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Comparison of Treatments for Frozen Shoulder

A Systematic Review and Meta-analysis

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Key Points

Question

Are any treatment modalities for frozen shoulder associated with better outcomes than other treatments?

Findings

In this meta-analysis of 65 studies with 4097 participants, intra-articular corticosteroid was associated with increased short-term benefits compared with other nonsurgical treatments, and its superiority appeared to last for as long as 6 months. The addition of a home exercise program and/or electrotherapy or passive mobilizations may be associated with added benefits.

Meaning

The results of this study suggest that intra-articular corticosteroid should be offered to patients with frozen shoulder at first contact.

Abstract

Importance

There are a myriad of available treatment options for patients with frozen shoulder, which can be overwhelming to the treating health care professional.

Objective

To assess and compare the effectiveness of available treatment options for frozen shoulder to guide musculoskeletal practitioners and inform guidelines.

Data Sources

Medline, EMBASE, Scopus, and CINHAL were searched in February 2020.

Study Selection

Studies with a randomized design of any type that compared treatment modalities for frozen shoulder with other modalities, placebo, or no treatment were included.

Data Extraction and Synthesis

Data were independently extracted by 2 individuals. This study followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline. Random-effects models were used.

Main Outcomes and Measures

Pain and function were the primary outcomes, and external rotation range of movement (ER ROM) was the secondary outcome. Results of pairwise meta-analyses were presented as mean differences (MDs) for pain and ER ROM and standardized mean differences (SMDs) for function. Length of follow-up was divided into short-term (≤12 weeks), mid-term (>12 weeks to ≤12 months), and long-term (>12 months) follow-up.

Results

From a total of 65 eligible studies with 4097 participants that were included in the systematic review, 34 studies with 2402 participants were included in pairwise meta-analyses and 39 studies with 2736 participants in network meta-analyses. Despite several statistically significant results in pairwise meta-analyses, only the administration of intra-articular (IA) corticosteroid was associated with statistical and clinical superiority compared with other interventions in the short-term for pain (vs no treatment or placebo: MD, −1.0 visual analog scale [VAS] point; 95% CI, −1.5 to −0.5 VAS points; $P < .001$; vs physiotherapy: MD, −1.1 VAS points; 95% CI, −1.7 to −0.5 VAS points; $P < .001$) and function (vs no treatment or placebo: SMD, 0.6; 95% CI, 0.3 to 0.9; $P < .001$; vs physiotherapy: SMD 0.5; 95% CI, 0.2 to 0.7; $P < .001$). Subgroup analyses and the network meta-analysis demonstrated that the addition of a home exercise program with simple exercises and stretches and physiotherapy (electrotherapy and/or mobilizations) to IA corticosteroid may be associated with added benefits in the mid-term (eg, pain for IA coritocosteriod with home exercise vs no treatment or placebo: MD, −1.4 VAS points; 95% CI, −1.8 to −1.1 VAS points; $P < .001$).

Conclusions and Relevance

The findings of this study suggest that the early use of IA corticosteroid in patients with frozen shoulder of less than 1-year duration is associated with better outcomes. This treatment should be accompanied by a home exercise program to maximize the chance of recovery.

Introduction

Adhesive capsulitis, also known as frozen shoulder, is a common shoulder concern manifesting in progressive loss of glenohumeral movements coupled with pain.[1] It is a fibroproliferative tissue fibrosis, and although the immunobiological advances in other diseases have helped dissect the pathophysiology of this condition, overall, the molecular mechanisms underpinning it remain poorly understood.[2,3,4,5]

Frozen shoulder manifests clinically as shoulder pain with progressive restricted movement, both active and passive, along with normal radiographic scans of the glenohumeral joint.[6] It classically progresses prognostically through 3 overlapping stages of pain (stage 1, lasting 2-9 months), stiffness (stage 2, lasting 4-12 months), and recovery (stage 3, lasting 5-24 months).[7] However, this is an estimated time frame, and many patients can still experience symptoms at 6 years.[8] A primary care–based observational study estimated its incidence as 2.4 per 100 000 individuals per year,[9] with prevalence varying from less than 1% to 2% of the population.[10]

A true evidence-based model for its medical management has not been defined, with a wide spectrum of operative and nonoperative treatments available. From the international to departmental level, management strategies vary widely, reflecting the lack of good-quality evidence.[11] The British Elbow and Shoulder Society/British Orthopaedic Association (BESS/BOA) has published recommendations in a patient care pathway for frozen shoulder, with a step-up approach in terms of invasiveness advised.[12] The UK Frozen Shoulder Trial, a randomized parallel trial comparing the clinical and cost-effectiveness of early structured physiotherapy, manipulation under anesthetic (MUA), and arthroscopic capsular release (ACR) is currently under way.[13] The aim of this systematic review is to present the available evidence relevant to treatment and outcomes for frozen shoulder with the ultimate objective of guiding clinical practice, both in primary and secondary care.

Methods

The present systematic review has been conducted and authored according to the Preferred Reporting Items

for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline.[14] Our patient, intervention, comparison, and outcome (PICO) was defined as follows: patients, patients with frozen shoulder of any etiology, duration, and severity; intervention, any treatment modality for frozen shoulder; comparison, any other treatment modality, placebo, or no treatment; and outcome, pain and function (primary outcomes) and external rotation range of movement (ER ROM) (secondary outcome) in the short term, midterm, or long term.

