-articular and subacromial injections, physical therapy, distension, angiography, manipulation under anesthesia and capsular release. The clinical outcomes considered included improvement pain, range of movement and function.

The assessment of multiple systematic reviews (AMSTAR) tool was used to assess the quality of the included reviews. This comprises 11 items that question the methodological quality of systematic reviews and has good face and content validity.14 Data extraction was performed by an author (MR) using a pre-piloted form and were checked by another author (LD). The form was piloted on three randomly selected reviews. The final data recorded included the objective, the methodology, and the details of studies including the participants, interventions, comparators, outcomes and results. This was not an effectiveness review, therefore, the aim was not to pool data from systematic reviews using techniques of meta-analysis but to review the quality of the existing evidence. The results are therefore described narratively.

Results

The initial search returned 758 references. After reviewing these and searching reference lists, a total of 11 reviews were included in this scoping review.1,15-24 Figure 1 provides an overview of the review process. There was no disagreement between the two assessors on the reviews which were chosen. Six reviews were excluded because they were not systematic;25-30 three because the results relating to frozen shoulder were not presented separately,31-33 one because it focused on non-specific symptoms in the shoulder,34 and one because it did not include frozen shoulder.35

Quality assessment. The inter-rater agreement was high (κ = 0.934). The small number of disagreements arose from the subjective use of the categories ‘no’ and ‘can’t answer’ on the AMSTAR tool, where reviews provided insufficient information to assess certain aspects of quality. When this occurred, the third reviewer (AR) arbitrated.

In general, the reviews were of good quality as they addressed the majority of the criteria set out in the AMSTAR tool. Most undertook a comprehensive search of the literature, duplicate study selection and data extraction, and some form of quality assessment which was incorporated into the conclusions. However, several reviews did not state whether publications were searched regardless of the type of publication, and some searches were limited by date19 and language.1,20 Only one review assessed the likelihood of publication bias,16 and none acknowledged potential conflicts of interest, both of which are considered to be important aspects of systematic reviews and are incorporated into the AMSTAR tool.14 Some reviews did not describe the results for frozen shoulder separately from other shoulder disorders, other than reporting limited results in tables.21,24

Studies included. Overall 91 primary studies were included in the 11 systematic reviews. The primary studies were published between 1954 and 2005. Overlap of studies is expected in a review of systematic reviews. Approximately two-thirds of the primary studies were included in only one review, with 15% included in two reviews, 10% in four reviews and 7% in six reviews. Systematic reviews tended to focus on a single treatment and used varied search strategies, which explains the limited overlap between systematic reviews.

Physical therapy. Two systematic reviews of varying quality were identified.20,22 Cleland and Durall20 undertook a limited search which found only two randomised controlled trials (RCTs). These suggested that corticosteroid injections may produce greater improvement than physiotherapy for patients with adhesive capsulitis. Green et al22 conducted a systematic review which was of higher quality because two independent reviewers undertook studies of the selection and extraction of the data, a comprehensive literature search was described, and a list of excluded studies was provided. From this review there was some evidence that laser therapy might be more effective than a placebo in the short term. However, this was based on a few small, poor-quality RCTs and the authors highlighted the need for further research.22

Steroid injections. Four systematic reviews evaluating steroid injections were included.1,16,17,24 The quality of these reviews varied, although all four fulfilled either 7 of 11 or 8 of 11 of the AMSTAR criteria. Shah and Lewis1 limited
their search strategy to English language studies and did not state whether study selection and quality assessment were undertaken by independent reviewers. Arroll and Goodyear-Smith did not discuss the results relating to frozen shoulder, despite their systematic review including studies on the frozen shoulder. Upon examination of the reference list we extracted information from the tables of results for rotator cuff tendonitis, three of which were for studies of frozen shoulder.

There was evidence that multiple corticosteroid injections may be more effective than physiotherapy in the short term. This was based, however, on the findings of a small number of RCTs investigating different interventions and using different outcomes, which made it difficult to draw firm conclusions.

