Title Page

BESS Patient Care Pathway: Frozen Shoulder

Keywords:

Frozen Shoulder

Adhesive Capsulitis

Guideline

Physiotherapy

Hydrodistension; hydrodilatation

Manipulation under anaesthesia

Steroid

Arthroscopic Capsular Release

Abstract

Background

Current guidelines from the British Elbow and Shoulder Society (BESS) were published in 2015 for managing frozen shoulder in the primary and secondary care setting. Updated guidelines have been developed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) methodology.

Methods

A multi-disciplinary BESS Working Group defined key management questions based on agreed outcome measures and time points. A literature search, conducted up to March 2023 following PRISMA guidelines, identified randomised controlled trials, systematic reviews, and meta-analyses. Quality assessments were performed using the GRADE Decision Framework, considering bias, imprecision, indirectness, and inconsistency. Data were extracted for meta-analysis. In the absence of high-quality trials, narrative reviews were created.

Results

Consensus opinions produced statements based on the quality and volume of evidence and the magnitude of desirable and undesirable effects. These statements form a comprehensive framework for managing frozen shoulder.

Discussion

This updated guideline provides evidence-based guidance for managing frozen shoulder and identifies key areas for future research.

Introduction

Frozen shoulder, also known as adhesive capsulitis, is a painful debilitating condition with insidious onset, typically leading to stiffness and disability in the shoulder, which lasts over 3 months.[1] The cumulative incidence of frozen shoulder is 2.4/1000 per year,[2] with the prevalence estimated to be between 2% and 5%.[3] It typically affects women between the ages of 45 and 60, with a peak age of 56.[4-7] Hormonal changes in peri-menopausal women are thought to contribute to the increased prevalence, although a causal link has not been identified.[8] The non-dominant arm has an increased risk of being affected, although 6-17% of patients develop contralateral frozen shoulder within 5 years.[6] The strongest association of frozen shoulder is with diabetes mellitus, where an incidence of 10.8% was found in patients with diabetes compared to 2.3% in patients without diabetes.[9] Other co-morbidities such as hypothyroidism, Dupuytren's disease, Parkinson's disease, osteoporosis, stroke, hyperlipidaemia and patients having undergone cardiac or neurosurgery have also been associated.[1, 5] Three overlapping stages of frozen shoulder have been described as painful, freezing and thawing.[10] However, owing to considerable overlap between stages, there is highly variable reference to the distinct stages in the literature presented, and its use in guidelines for treatment decision-making is limited.[11]

Frozen shoulder is a clinical diagnosis based on history and examination, commonly presenting as slow onset of pain near the deltoid insertion combined with a disproportionately severe loss of passive external rotation.[1] Routine radiographs for suspected frozen shoulder have been shown to have a low pick up rate for other pathology (osteoarthritis or tumours).[12] However it has been shown that, in patients age > 40

presenting with pain and stiffness, that an underlying tumour can be misdiagnosed as frozen shoulder, albeit with a low incidence.[13]

Frozen shoulder is a self-resolving pathology.[11] Therefore treatment goals are centred around improving pain and function as quickly as possible, to the patient's acceptable level. This underlies the need for shared decision-making in treating frozen shoulder.

Two national guidelines for the treatment of frozen shoulder exist in the United Kingdom.[1, 11] Guidelines from the British Elbow and Surgery Society (BESS) were last published in 2015,[1] before more recent multi-centred randomised controlled trials were published.[14] The National Institute for Health and Care Excellence (NICE) guidelines were updated in 2022,[11] but targeted` primary care only, without discussing treatment delivered in secondary care. Therefore, the BESS Frozen Shoulder Working Group therefore agreed it is appropriate to produce an up-to-date review of treatment options for frozen shoulder using a modern guideline methodology for both primary and secondary care.

Methods

UK-based shoulder surgeons, surgical trainees, specialist physiotherapists, primary care physicians and consultant radiologists were approached and voluntarily agreed to form the working group. Members were identified either as part of the BESS research committee or had expressed interest in reviewing literature in this field. The Working Group agreed on key

questions to frame the management of frozen shoulder in the Population, Intervention, Control and Outcomes (PICO) format (Table 1). Based on these questions, a search was performed on MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials for prospective comparative studies was performed. The literature search used the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) methodology.[15] No limitations on language or publication dates were placed, although untranslatable text was later excluded. Case-control and non-comparative studies were excluded. Publications were limited to cohort studies, randomised controlled trials (RCTs), systematic reviews and meta-analyses. The search data included all publications up until August 2023. Data was extracted to Covidence, where two authors performed primary abstract screening and secondary full-text screening. If there was a discrepancy, a third author reviewed the paper to assess for inclusion.

Data Extraction. According to the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) methodology,[16] data relevant to each PICO was extracted to Summary of Findings tables based on pre-determined specific outcome-measures. The data extracted included study size, outcome effect size and risk of bias assessment using the RoB-2 tool (Cochrane).[17]

Statistical Analysis. Where multiple studies examined identical outcomes, the mean difference was pooled, and random effect meta-analyses were performed, to minimise heterogeneity. If different outcome scores were used, a standardised mean difference was calculated. SPSS (M Corp. Released 2021. IBM SPSS Statistics for Macintosh, Version 28.0.

Armonk, NY: IBM Corp) and Meta-Mar (Ashkan Beheshti, 2018, https://www.meta-mar.com/) were used for analyses. A narrative review with cohort studies was performed, where RCTS were absent or had incomplete data to answer a PICO,.