Eligibility

Included studies had a randomized design of any type and compared treatment modalities for frozen shoulder with other treatment modalities, placebo, or no treatment. Additionally, at least 1 of our preset outcome measures needed to be included in the study. Studies that compared different types, regimens, dosages, or durations of the same intervention were excluded (eg, different doses of corticosteroid or different exercise types). Those assessing the effectiveness of the same modality applied in different anatomical sites (eg, subacromial vs intra-articular [IA] corticosteroid) were included. Participants had to be older than 18 years with a clinical diagnosis of adhesive capsulitis. No formal diagnostic criteria were used to define frozen shoulder; however, the use of inappropriate or inadequate diagnostic criteria was taken into account in risk-of-bias assessments. Duration of the condition was not a criterion nor were previous treatments and follow-up. Inclusion of patients with specific conditions (eg, diabetes) was not an exclusion criterion, and it was not taken into account in analyses, provided that their proportion in the treatment groups was comparable.

Nonrandomized comparative studies, observational studies, case reports, case series, literature reviews, published conference abstracts, and studies published in languages other than English were excluded. Studies including patients with the general diagnosis of shoulder pain were also excluded even if a proportion of them had frozen shoulder. Studies assessing the effectiveness of different types of physiotherapy-led interventions, exercise, or stretching regimens were also excluded.

Search Strategy

A thorough literature search was conducted by 3 of us (D.C., M.B., and M.M.) via Medline, EMBASE, Scopus, and CINAHL in February 2020, with the following Boolean operators in all fields: (*adhesive capsulitis* OR *frozen shoulder* OR *shoulder periarthritis*) AND (*treatment* OR *management* OR *therapy*) AND *randomi**). Relevant review articles were screened to identify eligible articles that may have been missed at the initial search. Additionally, reference list screening and citation tracking in Google Scholar were performed for each eligible article.

Screening

From a total of 73 299 articles that were initially identified, after exclusion of duplicate and noneligible articles, title and abstract screening, and the addition of missed studies identified subsequently, 65 studies were found to fulfil the eligibility criteria. Figure 1 illustrates the article screening process.

Risk-of-Bias Assessment and Grading the Certainty of Evidence

The internal validity (freedom from bias) of each included study was assessed with the Cochrane Collaboration's tool for assessing risk of bias in randomized trials separately by 2 of us (D.C. and M.B.), and a third independent opinion (M.M.) was sought when disagreements existed.[15] Studies were characterized as having low, high, or unclear overall risk of bias based on the following formula: low overall risk studies had high risk of bias in 2 or fewer domains; high overall risk studies had high risk of bias in more than 2 domains; unclear overall risk studies had unclear risk of bias in more than 2 domains,

unless they also had high risk of bias in more than 2 domains, in which case they were labeled as high overall risk. Risk of bias was assessed separately for outcome measures that included patient reporting (pain, function) and those that did not (ROM); all studies with nonmasked participants were labeled as high risk in the masking of outcome measures domain for patient-reported outcomes given that the assessors were the participants themselves.

Certainty of evidence was graded with the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) tool (eTable 1 in the Supplement).[16] The scale starts with high, and depending on how many of the 5 possible limitations used in the GRADE tool were present in each comparison, the study could be downgraded to moderate, low, and very low. Grading of evidence was performed by 2 authors (D.C. and M.B.) independently and any disagreements were resolved by discussion and involvement of a third assessor (M.M.). Each outcome measure within each comparison had its own evidence grade. Our recommendations for clinical practice were based on results of either high or moderate quality evidence with both clinical and statistical significance.

Data Extraction

Two of us (D.C. and M.B.) performed data extraction. The key characteristics of each eligible article were extracted and inserted in tables in Microsoft Word version 16.43 (Microsoft Corp) to facilitate analysis and presentation. For missing data, attempts were made to contact the original investigators for included studies published less than 10 years ago.

For the presentation of results, outcomes were divided into short-term (≤12 weeks), mid-term (>2 weeks to ≤12 months), and long-term (>12 months) follow-up. When sufficient data existed, short-term follow-up was subdivided into early short-term (2-6 weeks) and late short-term (8-12 weeks). All short-term follow-up points were converted to weeks, and all mid-term follow-up points to months for consistency and easier analysis.

Comparisons of interventions reported by fewer than 3 studies were included in the supplementary results table and were not analyzed or included in the article. When 3 or more studies contributed data for outcome measures at similar follow up times (ie, 2-6 weeks, 8-12 weeks, and 4-6 months), pairwise meta-analyses were conducted. Raw mean differences (MDs) with their accompanying 95% CIs were calculated and used in the tests for each comparison of pain and ER ROM because the tools used across studies were the same. Standardized mean differences (SMDs) were used for function because different functional scores were used.

When pain results were reported in different settings (eg, at rest, at night, with activity) in studies, only pain at rest was used in results. When both active and passive ROM were used as outcome measures, passive ROM was used in our results to increase homogeneity given that most studies used passive ROM. Results for the following outcome measures were recorded in tables and combined qualitatively only based on direction of effect to yield an overall effect for each comparison: abduction ROM, flexion ROM, and quality of life. However, these were not included in the results nor was the quality of the relevant evidence graded.

Additionally, comparisons that yielded both clinically and statistically significant results (ie, greater than or equal to the minimal clinically relevant difference and $P < .05$) underwent trial sequential analysis (TSA) to rule out a type I error and further reinforce our recommendations for clinical practice. TSA is a quantitative method applying sequential monitoring boundaries to cumulative meta-analyses in a similar fashion as the application of group sequential monitoring boundaries in single trials to decide whether they could be terminated early because of a sufficiently small P value. TSA is considered an interim meta-analysis; it helps control for type I and II errors and clarifies whether additional trials are needed by considering

required information size.[17] The TSA graph includes 2 horizontal lines, representing the conventional thresholds for statistical significance ($Z = 1.96$; $P < .05$); 1 vertical line, representing required information size; a curved red line, representing the TSA boundaries (ie, thresholds for statistical significance); and a blue line showing the cumulative amount of information as trials are added. A significant result is denoted by a crossing of the curved blue and red lines.

