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# PRACTICE

## UNCERTAINTIES

# What is the most effective treatment for frozen shoulder?

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Frozen shoulder is a painful condition that most commonly affects people in their 50s,<sup>1 2</sup> and may limit daily activities and disturb sleep.<sup>3</sup> Its annual prevalence has been estimated as 1.4 per 1000 patients in a UK study of two general practices (total population 17 000).<sup>4</sup>

The diagnosis is clinical (see box 1). Restriction or pain, or both, on shoulder elevation and external rotation have been consistently described in the literature,<sup>6-12</sup> yet there are insufficient data to evaluate diagnostic accuracy of signs and symptoms.<sup>6</sup> Restriction and pain are evident on passive as well as active testing, which differentiates it from rotator cuff disease (where passive movements are classically of full range).<sup>6</sup> Another differentiator is crepitus in the shoulder, which is more indicative of arthritis.<sup>12</sup> Three phases (pain, stiffness, and resolution) are described, but they often overlap. Patients may have “pain-predominant” or “stiffness-predominant” frozen shoulder.<sup>13</sup>

Although frozen shoulder is considered self limiting, long term longitudinal follow-up data are scarce. The largest longitudinal series to date (223 patients) showed that 41% of patients had persistent symptoms at a mean follow up of 4.4 years, but this was based in secondary care, where more severe and less tractable cases are likely to be seen.<sup>14</sup> The same study found recurrence rare, but the other shoulder was affected in 6-17% of patients within five years.<sup>14</sup> Reported associations include diabetes, cardiovascular disease, trauma, stroke, neurosurgery, and thyroid disease.<sup>5</sup>

Less invasive treatments are generally tried first, but earlier use of more invasive interventions, particularly surgical capsular

release, is increasing (box 2).<sup>18</sup> There is uncertainty as to when these should be offered, and their clinical and cost effectiveness.

## What is the evidence of uncertainty?

There are large gaps in evidence for effectiveness of treatments for frozen shoulder. The systematic review we analysed (see box 3) included 28 randomised controlled trials, one quasi-experimental study, and two case series.<sup>15</sup> There were insufficient studies with a similar intervention and comparator to quantify effectiveness. Most studies are at a high risk of bias; do not report adequate methods for randomisation, allocation concealment, and outcome assessment; and seem to be inadequately powered. Few studies report a consistent method for collection of data on harms.<sup>15</sup>

Overall, physiotherapy and intra-articular steroid injections have been shown to have some benefit. Although there is no convincing evidence to support other measures, we emphasise the absence of good evidence rather than evidence that these management options are ineffective (see table 1 [↗](#)).

A systematic review of six randomised controlled trials comparing intra-articular corticosteroid injection with placebo and with manual therapy and exercise shows short term benefit with improvement in pain, function, and range of movement (up to 6-7 weeks) compared with placebo<sup>15</sup> and possibly compared with manual therapy and exercise.<sup>19</sup> This evidence suggests that a single corticosteroid injection for people with frozen shoulder of up to a year in duration may hasten improvements in pain and function by some weeks. There is moderate evidence for hydrodilatation—distension of the

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This is one of a series of occasional articles that highlight areas of practice where management lacks convincing supporting evidence. The series adviser is David Tovey, editor in chief, the *Cochrane Library*. This paper is based on a research priority identified and commissioned by the National Institute for Health Research's Health Technology Assessment programme on an important clinical uncertainty. To suggest a topic for this series, please email us at [uncertainties@bmj.com](mailto:uncertainties@bmj.com).

**What you need to know**

- Consider the diagnosis in patients with pain and limitation of passive external rotation of the shoulder
- There is insufficient evidence to reliably recommend a treatment approach. Moderate evidence supports corticosteroid injection or hydrodilatation; and physiotherapy in reduction of pain and stiffness
- Consider specialist referral if the patient does not respond to conservative treatment or if the diagnosis is in doubt

**Box 1: Diagnostic criteria for frozen shoulder<sup>5-11</sup>**

The diagnosis is clinical:

- Pain arising insidiously in deltoid region with increasing shoulder stiffness
- Pain at the end of external rotation, and restriction of this movement on both active and passive testing
- No obvious crepitus on movement

X rays are not routinely required, but if obtained, should show a normal glenohumeral joint

**Box 2: Treatment options for frozen shoulder**

- Oral analgesia and watchful waiting<sup>15</sup>
- Physiotherapy, typically combinations of advice and education, exercises, manual therapy, thermotherapy, and electrotherapy. Care packages may also include acupuncture or corticosteroid injections<sup>16</sup>
- Acupuncture<sup>15</sup>
- Oral corticosteroid<sup>17</sup>
- Intra-articular corticosteroid injections<sup>15</sup>
- Hydrodilatation (injection of up to 40 mL of sterile saline solution, usually with corticosteroid, to distend the shoulder capsule)<sup>15</sup>
- Manipulation of the shoulder joint under general anaesthesia<sup>15</sup>
- Capsular release (surgical procedure, typically arthroscopic, to release contracted tissue)<sup>15</sup>