Quality Assessment. Each outcome underwent a certainty assessment using the GRADE Evidence to Decision framework[16] to determine the confidence that each effect estimate reflected the actual effect. This assessment was based on (1) the risk of bias, (2) inconsistency, (3) imprecision, and (4) indirectness.

Formulation of Recommendations. Four key factors based on GRADE, influenced the direction and strength of the recommendations:

- balance between desirable and undesirable outcomes,
- confidence in the effect of an intervention on essential outcomes,
- values and preferences of an intervention,
- resource allocation.

Recommendations were denoted as either 'for' or 'against', with the certainty being denoted as 'strong' or 'weak'. Where insufficient evidence was available to guide a direction of recommendation, this was denoted as 'neutral'. Recommendations were agreed upon by discussion within the multidisciplinary working group, to reach an unanimous consensus on the direction and strength of the recommendation based on the literature analysis.

Summary of Literature Review

A total of 116 studies were eligible for this review. The PRISMA flowchart of the literature review conducted is seen in Figure 1.

The group agreed on summary statements based on each PICO (Table 2). Based on this evidence, a flowchart was created (Figure 2). Summary of Findings tables can be found in the supplementary data.

Evidence-based on PICO questions

PICO 1: Does in-person physiotherapy improve symptoms faster than home exercises / single session physiotherapy / natural history in patients with frozen shoulder?

There were no randomised trials comparing physiotherapy to natural history over time. Two studies compared physiotherapy to a placebo glenohumeral joint injection.[18, 19] However, these were excluded from this PICO as the working group determined that a placebo injection was not the same as natural history. A single randomised controlled trial compared hospital-based exercise classes to in-person multimodal physiotherapy and home exercises.[20] The study found faster recovery and greater improvement in pain and function with hospital-based exercise classes. However, the study was underpowered.

Recommendations. It is unknown whether supervised physiotherapy provides any greater benefit than the natural history of a frozen shoulder. Recommendations can not be made

due to the lack of evidence. There is low certainty evidence that hospital-based group exercise class may lead to a faster recovery and greater improvement in pain and function than in-person multimodal physiotherapy or home exercises.

Suggestions for future research. There is a need for well-designed studies to:

- Compare physiotherapy to natural history for people with frozen shoulder.
- Compare in-person physiotherapy to home exercise / single-session physiotherapy / self-management for people with frozen shoulder.

PICO 2: Is in-person physiotherapy following Percutaneous or Surgical Intervention beneficial for people with Frozen Shoulder?

Physiotherapy following corticosteroid injection. Three RCTs comparing physiotherapy to no physiotherapy following glenohumeral corticosteroid injection were meta-analysed.[18, 19, 21] There is low certainty that in-person physiotherapy following corticosteroid injection results in improvement in external rotation, pain and disability at 6 weeks after injection. There is no evidence for a difference at 6 months in pain and disability.

Physiotherapy following glenohumeral joint distension. Four RCTs related to the role of physiotherapy following glenohumeral joint distension were identified but could not be meta-analysed due to the paucity of data, thus a narrative review was performed.[22-25] Buchbinder et al compared in-person physiotherapy to a sham intervention, finding no difference in pain, function or quality of life, but improved shoulder range of movement at 6

weeks, sustained at 6 months.[22] Kwak et al compared in-person physiotherapy to home exercise, finding a greater short-term improvement in shoulder range of movement up to 6 weeks from in-person physiotherapy. However, there was no difference between groups from 12 weeks up to one year.[24] An RCT comparing physiotherapy to no physiotherapy showed improvements in both groups, but this was underpowered and lacked data analysis.[23] Robinson et al compared in-person physiotherapy to a self-directed home exercise program, finding no difference in primary or secondary outcomes at any time point up to one year.[25] The trial was underpowered, so the conclusion should be interpreted with caution.

Recommendations:

- Current evidence, although low certainty, suggests that in-person physiotherapy should be considered following corticosteroid injection in the treatment of people with frozen shoulders, as it may provide a low-risk short-term benefit.
- The current evidence for in-person physiotherapy after glenohumeral distension to treat a frozen shoulder is limited. Although it may result in greater short-term improvement in the range of movement, it is unlikely to influence the long-term treatment outcome.

Suggestions for future research. There is a need for well-designed studies to:

- Determine the effect of physiotherapy following glenohumeral joint injections (low and high volume).

PICO 3: Do low volume (<20mls) gleno-humeral joint steroid injections expedite improvements in pain and function in FS compared to natural history or physiotherapy

7 RCTs were identified.[26-33] Although there was heterogeneity in the outcome measures used, the use of VAS scores and passive range of motion assessment demonstrated consistency. Meta-analyses at 6 and 12 months was not possible owing to limited studies assessing these longer-term outcomes.

The effect of steroid injections over physiotherapy alone demonstrated improvement up to 3 months in pain scores and range of motion (forward flexion, abduction and external rotation). The threshold for this representing a clinically important difference is difficult to assess, but this data demonstrated consistency, directness, and no significant risk of bias. The meta-analysis performed was supported by sufficient number of papers and participants. The short-term effect of steroids over physiotherapy on PROMs other than pain had limited evidence owing to heterogeneity of outcomes.

There was no difference between patients who had low volume steroid injection and those that had physiotherapy alone in pain, range of motion and PROMs in the long term after 3 months. Long term outcomes were less studied limiting the strength of this evidence.

Recommendations:

- Glenohumeral joint steroid injections should be considered as part of the non-operative treatment pathway for primary frozen shoulder in both primary and secondary care for short term symptom control.

- Long term benefit of glenohumeral joint steroid injections after 3 months is not seen, although the strength of this evidence is limited.