Finally, a network meta-analysis was conducted for treatments used by 3 or more studies for the primary outcome (pain) at late short-term (8-12 weeks) and mid-term (4-6 months) follow-up. Both direct and indirect comparisons were included in the model, and treatment rank probabilities were produced for the 2 follow-up time periods. The certainty of evidence deriving from network meta-analyses was not graded. Subgroup analyses for the effect of home exercise, different physiotherapy interventions, and chronicity of frozen shoulder were conducted when possible.

Definitions

The term *physiotherapy* was used for any supervised, physiotherapist-led, noninvasive treatment (mobilizations, application of ice and heat, diathermy, electrotherapy modalities). These were grouped and analyzed together. Exercises and stretching that were performed by the participants at home (home exercise program) or under a physiotherapist's supervision were not included in physiotherapy. Acupuncture and extracorporeal shock wave therapy (ESWT) were regarded as a separate intervention to physiotherapy. Interventions that had accompanying physiotherapy were grouped and analyzed separately from those that did not, regardless of intensity and frequency. For example, studies with a treatment group who received IA corticosteroid plus physiotherapy (eg, ice packs and diathermy) were included in the intervention category IA corticosteroid plus physiotherapy; those with a treatment group receiving only IA corticosteroid (with or without a home exercise program) were included in the IA corticosteroid category. Patients in the following groups were considered control groups and were analyzed together: no treatment, placebo, sham procedures, IA normal saline or lidocaine, simple analgesia, and home exercise alone.

The following tools and questionnaires that were found in included studies represented our function outcome measure: Shoulder Pain and Disability Index, American Shoulder and Elbow Surgeons shoulder score, Constant-Murley, and the Strengths and Difficulties Questionnaire. All patient-reported pain and function scales were uniformly converted to a scale from 0 to 10 and a scale from 0 to 100, respectively.

Statistical Analysis

The Review Manager version 5 (RevMan) software was used for pairwise meta-analyses and their accompanying forest plots and heterogeneity tests (χ^2 and I^2). TSA software version 0.9β (Copenhagen Trial Unit) was used for TSAs; random-effect models with 5% type I error and 20% power and O'Brien-Fleming α-spending function were used for all TSA analyses. The required information size was estimated by the software based on the power (20%), mean difference, variance, and heterogeneity. Stata version 16.1 (StataCorp) with the mvmeta extension (multivariate random-effects meta-regression) was used for network meta-analyses (frequentist approach).[18]

When exact mean and SD values were not reported in the included articles, approximate values (to the nearest decimal place) were derived from the graphs. When only interquartile ranges (IQRs) were reported, the SD was calculated as IQR divided by 1.35. When only the median was reported, the mean was assumed to be the same. When CIs of means were reported, SDs were calculated by dividing the length of the CI by 3.92 and then multiplying by the square root of the sample size. When SEs of mean were given, these were converted to SDs by multiplying them by the square root of the sample size. In studies in which only means and the population were given, the SD was imputed using the SDs of other similar studies using the prognostic method (ie, calculating the mean of all SDs).[19] Pooled means were calculated by adding all the

means, multiplied by their sample size, and then dividing this by the sum of all sample sizes. Pooled SDs were calculated with the following formula: $SD_{pooled} = \sqrt{(SD_1^2[n_1\text{-}1]) + (SD_2^2[n_2\text{-}1]) + \ldots + (SD_k^2[n_k\text{-}1]) / (n_1 + n_2 + \ldots + n_k - k)}$, where n indicates sample size and k, the number of samples. The following formula was used for the sample size calculation as part of GRADE's assessment for imprecision[20]:

$$N = \frac{2(a+b)^2 SD^2}{(x_1 - x_2)}$$

In which N indicates the sample size required in each of the groups; $(x_1 - x_2)$ indicates the minimal clinically relevant difference (MCRD), defined as 1 point for VAS pain, effect size of 0.45 for functional scores, and 10° for ER ROM; SD^2 indicates the population variance, calculated using pooled SD from our treatment groups; $a = 1.96$, for 5% type I error; and $b = 0.842$, for 80% power.

The MCRD for function on functional scales would have been set at 10 points. However, because SMDs were used, which produce effect sizes, rather than MDs, the 10 points were divided by the population SD (ie, 22) that was used to calculate the optimal information size (effect sizes can be converted back to functional scores when multiplied by SD).

Potential publication bias was evaluated by Egger test for asymmetry of the funnel plot in comparisons including more than 10 studies. Expecting wide-range variability in studies' settings, a random-effects metasynthesis was employed in all comparisons.

Subgroup analyses were conducted with independent samples t tests in Graphpad version 8 (Prism) comparing pooled means and SDs. All statistical significance levels were set at $P < .05$, tests were 2-tailed, and clinical significance was defined as a MD or SMD being equal or higher than our predefined MCRD.

Results

Of the 65 eligible studies, a total of 34 studies[21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54] were included in pairwise meta-analyses with a total of 2402 participants with frozen shoulder. Duration of symptoms ranged from 1 month to 7 years and length of follow-up from 1 week to 2 years, with most follow-up occurring at 6 weeks, 12 weeks, and 6 months.

Table 1 summarizes the main characteristics of the included studies.[21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87] eTable 2 in the Supplement shows the results of the risk-of-bias assessment.