**Acupuncture.** One systematic review evaluated the effectiveness of acupuncture. This review fulfilled 8 of 11 of the AMSTAR criteria. However, the three RCTs relating specifically to adhesive capsulitis reported poorly on the methods used and the descriptions of interventions. In addition, the three RCTs compared different interventions, comparators and outcomes, and reported varying results as to the effectiveness of acupuncture.

**Oral steroids.** One systematic review evaluated oral steroids for the treatment of adhesive capsulitis. This review fulfilled the majority of the AMSTAR criteria. A comprehensive search strategy, duplicate study selection and quality assessment were undertaken. The likelihood of publication bias was not assessed. There was evidence based on a few small RCTs (n = 179, median = 32) that a short course of oral steroids might provide short-term benefit of less than six weeks compared to a placebo or no treatment. The authors of this review advised that because of the potential adverse effects of oral steroids, a risk-benefit analysis...
should be performed for each patient before considering this form of treatment for frozen shoulder.

**Arthrographic distension.** One systematic review by Buchbinder et al.\(^\text{19}\) was included and was found to be of the highest methodological quality, fulfilling 9 of 11 of the AMSTAR criteria. There was evidence that arthrographic distension might be effective, but this was based on a small number of RCTs with small sample size and poor methodological quality (n = 196, median 45).

**Surgery.** There was no systematic review evaluating open or arthroscopic surgery in the management of patients with primary frozen shoulder. Manipulation under anaesthesia was included in two systematic reviews that reviewed a range of interventions, however, there is a lack of evidence to draw conclusions about effectiveness.

**All interventions.** Two systematic reviews\(^\text{15,21}\) studied a range of interventions. One\(^\text{15}\) was of poor quality because it did not use duplication of study selection or data extraction and did not assess the quality of the included studies. There was some evidence that physiotherapy might have a positive effect, but the quality of the included studies was not described and studies were generally small (n = 722, median = 43).

Although quality assessment revealed that 6 of 11 AMSTAR criteria were fulfilled in the review by Green et al.,\(^\text{21}\) it was not possible to determine whether a comprehensive search strategy was undertaken and the reporting of results specific to frozen shoulder was poor, which made it difficult to draw conclusions. RCTs included in this review generally had small sample size and were of poor quality, with a lack of uniformity in labelling and defining shoulder disorders and use of outcomes.

**Discussion**

This paper is an assessment of the systematic reviews focusing on interventions used in the management of the frozen shoulder. Although a comprehensive search strategy was undertaken, with no date or language restrictions, the limited resources available inhibited the searching of ‘grey’ literature and it is possible that this may have introduced publication bias. Study selection, data extraction and quality assessment were undertaken by two independent reviewers, although data extraction was not blinded to the source of the systematic review owing to familiarity with the literature.

**Study findings.** We found insufficient evidence for assessing a range of interventions used to manage frozen shoulder. There are difficulties in conducting systematic reviews owing to a lack of consensus on the terminology, treatment regimes and outcome measurement. Therefore there are a few small trials investigating each intervention, using different regimes of treatment, comparators and outcomes. Thus it is difficult to determine the effectiveness of interventions for frozen shoulder.

Physical therapy is commonly used in the management of these patients. However, in the two systematic reviews which were included in this review, there was no agreement regarding the effectiveness of physical therapy. Reviews of the use of corticosteroid injections also disagree about their effectiveness. Generally, RCTs are small and of variable quality. Many do not use adequate concealment of allocation or intention-to-treat analysis. There is also insufficient evidence for the effectiveness for acupuncture, and the reporting of methods and interventions in this field is limited.

Oral steroids are often used in patients with frozen shoulder and studies suggest a short-term benefit compared to placebo or no treatment. One review found some benefit from arthrographic distension for patients with adhesive capsulitis.

Surgery may be recommended for patients with frozen shoulder with long-standing restrictions in range of movement,\(^\text{25}\) who have failed to respond to conservative treatment after six months.\(^\text{28}\) A literature review by Chambler and Carr\(^\text{8}\) examined the role of surgery in frozen shoulder and found little evidence that it changes the natural progression of the disease. However, we found no systematic reviews of surgery for the treatment for frozen shoulder.