Suggestions for future research. There is a need for well-designed studies to:

- Determine the role of glenohumeral steroid injections in patients with early or late presentation of frozen shoulder.
- Determine the role of glenohumeral steroid injections and alternative injections in patients with specific risk factors such as diabetes.

PICO 4: Do high volume (>=20mls) gleno-humeral joint steroid injections (also referred to as "hydrodilatation" or "hydrodistention") expedite improvements in pain and function in FS compared to natural history or physiotherapy?

Three randomised controlled studies and one non-randomised prospective comparative study. [23, 34-36] Data is limited by a sparsity of randomised controlled trials to date investigating hydrodilatation versus physiotherapy or natural progression. The results from this meta-analysis found statistically significant early improvements in abduction following hydrodilatation at up to 3 months compared to conservative management (p=0.0006, high certainty). The remaining analyses showed improvement in pain, disability and external rotation following hydrodilatation at up to 3 months (moderate certainty), however, these did not reach statistical significance with data limited by high heterogeneity. Meta-analysis was not possible to assess long-term outcomes.

Elleuch et al reported significant improvements in pain, function, and range of motion at 1 week with these benefits sustained up to 12 months in their prospective, non-randomised study. [35] Sharma et al did not demonstrate any statistically significant difference at 12 months in their RCT. [36]

Transient flushing and after-pain were reported in 14% of patients following hydrodilatation. [36] There were no other adverse events secondary to hydrodilatation reported in any of the included studies.

Recommendations:

- There is evidence to support the use of hydrodilatation over physiotherapy or supportive therapy for frozen shoulder for short to medium-term improvement in pain and abduction range of motion.
- There is insufficient evidence to comment on the long-term outcomes from hydrodilatation versus physiotherapy or supportive therapy.

PICO 5: Is low volume glenohumeral joint steroid injection beneficial compared to low volume placebo or local anaesthetic injection for frozen shoulder?

Three studies were included in the synthesis of evidence and meta-analyses.[37-39] Saline injections were used as the control groups in two studies and local anaesthetic in the other study. A fourth RCT was available but provided outcomes as difference from baseline rather than an actual number for the outcome measures and thus was excluded.[19]

Range of motion (external rotation), a PROM and a VAS score were measured for all 3 RCTs. However, the time intervals differed, except for the 3 month post-interventional point. This time point was used for the meta-analysis across all three studies. Mean difference at 3 months for VAS and PROMS showed no difference between the interventions. Mean difference in external rotation did improve more with steroid injection. With moderate bias in study designs, a moderate level of caution is required in drawing conclusions from this. Consideration should be taken with these findings, as they demonstrate inconsistency, when compared to PICO 3 and 6, both of which showed evidence for short term improvement with steroid injections.

No serious adverse events were reported in two studies,[39, 40] and serious adverse events were not mentioned in the third article.[37]

Recommendations. Meta-analysis found an improvement in external rotation at 3 months with steroid injection compared to placebo or saline, but no difference with VAS or PROMS outcomes. Analysis for other time points was not possible due to the heterogenicity of time points used in the studies.

Whilst meta-analysis of available placebo-controlled trials showed limited differences between steroid and placebo injections at 3 months, this finding should be interpreted cautiously given:

- The small number of studies available for this specific comparison
- The conflicting evidence from PICO 3 showing benefit over physiotherapy alone

- The possibility that even placebo injections may have therapeutic benefit through capsular distension

PICO 6: Do low volume (<=20mls) freehand gleno-humeral joint steroid injections expedite improvements in pain and function in FS compared to US guided low volume injections?

Four randomised controlled studies were identified.[41-44] Meta-analyses was performed accounting for unstandardised mean differences. As data was presented differently between papers (2 studies presenting absolute changes as opposed to mean score), it was not possible to pool all the data. Lee et al showed that improvements in pain and ROM after 1 and 4 weeks were more prominent in the US-guided group, but the differences were not statistically significant, except for the changes in extension where the improvements were significantly higher in the US guided group (p = 0.01).[41] Raeissadat et al showed statistically significant improvement in flexion in the US-guided group compared to the landmark-guided group for the first 3 weeks (P=.039 in the first week, P=.001 in the second week, P=.025 in the third week).[43] However, there were no significant differences between the 2 groups from the fourth week until the end of the study. It was not possible to pool the function data from the two studies as one study[41] presented data as general function of shoulder and second study[43] presented Oxford shoulder score but no difference was identified between the two groups.

Pooled data demonstrate that there is no difference in range of motion, pain or function between ultrasound guided or blinded glenohumeral joint injections. Lower quality

evidence suggests that ultrasound guided injection may result in slightly reduced pain in the first week but certainty is low. The evidence is limited by a lack of high-quality studies, and the lack of studies using validated functional outcome measures.

Recommendations. The available evidence suggests that low volume steroid injections, however delivered, are associated with pain relief and improved range of movement (see PICO 3) but there is no difference in clinical outcome if this injection is delivered ultrasound guided or freehand.

PICO 7: Do high volume (>=20mls) gleno-humeral joint steroid injections expedite improvements in pain and function in FS compared to low volume gleno-humeral joint steroid injections?

The authors identified 13 randomised controlled trials addressing this subject, embedded within two contemporary systematic reviews with meta-analysis. Saltychev et al included 6 studies assessing high volume injections with steroid to low volume injections with steroid. [32, 40, 45-49] Their inclusion criteria included stiffness of any cause, including osteoarthritis, and the meta-analysis combined all follow-up timepoints. For these reasons the data was not used to assess the treatment effect, however their comprehensive risk of bias review of individual studies informed the data certainty assessment.