Table 2 summarizes the findings of the present review. Where feasible (ie, results at similar follow-up times in at least 3 studies), pairwise meta-analyses were conducted. The results of abduction ROM, flexion ROM, and quality of life were pooled only based on direction of effect, and their certainty of evidence was not graded. eTable 3 in the Supplement summarizes the results of comparisons reported by 1 or 2 studies only. eTable 4 in the Supplement demonstrates how the strength of evidence for each outcome measure within each comparison was derived for all follow-up time categories, per GRADE. eTable 5 in the Supplement shows the heterogeneity for each comparison (I^2 statistic) and where studies were removed to reduce heterogeneity based on sensitivity analyses.

Pairwise Meta-analysis

We conducted pairwise meta-analysis comparing the effectiveness of each intervention with other

interventions (or placebo/no treatment) in the short-term (early, 2-6 weeks; late, 8-12 weeks) and mid-term (4-6 months). Data for long-term follow-up (>12 months) were inadequate for analyses. Numerical data are only presented for the statistically significant comparisons; those for nonsignificant comparisons appear in the forest plots (eFigure 1, eFigure 2, and eFigure 3 in the Supplement).

IA Corticosteroid vs No Treatment or Placebo

Short-term IA corticosteroid appeared to be associated with superior outcomes compared with control for early short-term pain (moderate certainty; MD, −1.4 visual analog scale [VAS] points; 95% CI, −1.8 to −0.9 VAS points; $P < .001$), ER ROM (high certainty; MD, 4.7°; 95% CI, 2.7° to 6.6°; $P < .001$), and function (high certainty; SMD, 0.6; 95% CI, 0.3 to 0.9; $P < .001$) and late short-term pain (moderate certainty; MD, −1.0 VAS points; −1.5 to −0.5 VAS points; $P < .001$), ER ROM (high certainty; MD, 6.8°; 95% CI, 3.4° to 10.2°; $P < .001$), and function (moderate certainty; SMD, 0.6; 95% CI, 0.3 to 0.8; $P < .001$).

Mid-term IA corticosteroid was associated with better outcomes than control only for function (moderate certainty; SMD, 0.3; 95% CI, 0.1 to 0.5; $P = .01$). However, effects for pain and ER ROM were similar (moderate certainty for both).

Physiotherapy vs No Treatment or Placebo Physiotherapy was found to be associated with improved outcomes compared with control in the early short-term for ER ROM (moderate certainty; MD, 11.3°; 95% CI, 8.6°-14.0°; $P < .001$). Data for other follow-up time periods were insufficient for quantitative analysis.

IA Corticosteroid Plus Physiotherapy vs No Treatment or Placebo Combined treatment with IA corticosteroid plus physiotherapy was associated with superior outcomes vs control for early short-term ER ROM (high certainty; MD, 17.9°; 95% CI, 12.1°-23.7°; $P < .001$). Data for other follow-up periods were insufficient for quantitative analysis.

IA Corticosteroid vs Physiotherapy

Short-term IA corticosteroid was associated with significant benefits compared with physiotherapy for early short-term function (moderate certainty; MD, 0.5; 95% CI, 0.2 to 0.7; $P < .001$) and late short-term pain (high certainty; MD, −1.1 VAS points; 95% CI, −1.7 to −0.5 VAS points; $P < .001$) only. Differences for early short-term pain (moderate certainty), late short-term function (moderate certainty), and early and late short-term ER ROM (moderate and high certainty, respectively) were insignificant.

Mid-term IA corticosteroid was associated with better outcomes than physiotherapy for ER ROM (moderate certainty; MD, 4.6°; 95% CI, 0.7°-8.6°; $P = .02$). However, no significant differences in pain (low certainty) or function (moderate certainty) were observed.

IA Corticosteroid Plus Physiotherapy vs IA Corticosteroid Only

Short-term Compared with IA corticosteroid alone, combined treatment with IA corticosteroid plus physiotherapy was only associated with superior outcomes for early short-term ER ROM (moderate certainty; MD, 11.6°; 95% CI, 3.7°-19.4°; $P = .004$). Pain and function in the early short-term (moderate and low certainty, respectively) and late short-term function (high certainty) were similar between groups.

Mid-term No significant differences were found between the groups in pain, function, or ER ROM. These results had high, moderate, and high certainty, respectively.

IA Corticosteroid Plus Physiotherapy vs Physiotherapy Only

Short-term Combined therapy with IA corticosteroid plus physiotherapy was associated with significant benefits compared with physiotherapy alone only for early short-term function (low certainty; SMD, 0.7; 95% CI, 0.3-1.0; $P < .001$). Differences for early short-term pain and ER ROM and late short-term function were not significant (moderate certainty for all).

Mid-term No significant differences were found between the groups for pain, function, or ER ROM. These comparisons had moderate, low, and high certainty, respectively.

IA Corticosteroid vs Subacromial Corticosteroid

Short-term Compared with subacromial administration, administering corticosteroid intra-articularly was only associated with superior outcomes for early short-term pain (moderate certainty; MD, −0.6 VAS points; 95% CI, −1.1 to −0.1 VAS points; $P = .02$) and late short-term function (moderate certainty; SMD, 0.3; 95% CI, 0 to 0.6; $P = .03$). Improvements in late short-term pain (moderate certainty) and ER ROM (high certainty) and early short-term function (high certainty) were similar with the 2 interventions.

Mid-term No significant differences were found between the groups for pain or ER ROM. These comparisons had moderate and high certainty, respectively.

Arthrographic Distension Plus IA Corticosteroid vs IA Corticosteroid Only Adding arthrographic distension to IA corticosteroid appeared to be associated with greater improvements in early and late short-term pain (early: high certainty; MD, −0.9 VAS points; −1.3 to −0.4 VAS points; $P < .001$; late: high certainty; MD, −0.8 VAS points; 95% CI, −1.1 to −0.5 VAS points; $P < .001$). Early and late short-term function (moderate and high certainty, respectively) and early and late short-term ER ROM (high certainty for both) were similar with or without distension.