The management of patients with frozen shoulder requires a multidisciplinary approach involving general practitioners, physiotherapists and orthopaedic surgeons, as interventions are seldom used in isolation. Two systematic reviews assessed the effectiveness of multiple treatments,\(^\text{15,21}\) but there was insufficient evidence from small, poor-quality RCTs to determine the effectiveness of different interventions.

**Quality of reviews and primary studies.** The quality of the systematic reviews was generally good, with most fulfilling the majority of the AMSTAR criteria, although two studies undertook limited searches\(^\text{1,20}\) and one did not assess the quality of the studies included.\(^\text{15}\) The systematic reviews included in this study are now out of date since the most recent searches were undertaken in 2006.\(^\text{1,19}\)

The quality of evidence from papers included in these systematic reviews was consistently poor and highlights the need for more rigorous, higher-quality research. Important aspects which were often not addressed included adequate randomisation, allocation concealment, patient follow-up, intention-to-treat analysis, appropriate statistical and cost-effectiveness analyses, appropriate sample sizes and power calculations, baseline comparability and the reporting of adverse events.\(^\text{16-20,22,24}\) Two reviews also recommended using the CONSORT statement to design and report further trials.\(^\text{18,19}\) The majority of primary studies did not have sufficient power to detect a statistically significant result, with sample sizes generally below 50 participants.

**Areas for further research.** Our findings suggest that the following should be considered when undertaking future research: standardisation of the diagnostic criteria for frozen shoulder, and standardisation of treatment outcomes.

**Standardisation of diagnostic criteria for frozen shoulder.** The systematic reviews included in this review all highlight difficulties in defining the study population, as there
is no standard set of criteria to define the frozen shoulder. Studies tend to include patients with a diagnostic label of frozen shoulder, adhesive capsulitis, stiff shoulder or peri-arthritis. Bulgen et al\(^{36}\) suggested that the following criteria should be considered: pain in the shoulder for at least one month; night pain; inability to lie on the affected side; restriction of active and passive movement and restriction in external rotation by at least 50%. De Jong et al\(^{37}\) adds that ‘lack of clinical or radiological evidence of other pathology which could account for similar symptoms’ should be considered.

Debate also exists around the timing of interventions and at which stage the condition should be treated. There are three stages in frozen shoulder involving: pain, stiffness and recovery.\(^{38}\) It has been suggested that in order to achieve the best results treatment should be tailored to the stage of the disease.\(^{39}\) However, there is a lack of documentation and/or standardisation of the stage of disease in the literature. The mean duration of symptoms in one systematic review ranged from one month to 26 months,\(^{18}\) and in another from two months to eight months.\(^{19}\)

**Standardisation of treatment outcomes.** The heterogeneous choice of outcome measures used in RCTs in this field makes it difficult to compare results from different studies. Commonly used outcomes include pain, often measured using visual analogue scales; range of movement, measured using hydrogoniometers and inclinometers; and patient-reported outcomes such as function and quality of life as measured using the Oxford Shoulder Score.\(^{40}\) Green et al\(^{21}\) suggest that range of measures should be used and stress the importance of disability. Poolman et al\(^{41}\) suggest that ‘subjective’ measures may be of greatest relevance, as these assess effectiveness from the patient’s perspective. Future research should define specific outcome measures, and there is a need to standardise measures across studies.

There is insufficient evidence to draw firm conclusions about the effectiveness of treatments commonly used in the management of patients with frozen shoulder. Systematic reviews have attempted to synthesise information from a number of studies, but these are generally too small and evaluate different treatments using different comparators and outcomes. Further evidence is needed to inform clinical practice. In particular, we found no systematic reviews evaluating surgical treatment for the management of frozen shoulder. There is a need for standardisation of diagnostic criteria used to describe the groups to be studied, standardisation of outcome measurement and improved quality of RCTs in this field.

**Supplementary materials**

Tables showing i) the characteristics of the included systematic reviews, ii) a summary of the quality assessment of the included systematic reviews and iii) the extent of overlap in primary studies between systematic reviews is available with the online version of this article on our website at www.jbjs.org.uk

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**References**

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