Poku et al included 8 RCTs studies of high volume injections with steroid to low volume injections with steroid.[50-52] Follow-up was quantified as early (<6 weeks) and late (>6 weeks).

All studies had some degree of blinding so risk of bias was low. Some of the studies were underpowered. There was variability with treatment regimes (one vs three injections), follow-up period and outcome measures. The benefit of high volume was an improvement in pain and disability in the initial outcomes which was not seen at the end of the study period. However, overall, an improvement with external rotation was seen with high volume which was maintained at final follow-up. Meta-analysis of longer-term follow-up (12 months) was not possible as most studies did not run beyond 6 months.

Recommendations. The available evidence suggests that High volume (≥20mls) glenohumeral joint steroid injection may provide an improvement in shoulder disability and pain (quantified by patient reported outcomes), and external rotation when compared to low volume (≤20mls) gleno-humeral joint steroid injection in the short term for the treatment of frozen shoulder.

Suggestions for future research. There is a need for well-designed studies to determine the benefit of hydrodistension in the management of frozen shoulder, versus low volume steroid injection, in terms of clinical and cost effectiveness.

PICO 8: Do high-volume (>=20mls) glenohumeral joint steroid injections expedite improvements in pain and function versus high-volume placebo (saline) injection or local anaesthetic-only injections?

There were no studies that fulfilled the criteria to assess if the high-volume glenohumeral joint steroid injections expedite improvements in pain and function versus high-volume placebo (saline) injections or local anaesthetic-only injections. A recent systematic review has highlighted the potential value of non-steroid injections in the treatment of frozen shoulder and these may be of particular relevance to patients more susceptible to the side effects of steroid injections (eg: Diabetics).[53]

Recommendations. Due to a lack of randomised controlled trials meeting the criteria and no eligible papers for review, no specific recommendations can be provided based on the available evidence.

Suggestions for future research. There is a need for a well-designed study to assess the role of steroids, and their alternative, within high-volume glenohumeral injections.

PICO 9: Is MUA (and steroid injection) more effective than non-operative treatment in patients with frozen shoulder.

Three randomised controlled studies [14, 54, 55] and one meta-analysis [56] were identified addressing this subject. The meta-analysis incorporated all the three randomised controlled trials identified independently and a decision was made to use this meta-analysis of current best evidence.

The authors of the meta-analysis [56] perceived the Jacobs study to incorporate a hydrodilatation as part of the steroid injection and is not part of the specific question for this particular PICO.[54] They also assessed bias of the papers included with UK FROST having a low risk of bias, except for performance and detection bias.[14] Kivimaki et al had slightly more concern with performance, detection, attrition, and possible other bias.[55]

No serious adverse events were reported in the Kivimaki paper.[55] UK FROST reported two serious adverse events (1%) in the MUA group, including 1 septic arthritis (0.5%) and 1 accident and emergency attendance.[14]

This appears to be a good quality meta-analysis of the available literature. They have performed a risk of bias assessment on both papers with UK FROST appearing to be the most robust data. Both groups demonstrated improvement in OSS and pain scores, but mean difference for all presented outcome measures showed no difference between the interventions. It should be noted, that there was a 15% crossover in the non-operative group, of which a third had a subsequent MUA.

A further economic analysis as part of UK FROST, highlighted that despite MUA being more expensive, it was more likely to represent higher cost-effectiveness per quality-adjusted life year than physiotherapy alone.

Recommendations.

We recommend that MUA should be considered as a viable treatment option, particularly when considering its cost-effectiveness. The choice between MUA and conservative

treatment should be based on shared decision-making, taking into account patient preference, local waiting times for physiotherapy versus surgical intervention, and the understanding that while final outcomes may be similar, the pathway to achieving these outcomes may differ. Further research is needed to clarify the role of MUA in achieving earlier symptomatic improvement.

PICO 10: Is arthroscopic release more effective than non-operative treatment in patients with FS?

Four studies were included in the synthesis of evidence.[14, 57-59] Physiotherapy and steroid injection were each used as the control groups in two studies. A fifth RCT was available but had no numerical data available and thus was excluded.[60] Due to missing data and heterogeneity in outcome use and time intervals, pooled estimates were not produced. A narrative assessment of treatment effect was therefore undertaken.

No adverse events were reported in either groups in either the Smiterman or De Carli paper, but the serious adverse events rate in UK FROST was 4% (ACR) vs 0% (physiotherapy).

Time intervals for range of motion data differed. Mean difference at 3 months and 12 months for forward flexion, abduction and external rotation was higher in arthroscopic capsular release than either steroid or physiotherapy. With moderate bias in study designs, effects from single studies and a lack of confidence interval, a high level of caution is required in drawing conclusions from this.

Within the RCTs available, there was heterogeneity in the outcome measures studied. Of the trials identified, three were felt to be at a moderate risk of bias. UK FROST was the only appropriately powered RCT and was deemed to be of low risk of bias.[14] The results from this study found statistically poorer 3 month outcomes for ACR compared to physiotherapy as quantified by the Oxford Shoulder Score. At 6 months, no difference was observed but at 12 months a statistical difference in favour of ACR was observed. Importantly, neither the 3- or 12-month outcomes exceeded the minimally clinically important difference. Analysis was 'per randomisation', with 15% of the physiotherapy group requiring further treatment. Outcomes based on chronicity of symptoms were not assessed.