Acupuncture Plus Physiotherapy vs Physiotherapy Only No differences were found with the addition of acupuncture to physiotherapy for early short-term pain and ER ROM. These comparisons had low and high certainty, respectively.

Clinically Significant Results and Trial Sequential Analysis

Despite several statistically significant differences in pairwise comparisons, most did not reach the threshold for MCRD. Only IA corticosteroid vs no treatment or placebo for early and late short-term pain and function, physiotherapy with and without IA corticosteroid vs no treatment or placebo for early short-term ER ROM, IA corticosteroid vs physiotherapy for early short-term function and late short-term pain, and combination therapy with IA corticosteroid plus physiotherapy compared with IA corticosteroid for early short-term ER ROM and with physiotherapy for early short-term function reached MCRD.

For the primary outcome measure, the clinically and statistically significant results underwent TSA, which confirmed the results ruling out a type I error in 2 comparisons (IA corticosteroid vs no treatment or placebo for early and late short-term pain) but not in the comparison of IA corticosteroid vs physiotherapy for late short-term pain. This suggests that more studies may be needed to confirm the benefit of IA corticosteroid compared with physiotherapy with more confidence.

eFigures 1 to 3 in the Supplement illustrate the results of the pairwise meta-analyses and associated forest plots for early short-term, late short-term, and mid-term follow up for pain and ER ROM. eFigure 4 in the Supplement illustrates the forest plots for function, and eFigure 5 and eFigure 6 in the Supplement illustrate the TSA graphs.

Network Meta-analysis

Figure 2 and Figure 3 show the network maps and treatment rank probabilities for the primary outcome measure (pain) for late short-term (8-12 weeks) and mid-term (4-6 months) follow-up, respectively. eFigure 7 and eFigure 8 in the Supplement illustrates the network forests with their consistency tests.

In the late short-term, arthrographic distension plus IA corticosteroid had the highest probability (96%) of being the most effective treatment. IA corticosteroid had the highest probability (85%) of being the second most effective. Physiotherapy was the least effective treatment, followed by no treatment or placebo. No

data existed in the late short-term for combined treatment with IA corticosteroid plus physiotherapy (Figure 2B).

In the mid-term, combined treatment with IA corticosteroid plus physiotherapy had the highest probability (43%) of being the best treatment with physiotherapy. IA corticosteroid had the highest probability (34%) of being the second best treatment. No treatment or placebo followed by subacromial corticosteroid had the highest probability of being the worst interventions (Figure 3B).

Subgroup Analysis

The potential benefit of home exercise was assessed by comparing the mean improvement in pain in patients who received (1) IA corticosteroid plus a home exercise program vs IA corticosteroid without home exercise, and (2) no treatment or placebo plus home exercise vs no treatment/placebo without home exercise. For the first comparison, a statistically significant (but clinically small) mean benefit of home exercise on pain improvement was identified at 8 to 12 weeks (MD, −0.5 VAS points; 95% CI, −0.9 to −0.1 VAS points; $P = .01$). The benefit of home exercise was much more substantial (clinically and statistically) in those receiving no treatment or placebo (MD, −1.4 VAS points; 95% CI, −1.8 to −1.1 VAS points; $P < .001$). Both results are based on 10 studies[22,24,25,28,42,43,45,46,48,49] with low overall risk of bias.

Similarly, we assessed for an effect of IA placebo by comparing samples who received IA placebo and no treatment from the IA corticosteroid vs no treatment or placebo comparison. Both subgroups received a home exercise program. Based on 9 studies[22,24,25,28,42,43,45,46,49] with high overall risk of bias, IA placebo was associated with statistically and clinically significant effects on pain compared with no treatment (MD, −1.6 VAS points; 95% CI, −2.1 to −1.1 VAS points; $P < .001$).

There was insufficient data for a similar subgroup analysis at mid-term follow-up. Subgroup analyses for the effect of chronicity on the effectiveness of treatment modalities could not be evaluated because studies including patients with mixed stages and chronicity of frozen shoulder did not include subgroup data. Finally, subgroup analyses according to physiotherapeutic interventions were not possible because of high clinical heterogeneity (various combinations of modalities and treatment durations used). Most studies used electrotherapy modalities (transcutaneous electrical nerve stimulation, therapeutic ultrasound, diathermy) combined with mobilizations, stretching, or exercises with or without heat and ice packs.

Discussion

To our knowledge, this is the first systematic review and network meta-analysis to comprehensively analyze all nonsurgical randomized clinical trials pertaining to the treatment of frozen shoulder as well as the largest systematic review ever published in the field. Based on the available evidence, it appears that the use of an IA corticosteroid for patients with frozen shoulder of duration less than 1 year is associated with greater benefits compared with all other interventions, and its benefits may last as long as 6 months. This has important treatment ramifications for the general and specialist musculoskeletal practitioner, providing them with an accessible, cost-effective,[88] and evidence-based treatment to supplement exercise regimes, which we anticipate will inform national guidelines on frozen shoulder treatments moving forward.

In the short-term, IA corticosteroid appeared to be associated with better outcomes compared with no treatment in all outcome measures. Adding arthrographic distension to IA corticosteroid may be associated with positive effects that last at least as long as 12 weeks compared with IA corticosteroid alone; however, these benefits are probably not clinically significant. Compared with physiotherapy, IA corticosteroid seemed to be associated with better outcomes, with clinically significant differences. Combination therapy with IA corticosteroid plus physiotherapy may be associated with significant benefits compared with IA corticosteroid alone or physiotherapy alone for ER ROM and function, respectively, at 6 weeks. Compared

with control, combined IA corticosteroid plus physiotherapy appeared to be associated with an early benefit in ER ROM (as long as 6 weeks), with clinical significance. Subacromial administration of corticosteroid appeared to be as efficacious as IA administration. The addition of acupuncture to physiotherapy did not seem to be associated with any added benefits. Based on the network meta-analysis, arthrographic distension with IA corticosteroid was probably the most effective intervention for pain at 12 weeks follow-up. IA corticosteroid alone ranked second, and as demonstrated by the pairwise meta-analysis, the benefit of adding distension appeared clinically nonsignificant.