The remaining studies provided limited additional evidence. Although mean difference scores were calculated which demonstrated consistency with improvement in pain scores and PROMs at 12 months, also demonstrated by Zhu,[61] the lack of comprehensive reporting of effect sizes, confidence intervals and moderate risk of bias means that these results should be treated with caution. Meta-analyses, if possible is likely to demonstrate heavy weighting towards UK FROST.

No studies identified the effect of the intervention or control in the short term (<1 week). The impact of diabetes or refractory frozen shoulder could not be assessed as no studies performed additional subgroup analysis.

Recommendations:

- Shared decision making with current best evidence should be undertaken prior to arthroscopic capsular release, as outcomes do not suggest a superior minimum clinical importance improvement at 12 months, compared to alternative treatment.
- Current research has not addressed confounders such as acute versus chronic frozen shoulder, diabetic status, or the presence of concomitant pathology.

PICO 11: Is arthroscopic release more effective than hydrodilatation in patients with FS?

A total of 1 study was identified.[62] There is insufficient evidence at present to determine whether ACR is more effective than HD in treatment of frozen shoulder. It should be noted that the risk profile between both interventions have not been directly compared in a single study, but the serious adverse events rate for ACR was 4% in UKFROST,[14] whereas studies included in PICO 4 and 7 showed a low serious risk profile for HD.

Recommendations. Patients should be aware that there is insufficient evidence at present to recommend one treatment over another, and the risks and benefits of each.

Future Research. Initially, determine optimum method of hydrodilatation; volume, location of injection, method of delivery, dose of steroids, role of rupturing capsule, complications, recurrence rates, costs. Following this, an adequately powered RCT to include stage of disease, duration of symptoms and diabetes status. There is a need for well-designed studies to determine the benefit of arthroscopic release over hydrodistension in the management of frozen shoulder in terms of clinical and cost effectiveness.

Discussion

The recommendations made within this paper are based on the available evidence and through the conduct of the literature review it has become clear that there are notable deficiencies in the research which underpins the treatment of this very common, and often disabling condition.

The role of glenohumeral corticosteroid injections presents an interesting paradox in our findings. Whilst PICO 3 demonstrated clear benefit of steroid injection over physiotherapy alone in the short term, PICO 5 found limited difference between steroid and placebo injections at 3 months. This apparent contradiction may be explained by several factors. Firstly, the mechanical effect of any injection (steroid or placebo) may itself be therapeutic through capsular distension. Secondly, the placebo-controlled trials were fewer in number and generally smaller than those comparing injection to physiotherapy. Additionally, PICO 6 demonstrated that the method of delivery (ultrasound-guided versus freehand) did not significantly impact outcomes, suggesting that the act of injection itself may be important. These findings, when taken together, support the use of glenohumeral injection as a therapeutic intervention, whilst highlighting the complexity of determining the relative contributions of mechanical distension versus pharmacological effect.

Discussions about optimal management extend further than the work presented here, with questions raised about the optimal contents of any injectate used in the treatment of frozen shoulder and this question has been addressed in a recent systematic review [53].

The recommendations in these guidelines are based on systematic review of the available evidence, utilising the GRADE methodology to assess quality and strength of evidence. While we acknowledge significant practical challenges in healthcare delivery, including variable waiting times for different treatment modalities, these guidelines intentionally focus on clinical effectiveness rather than service delivery constraints. This approach ensures the recommendations remain applicable across different healthcare settings and timeframes. The pragmatic implementation of these guidelines, including considerations of local resource availability and access times, must be determined by local care teams. Only UK FROST specifically incorporated service delivery considerations into its methodology, finding that despite being more expensive, MUA was more likely to be cost-effective per quality-adjusted life year than physiotherapy alone. However, the interpretation of timing-dependent outcomes from this and other studies could support different treatment approaches depending on local service delivery capabilities and costs per treatment in different settings. These guidelines is to present the evidence for clinical effectiveness, allowing healthcare providers to develop local protocols that optimise patient care within their specific service delivery constraints. Future research would benefit from more explicit consideration of how treatment timing and access affect outcomes[63], as this could help inform both clinical recommendations and service delivery planning.

The work presented here aims to deliver an evidence-based algorithm treatment that is applicable 'today' whilst highlighting the strength and fragility of some of the data on which these recommendations are based on, and importantly highlight key areas for future research.

Declarations

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Contributorship. AA[1], AA[2], CC, LW were involved in performing the literature search. All other authors and members of the Working Group were involved in data extraction, analysing and writing up of specific set PICO questions. Recommendations were set as an

agreement between all members. All members reviewed the manuscript. In addition, NR and SG were responsible for designing the review and writing up the manuscript.

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Disclaimer

The information set out in this publication is intended for use as a guide of a general nature and may not be relevant to a particular patient's circumstances. This publication is not exhaustive of the subject matter and when implementing any recommendations contained in this publication, please exercise own independent judgement or seek appropriate professional advice relevant to own particular circumstances. These recommendations cannot guarantee discharge of the duty of care owed to patients.

The text is directed to health professionals possessing appropriate qualifications and skills in ascertaining and discharging their professional (including legal) duties. It is not to be regarded as clinical advice and is no substitute for a full examination and consideration of medical history in reaching a diagnosis and treatment.

References

1. Rangan A, Goodchild L, Gibson J, et al. BESS/BOA Patient Care Pathways: Frozen Shoulder. *Shoulder and Elbow* 2015; 7: 299-307.