Most compared interventions appeared to be associated with similar outcomes at 6-month follow up, without significant differences. The only intervention that was associated with mid-term statistically significant benefits compared with control and physiotherapy (without reaching clinical significance) was IA corticosteroid for function and ER ROM. No mid-term data exist assessing the effectiveness of adding arthrographic distension to IA corticosteroid and acupuncture to physiotherapy or comparing physiotherapy (with or without IA corticosteroid) with no treatment. Our network meta-analysis found that combined therapy with IA corticosteroid and physiotherapy, physiotherapy alone, and IA corticosteroid alone were the most effective interventions for pain at 6 months follow-up. However, according to our pairwise meta-analyses, their clinical benefit compared with other treatments (or even no treatment) appeared very small.

A home exercise program with simple ROM exercises and stretches administered with or without IA corticosteroid appeared to be associated with short-term pain benefits. This was statistically significant but clinically nonsignificant compared with no treatment when accompanied by IA corticosteroid. It was both clinically and statistically significant on its own.

Several systematic reviews have been published assessing the effectiveness of therapeutic interventions for frozen shoulder. Sun et al[89] looked at the effectiveness if IA corticosteroid by comparing it with no treatment, and their findings were similar to ours, reporting that IA corticosteroid may be associated with benefits on pain, function, and ROM that are most pronounced in the short-term and can last as long as 6 months. The systematic review of both randomized and observational studies by Song et al[90] is also in agreement with our results, showing a possible early benefit of IA corticosteroid, which likely diminishes in the mid-term. An earlier systematic review by Maund et al,[88] which was only based on limited evidence (meta-analyses of 2 and 3 studies), was largely inconclusive, demonstrating possible benefits of IA corticosteroid (with and without physiotherapy) in conjunction with a home exercise program. A Cochrane review on arthrographic distension[91] was also in agreement with our results, showing that arthrographic distension with IA corticosteroid may be associated with short-term benefits in pain, ROM, and function. Their comparison of combined treatment vs IA corticosteroid alone yielded no significant differences; however, it was only based on 2 studies. A 2018 systematic review by Saltychev et al[92] also supports our findings, having demonstrated a small but clinically insignificant benefit of the addition of arthrographic distension to IA corticosteroid. In their systematic review, Catapano et al[93] reported that the addition of arthrographic distension to IA corticosteroid may be associated with a clinically significant benefit at 3 months; however, no quantitative analyses were conducted. Finally, a Cochrane review investigating the effects of manual therapy and exercise[94] concluded that they are probably associated with worse outcomes compared with IA corticosteroid in the short-term, which is in accordance with the findings of the present review, and another study[95] investigating the effectiveness of electrotherapy modalities was inconclusive because of lack of sufficient evidence.

In this review we aimed to assess the comparative effectiveness of all interventions for frozen shoulder, both surgical and nonsurgical; however, conclusions on the former could not be reached given that included studies did not assess the same interventions, which precluded pooling their results. The existing literature is conflicting regarding the superiority of arthroscopic capsular release (ACR) over nonoperative modalities; De Carli et al[62] reported no short-term or long-term benefits of ACR plus MUA compared with

IA corticosteroid plus physiotherapy in function or ROM. Conversely, Mukherjee et al[75] found that ACR was associated with significant improvements in pain, function, and ROM compared with IA corticosteroid in the short-term and mid-term. Gallacher et al[63] demonstrated mixed results, concluding that compared with IA corticosteroid plus arthrographic distension, combined treatment with ACR and IA corticosteroid may be associated with improved function, external rotation, and flexion ROM but not quality of life and abduction ROM in the short-term and mid-term. The risk of complications, where reported, was not higher in the surgical groups.[63] The existing evidence on MUA, which is not a surgical procedure per se although it is administered under general anesthesia, is more consistent, suggesting its lack of long-term superiority compared with other commonly used nonsurgical treatments or even no treatment.[65,71,76]

Because of the paucity of robust evidence, no firm recommendations exist for clinical practice. The National Institute of Health and Care Excellence (NICE) guidelines,[96] influenced in turn by the BESS/BOA recommendations, recommend a stepped approach, starting with physiotherapy and only considering IA corticosteroid if there is no, or slow, progress.[96] With our review, we provide convincing evidence that IA corticosteroid is associated with better short-term outcomes than other treatments, with possible benefits extending in the mid-term; therefore, we recommend its early use with an accompanying home exercise program. This can be supplemented with physiotherapy to further increase the chances of resolution of symptoms by 6 months.

Most patients in the included studies had duration of symptoms of less than 1 year; therefore, our management recommendations are strongest for this subgroup, which includes patients most commonly encountered in clinical practice. Based on the underlying pathophysiology of the condition, usual practice is to only administer IA corticosteroid in the painful and not freezing phase (also advised by NICE guidance[95]); however, this is not backed up by evidence. In our review, studies that included patients with symptoms for more than 1 year reported equally substantial improvements in outcome measures including ROM and function; therefore, the benefits of corticosteroids may also apply to the freezing phase of frozen shoulder.[48,79]

Limitations

Despite the comprehensiveness and rigor of our methods, which include thorough risk of bias assessments and grading of evidence, we do recognize its limitations. Frozen shoulder of all chronicity was analyzed together; therefore; conclusions about specific stages and their most effective management could not be drawn. Most studies included a home exercise program, but its frequency, intensity, and duration were not taken into account in comparisons nor were separate analyses made adjusting for it. Finally, physiotherapy interventions, regardless of nature and duration, were grouped and analyzed together to minimize imprecision; in reality, some might be more effective than others. However, we only present findings that derived from thorough quantitative analyses, which were in turn substantially reinforced by the TSA, minimizing the risk for type I errors; most previous similar meta-analyses did not use TSA. Additionally, we present the first network meta-analysis including all conservative treatments for frozen shoulder. Furthermore, we based our recommendations on both statistically and clinically significant results.