2. van der Windt DA, Koes BW, de Jong BA, et al. Shoulder disorders in general practice: incidence, patient characteristics, and management. *Ann Rheum Dis* 1995; 54: 959-964. DOI: 10.1136/ard.54.12.959.
3. Hsu JE, Anakwenze OA, Warrender WJ, et al. Current review of adhesive capsulitis. *J Shoulder Elbow Surg* 2011; 20: 502-514. 20101216. DOI: 10.1016/j.jse.2010.08.023.
4. Gray M, Wallace A and Aldridge S. Assessment of shoulder pain for non-specialists. *BMJ (Clinical research ed)* 2016; 355: i5783. 20161207. DOI: 10.1136/bmj.i5783.
5. Hand C, Clipsham K, Rees JL, et al. Long-term outcome of frozen shoulder. *J Shoulder Elbow Surg* 2008; 17: 231-236. 20071112. DOI: 10.1016/j.jse.2007.05.009.
6. Rizk TE and Pinals RS. Frozen shoulder. *Semin Arthritis Rheum* 1982; 11: 440-452. DOI: 10.1016/0049-0172(82)90030-0.
7. Kelley MJ, Shaffer MA, Kuhn JE, et al. Shoulder pain and mobility deficits: adhesive capsulitis. *J Orthop Sports Phys Ther* 2013; 43: A1-31. 20130430. DOI: 10.2519/jospt.2013.0302.
8. Kraal T, Lübbers J, van den Bekerom MPJ, et al. The puzzling pathophysiology of frozen shoulders - a scoping review. *J Exp Orthop* 2020; 7: 91. 20201118. DOI: 10.1186/s40634-020-00307-w.
9. Bridgman JF. Periarthritis of the shoulder and diabetes mellitus. *Ann Rheum Dis* 1972; 31: 69-71. DOI: 10.1136/ard.31.1.69.
10. Dias R, Cutts S and Massoud S. Frozen shoulder. *BMJ (Clinical research ed)* 2005; 331: 1453-1456. DOI: 10.1136/bmj.331.7530.1453.
11. NICE. *Shoulder Pain: Scenario - Frozen Shoulder*. Nov' 2022 2022. https://cks.nice.org.uk/topics/shoulder-pain/management/frozen-shoulder/.
12. Roberts S, Dearne R, Keen S, et al. Routine X-rays for suspected frozen shoulder offer little over diagnosis based on history and clinical examination alone. *Musculoskeletal Care* 2019; 17: 288-292. 20190329. DOI: 10.1002/msc.1396.
13. Sano H, Hatori M, Mineta M, et al. Tumors masked as frozen shoulders: a retrospective analysis. *J Shoulder Elbow Surg* 2010; 19: 262-266. 20090701. DOI: 10.1016/j.jse.2009.05.010.
14. Rangan A, Brealey S, Keding A, et al. Management of adults with primary frozen shoulder in secondary care (UK FROST): a multicentre, pragmatic, three-arm, superiority randomised clinical trial. *Lancet (London, England)* 2020; 396. DOI: 10.1016/S0140-6736(20)31965-6.
15. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ (Clinical research ed)* 2021; 372: n71. 20210329. DOI: 10.1136/bmj.n71.
16. Alonso-Coello P, Oxman AD, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. *BMJ (Clinical research ed)* 2016; 353: i2089. 20160630. DOI: 10.1136/bmj.i2089.
17. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ (Clinical research ed)* 2019; 366: l4898. 2019/08/30. DOI: 10.1136/bmj.l4898.
18. Carette S, Moffet H, Tardif J, et al. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder: a placebo-controlled trial. *Arthritis Rheum* 2003; 48: 829-838. 2003/03/13. DOI: 10.1002/art.10954.

19. Ryans I, Montgomery A, Galway R, et al. A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis. *Rheumatology (Oxford)* 2005; 44: 529-535. 2005/01/20. DOI: 10.1093/rheumatology/keh535.
20. Russell S, Jariwala A, Conlon R, et al. A blinded, randomized, controlled trial assessing conservative management strategies for frozen shoulder. *J Shoulder Elbow Surg* 2014; 23: 500-507. 2014/03/19. DOI: 10.1016/j.jse.2013.12.026.
21. Mobini M, Kashi Z, Bahar A, et al. Comparison of corticosteroid injections, physiotherapy, and combination therapy in treatment of frozen shoulder. *Pakistan Journal of Medical Science* 2012; 28.
22. Buchbinder R, Youd JM, Green S, et al. Efficacy and cost-effectiveness of physiotherapy following glenohumeral joint distension for adhesive capsulitis: a randomized trial. *Arthritis Rheum* 2007; 57: 1027-1037. 2007/08/01. DOI: 10.1002/art.22892.
23. Park SW, Lee HS and Kim JH. The effectiveness of intensive mobilization techniques combined with capsular distension for adhesive capsulitis of the shoulder. *J Phys Ther Sci* 2014; 26: 1767-1770. 2014/12/02. DOI: 10.1589/jpts.26.1767.
24. Kwak KI and Kim EK. The clinical effect of hydraulic distension plus manual therapy on patients with frozen shoulder. *J Phys Ther Sci* 2016; 28: 2393-2396. 2016/09/16. DOI: 10.1589/jpts.28.2393.
25. Robinson PM, Norris J and Roberts CP. Randomized controlled trial of supervised physiotherapy versus a home exercise program after hydrodilatation for the management of primary frozen shoulder. *J Shoulder Elbow Surg* 2017; 26: 757-765. 2017/03/21. DOI: 10.1016/j.jse.2017.01.012.
26. van der Windt DA, Koes B, Devillé W, et al. Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial. *BMJ* 1998; 7: 1292-1296.
27. Anjum R, Aggarwal J, Gautam R, et al. Evaluating the Outcome of Two Different Regimes in Adhesive Capsulitis: A Prospective Clinical Study. *Med Princ Pract*, 2020; 29: 225-230.
28. Ranalletta M, Rossi LA, Bongiovanni SL, et al. Corticosteroid Injections Accelerate Pain Relief and Recovery of Function Compared With Oral NSAIDs in Patients With Adhesive Capsulitis: A Randomized Controlled Trial. *Am J Sports Med* 2016; 44: 474 - 481.
29. Arslan S and Celiker R. Comparison of the efficacy of local corticosteroid injection and physical therapy for the treatment of adhesive capsulitis. *Rheumatol Int*, 2001; 21: 20-23.
30. Ahmad Khan RD, Shahzad K, Khan S, et al. Comparison of physiotherapy with and without intra-articular corticosteroid injection for treatment of frozen shoulder: A comparative study. *J Pak Med Assoc*, 2021; 71: S17-S21.
31. Dehghan A, Pishgooei N, Salami M, et al. Comparison between NSAID and intra-articular corticosteroid injection in frozen shoulder of diabetic patients; a randomized clinical trial. *Exp Clin Endocrinol Diabetes* 2013; 121: 75-79.
32. Sharma SP, Bærheim A, Moe-Nilssen R, et al. Adhesive capsulitis of the shoulder, treatment with corticosteroid, corticosteroid with distension or treatment-as-usual; a randomised controlled trial in primary care. *BMC Musculoskelet Disord* 2016; 26.
33. Roh YH, Yi S, Noh J, et al. Intra-articular corticosteroid injection in diabetic patients with adhesive capsulitis: a randomized controlled trial. *Knee Surg Sports Traumatol Arthrosc* 2012; 20: 1947-1952.