Conclusions

Based on the findings of the present review, we recommend the use of IA corticosteroid for patients with frozen shoulder of duration less than 1 year because it appeared to have earlier benefits than other interventions; these benefits could last as long as 6 months. We also recommend an accompanying home exercise program with simple ROM exercises and stretches. The addition of physiotherapy in the form of an electrotherapy modality and supervised mobilizations should also be considered because it may add mid-term benefits and can be used on its own, especially when IA corticosteroid is contra-indicated.

Implicated health care professionals should always emphasize to patients that frozen shoulder is a self-limiting condition that usually lasts for a few months but can sometimes take more than 1 year to resolve and its resolution may be expedited by IA corticosteroid. This should be offered at first contact, and an informed decision should be made by the patient after the risks and alternative therapies are presented to them. In the future, other interventions that have shown promising results and currently have inadequate evidence for definitive conclusions (eg, MUA, ACR, specific types of electrotherapy and mobilizations) should be assessed with large, well-designed randomized studies. Finally, future studies should include subgroup analyses assessing the effectiveness of specific interventions on frozen shoulder of different chronicity and stage.

Notes

Supplement.

eTable 1. Explanation of the Components of the GRADE Tool and How They Were Assessed

eTable 2. Risk of Bias Assessments

eTable 3. Results of Comparisons of Interventions Assessed by Fewer Than 3 Studies and Were Not Pooled Qualitatively or Quantitatively

eTable 4. Results of Grading of the Certainty of Evidence According to the GRADE Tool for Each Comparison of Interventions

eTable 5. Results of Statistical Inconsistency Assessment for Each Pairwise Meta-analysis

eFigure 1. Results of Pairwise Meta-analyses with Respective Mean Differences for Early Short-term Outcomes

eFigure 2. Results of Pairwise Meta-analyses With Respective Mean Differences for Late Short-term Outcomes

eFigure 3. Results of Pairwise Meta-analyses With Respective Mean Differences for Mid-term Outcomes

eFigure 4. Results of Pairwise Meta-analyses With Respective Mean Differences for Function

eFigure 5. TSA Results for IA Corticosteroid vs No Treatment or Placebo for Early Short-term Pain

eFigure 6. TSA Results for IA Corticosteroid vs No Treatment or Placebo for Late Short-term Pain

eFigure 7. Network Forest Plots With Consistency Test for Late Short-term Pain

eFigure 8. Network Forest Plots With Consistency Test for Mid-term Pain

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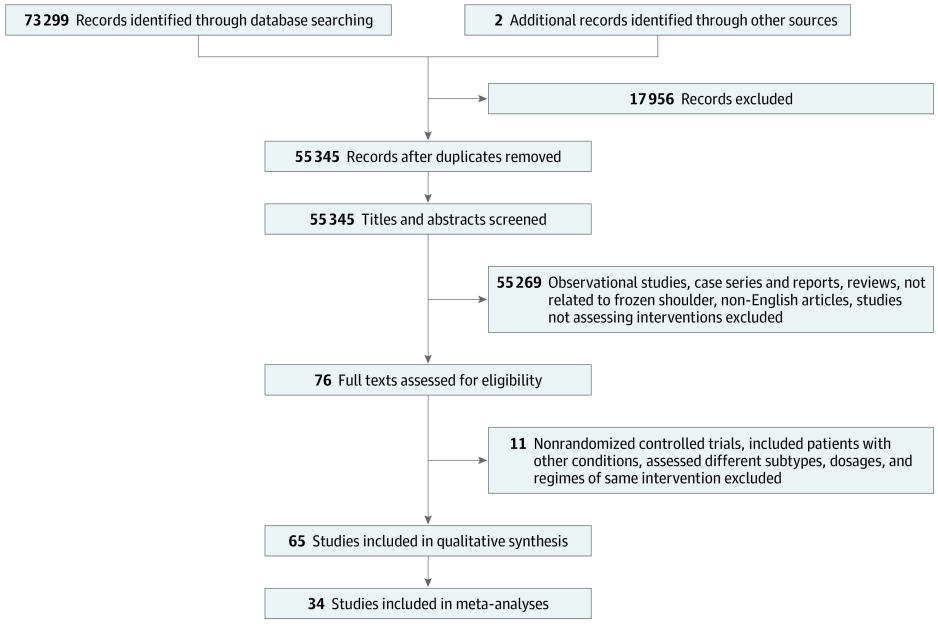
Figures and Tables

Figure 1.



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Flow Diagram Summarizing the Article Selection Process

Table 1.