34. Buchbinder R, Green S, Forbes A, et al. Arthrographic joint distension with saline and steroid improves function and reduces pain in patients with painful stiff shoulder: results of a randomised, double blind, placebo controlled trial. *Ann Rheum Dis* 2004; 63: 302-309. 2004/02/14. DOI: 10.1136/ard.2002.004655.
35. Elleuch MH, Yahia A, Ghroubi S, et al. [The contribution of capsular distension to the treatment of primary adhesive capsulitis of the shoulder: a comparative study versus rehabilitation]. *Ann Readapt Med Phys* 2008; 51: 722-728. 2008/10/18. DOI: 10.1016/j.annrmp.2008.08.008.
36. Sharma SP, Bærheim A, Moe-Nilssen R, et al. Adhesive capsulitis of the shoulder, treatment with corticosteroid, corticosteroid with distension or treatment-as-usual; a randomised controlled trial in primary care. *BMC Musculoskelet Disord* 2016; 17: 232. 2016/05/28. DOI: 10.1186/s12891-016-1081-0.
37. Oh SH, Sung WS, Oh SH, et al. Comparative analysis of intra-articular injection of steroid and/or sodium hyaluronate in adhesive capsulitis: prospective, double-blind, randomized, placebo-controlled study. *JSES Int* 2021; 5: 1091-1104. 2021/11/13. DOI: 10.1016/j.jseint.2021.07.017.
38. Yoon SH, Lee HY, Lee HJ, et al. Optimal dose of intra-articular corticosteroids for adhesive capsulitis: a randomized, triple-blind, placebo-controlled trial. *Am J Sports Med* 2013; 41: 1133-1139. 2013/03/20. DOI: 10.1177/0363546513480475.
39. Bal A, Eksioglu E, Gulec B, et al. Effectiveness of corticosteroid injection in adhesive capsulitis. *Clin Rehabil* 2008; 22: 503-512. 2008/05/31. DOI: 10.1177/0269215508086179.
40. Yoon JP, Chung SW, Kim JE, et al. Intra-articular injection, subacromial injection, and hydrodilatation for primary frozen shoulder: a randomized clinical trial. *J Shoulder Elbow Surg* 2016; 25: 376-383. 2016/03/02. DOI: 10.1016/j.jse.2015.11.009.
41. Lee HJ, Lim KB, Kim DY, et al. Randomized controlled trial for efficacy of intra-articular injection for adhesive capsulitis: ultrasonography-guided versus blind technique. *Arch Phys Med Rehabil* 2009; 90: 1997-2002. 2009/12/09. DOI: 10.1016/j.apmr.2009.07.025.
42. Lee HJ, Ok JH, Park I, et al. A Randomized Comparative Study of Blind versus Ultrasound Guided Glenohumeral Joint Injection of Corticosteroids for Treatment of Shoulder Stiffness. *Clinics in Shoulder and Elbow* 2015; 18.
43. Raeissadat SA, Rayegani SM, Langroudi TF, et al. Comparing the accuracy and efficacy of ultrasound-guided versus blind injections of steroid in the glenohumeral joint in patients with shoulder adhesive capsulitis. *Clin Rheumatol* 2017; 36: 933-940. 2016/08/28. DOI: 10.1007/s10067-016-3393-8.
44. Cho CH, Min BW, Bae KC, et al. A prospective double-blind randomized trial on ultrasound-guided versus blind intra-articular corticosteroid injections for primary frozen shoulder. *Bone Joint J* 2021; 103-b: 353-359. 2021/02/02. DOI: 10.1302/0301-620x.103b2.Bjj-2020-0755.R1.
45. Saltychev M, Laimi K, Virolainen P, et al. Effectiveness of Hydrodilatation in Adhesive Capsulitis of Shoulder: A Systematic Review and Meta-Analysis. *Scand J Surg* 2018; 107: 285-293. 2018/05/17. DOI: 10.1177/1457496918772367.
46. Gam AN, Schydlowsky P, Rossel I, et al. Treatment of "frozen shoulder" with distension and glucorticoid compared with glucorticoid alone. A randomised controlled trial. *Scand J Rheumatol* 1998; 27: 425-430. 1998/12/17. DOI: 10.1080/030097498442244.
47. Park KD, Nam HS, Lee JK, et al. Treatment effects of ultrasound-guided capsular distension with hyaluronic acid in adhesive capsulitis of the shoulder. *Arch Phys Med Rehabil* 2013; 94: 264-270. 2012/10/16. DOI: 10.1016/j.apmr.2012.10.002.

48. Ahn JK, Kim J, Lee SJ, et al. Effects of Ultrasound-guided intra-articular ketorolac injection with capsular distension. *J Back Musculoskelet Rehabil* 2015; 28: 497-503. 2014/10/18. DOI: 10.3233/bmr-140546.
49. Lee DH, Yoon SH, Lee MY, et al. Capsule-Preserving Hydrodilatation With Corticosteroid Versus Corticosteroid Injection Alone in Refractory Adhesive Capsulitis of Shoulder: A Randomized Controlled Trial. *Arch Phys Med Rehabil* 2017; 98: 815-821. 2016/11/16. DOI: 10.1016/j.apmr.2016.10.012.
50. Poku D, Hassan R, Migliorini F, et al. Efficacy of hydrodilatation in frozen shoulder: a systematic review and meta-analysis. *Br Med Bull* 2023; 147: 121-147. 2023/07/27. DOI: 10.1093/bmb/ldad018.
51. Tveitå EK, Tariq R, Sesseng S, et al. Hydrodilatation, corticosteroids and adhesive capsulitis: a randomized controlled trial. *BMC Musculoskelet Disord* 2008; 9: 53. 2008/04/22. DOI: 10.1186/1471-2474-9-53.
52. Paruthikunnan SM, Shastry PN, Kadavigere R, et al. Intra-articular steroid for adhesive capsulitis: does hydrodilatation give any additional benefit? A randomized control trial. *Skeletal Radiol* 2020; 49: 795-803. 2019/12/18. DOI: 10.1007/s00256-019-03316-8.
53. Berner JE, Nicolaides M, Ali S, et al. Pharmacological interventions for early-stage frozen shoulder: a systematic review and network meta-analysis. *Rheumatology (Oxford)* 2024 20240327. DOI: 10.1093/rheumatology/keae176.
54. Jacobs LG, Smith MG, Khan SA, et al. Manipulation or intra-articular steroids in the management of adhesive capsulitis of the shoulder? A prospective randomized trial. *J Shoulder Elbow Surg* 2009; 18: 348-353. 2009/04/28. DOI: 10.1016/j.jse.2009.02.002.
55. Kivimäki J, Pohjolainen T, Malmivaara A, et al. Manipulation under anesthesia with home exercises versus home exercises alone in the treatment of frozen shoulder: a randomized, controlled trial with 125 patients. *J Shoulder Elbow Surg* 2007; 16: 722-726. 2007/10/13. DOI: 10.1016/j.jse.2007.02.125.
56. Rex SS, Kottam L, McDaid C, et al. Effectiveness of interventions for the management of primary frozen shoulder : a systematic review of randomized trials. *Bone Jt Open* 2021; 2: 773-784. 2021/09/25. DOI: 10.1302/2633-1462.29.Bjo-2021-0060.R1.
57. Mukherjee RN, Pandey RM, Nag HL, et al. Frozen shoulder - A prospective randomized clinical trial. *World J Orthop* 2017; 8: 394-399. 2017/06/02. DOI: 10.5312/wjo.v8.i5.394.
58. Smitherman JA, Struk AM, Cricchio M, et al. Arthroscopy and manipulation versus home therapy program in treatment of adhesive capsulitis of the shoulder: a prospective randomized study. *J Surg Orthop Adv* 2015; 24: 69-74. 2015/04/02.
59. De Carli A, Vadalà A, Perugia D, et al. Shoulder adhesive capsulitis: manipulation and arthroscopic arthrolysis or intra-articular steroid injections? *Int Orthop* 2012; 36: 101-106. 2011/08/13. DOI: 10.1007/s00264-011-1330-7.
60. Zhu Q, Jiang Y, Wang H, et al. Comparison of Intra-Articular Injection and Arthroscopic Capsular Release in Stages I and II of Primary Frozen Shoulder, a Randomized Clinical Trial. *International journal of gerontology* 2019; 13: 81-86.
61. Zhu Q, Jiang Y, Wang H, et al. Comparison of intra-articular injection and arthroscopic capsular release in stages i and II of primary frozen shoulder, a randomized clinical trial. *International journal of gerontology* 2019; 13: 81-86. Journal article. DOI: 10.6890/IJGE.201903-13(1).0016.

62. Gallacher S, Beazley JC, Evans J, et al. A randomized controlled trial of arthroscopic capsular release versus hydrodilatation in the treatment of primary frozen shoulder. *J Shoulder Elbow Surg* 2018; 27: 1401-1406. 2018/05/26. DOI: 10.1016/j.jse.2018.04.002.
63. Thomas W, Jenkins E, Owen J, et al. Treatment of frozen shoulder by manipulation under anaesthetic and injection: does the timing of treatment affect the outcome? *The Journal of bone and joint surgery British volume* 2011; 93. DOI: 10.1302/0301-620X.93B10.27224.