Main Characteristics of Populations, Interventions, and Outcome Measures of Included Randomized Trials

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Abbreviations: ABD, abduction; ACR, arthroscopic capsular release; AROM, active range of movement; ASES, American Shoulder and Elbow Surgeons questionnaire; BPI-SF, Brief Pain Inventory–Short Form; CM, Constant-Murley score; DASH, Disabilities of the Arm, Shoulder, and Hand questionnaire; EA, electroacupuncture; ELE, elevation; EQ-5D, Euro-Qol–5 Dimensions questionnaire; ER, external rotation; ESWT, extracorporeal shock wave therapy; EXT, extension; FL, flexion; HAQ, Health Assessment Questionnaire; IA, intra-articular; IFE, interferential electrotherapy; IR, internal rotation; IRR, infrared radiotherapy; LA, local anesthetic; MPQ, McGill Pain Questionnaire; MUA, manipulation under anesthesia; NPRS, numerical pain rating scale; NSAID, nonsteroidal anti-

inflammatory drug; OSS, Oxford Shoulder Score; PET, problem elicitation technique; PNF, proprioceptive neuromuscular facilitations; PROM, passive range of movement; qDASH, quick DASH; QoL, quality of life; SA, subacromial; SDQ, Shoulder Disabilities Questionnaire; SF-36, 36-item short-form survey; SPADI, Shoulder Pain and Disability Index; SRQ, self-reporting questionnaire; SST, Simple Shoulder Test; TDP, transcutaneous infrared thermotherapy; TENS, transcutaneous electrical nerve stimulation; UCLA, University of California Los Angeles questionnaire; US, ultrasound; VAS, visual analog scale.

[a]Studies included in meta-analyses.

Table 2.

Results of Pairwise Comparisons of Interventions of the Included Studies

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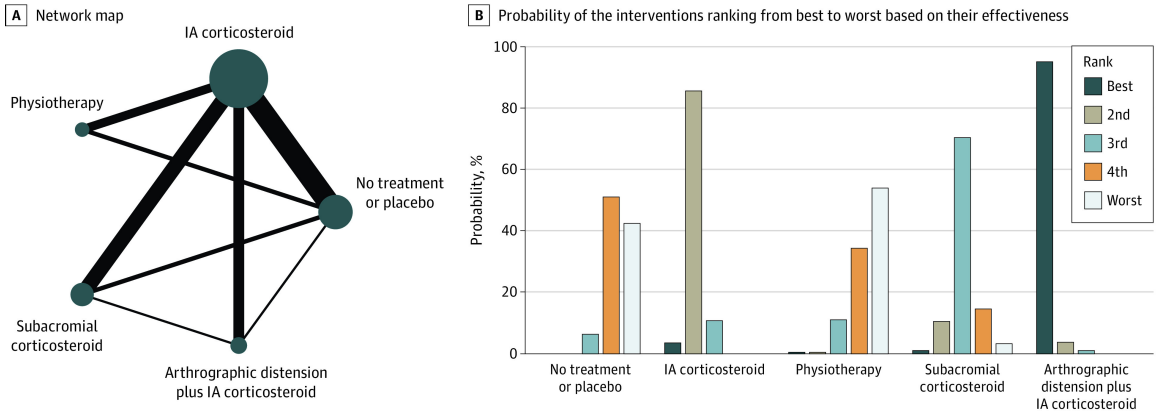
Abbreviations: ABD, abduction; ER, external rotation; ESWT, extracorporeal shock wave therapy; FL, flexion; IA, intra-articular; NA, not applicable; QoL, quality of life; ROM, range of movement; SA, subacromial.

[a]Meta-analysis undertaken.

[b]Results of meta-analysis clinically and statistically significant.

[c]Meta-analysis abandoned because of very high statistical inconsistency ($I^2 > 75\%$).

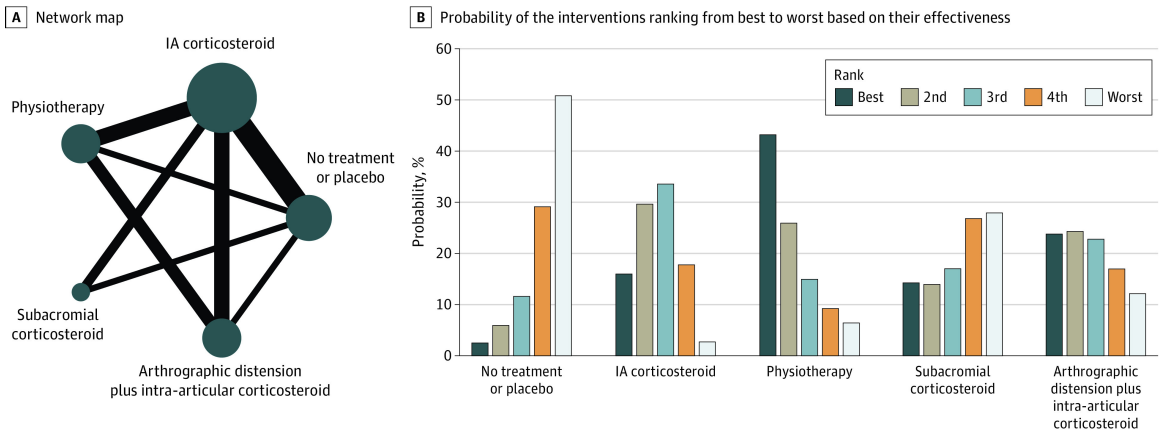
Figure 2.



Results of Network Analysis for Pain at Late Short-term (8-12 weeks) Follow-up

A, The size of the circles denotes the contribution of participants in each intervention and the thickness of the lines between circles represents the contribution of studies comparing the two interventions. B, The bar graph shows the probability of the 6 interventions ranking from best to worst based on their effectiveness. IA indicates intra-articular.

Figure 3.



Results of Network Analysis for Pain at Mid-term (4-6 months) Follow-up

A, The size of the circles denotes the contribution of participants in each intervention and the thickness of the lines between circles represents the contribution of studies comparing the two interventions. B, The bar graph shows the probability of the 6 interventions ranking from best to worst based on their effectiveness. IA indicates intra-articular.