**Box 3: Search strategy and study selection**

We have referenced the most up to date systematic review, published in 2012, for individual treatment comparisons.<sup>15</sup> We searched Medline for randomised controlled trials undertaken since then (up to May 2015) using the search strategy from the 2012 review combined with a validated filter for randomised controlled trials. We screened the results for new trials of manipulation under anaesthesia, capsular distension, and capsular release only, as physiotherapy interventions had been studied in Cochrane reviews published in 2014.

shoulder capsule with normal saline and corticosteroid—instead of a corticosteroid injection.<sup>15</sup> Exercise and mobilisation may augment the effect of steroid injection for some outcomes, but there is insufficient evidence to reach a conclusion.

Designing trials and quantifying the efficacy of physiotherapy is fraught with difficulty. It is a complex intervention encompassing a range of physical techniques, advice, education, painkillers, thermal or electrotherapy, and steroid injection that may have varying efficacy and may be delivered in varying intensities.<sup>8,9</sup>

Our updated Medline searches identified:

- A randomised trial of 64 patients comparing fluoroscopy guided anterior distension with ultrasonography guided posterolateral capsular distension<sup>21</sup>
- A randomised trial of 48 patients comparing ultrasonography guided and fluoroscopy guided capsular distension<sup>22</sup>
- A four-armed study with 53 participants investigating intensive mobilisation techniques combined with capsular distension.<sup>23</sup>

All the studies had a high risk of bias and seem to be inadequately powered.

## Is ongoing research likely to provide relevant evidence?

We searched <http://clinicaltrials.gov> and the WHO International Clinical Trials Registry Platform and identified six ongoing

randomised trials (table 2⇓). These trials are likely to provide evidence on four commonly used current interventions—that is, intra-articular injection with physiotherapy, hydrodilatation, manipulation under anaesthesia, and capsular release.

## What should we do in light of the uncertainty?

Communicate to patients that frozen shoulder is a benign and usually self limiting condition. Simple advice on activity modification and pain control may suffice (see box 4). Listen to the patient, and be prepared to adapt treatment, for example by referring on if their symptoms are not resolved or if the diagnosis is in doubt.

Consider referral for physiotherapy. Based on a survey of 289 UK physiotherapists,<sup>16</sup> physiotherapy care for frozen shoulder includes advice and education, which patients consider crucial.<sup>30</sup> In the pain-predominant stage, it is also likely to include an intra-articular steroid injection, a technique practised by many physiotherapists, and for which there is moderate evidence of effectiveness.

Current trends in practice involve escalation to more invasive treatments including manipulation under anaesthesia or arthroscopic capsular release, but there is insufficient evidence to recommend these. Although not clearly established, frozen shoulder may be associated with diabetes, and diabetic patients may be more resistant to treatment.<sup>22</sup>

**Box 4: What patients need to know***What should you expect?*

- At first, pain is the main problem. It can spread down the arm and is often worse in bed, especially if lying on the affected side, disturbing sleep.
- The pain slowly eases, but stiffness increases, becoming the main problem, before gradually resolving.
- The whole process may last from a few months to two to three years, but the pain does not last for the whole time.

*How can you help yourself?*

- When in pain, the emphasis is on pain relief and gentle use of your arm to ease spasm and maintain movement.
- Using your arm will not do any harm, but avoid aggravating your pain by doing too much. Take pain medication as advised. You may find hot packs helpful.
- In bed, support the arm with pillows as a reminder not to roll onto it.
- As time passes you will feel less need for pain relief.

*What are the common treatments?*

- Treatments other than pain medication are not always needed; but steroid injections are often used to reduce inflammation and pain in the shoulder, and physiotherapy may help to diminish pain and restore movement.
- A minority of people are referred to hospital with frozen shoulder, where additional options include release of the tight tissues by an injection or by keyhole surgery.
- It remains unclear which options are most effective. You should discuss treatment options with your clinician, based on your needs and preferences.

To address these uncertainties, it would be appropriate to encourage suitable patients to participate in trials designed to answer questions on which treatments are most effective (box 5).

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Patient consent obtained.

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**Box 5: Recommendations for future research**

Adequately powered randomised controlled trials with:

- Population—Patients with a clinical diagnosis of frozen shoulder
  - Studies should specifically address either the pain-predominant phase or the stiffness-predominant phase of frozen shoulder
  - The pain predominant phase is the priority, because most patients find this the most trying phase
- Interventions and comparisons:
  - Conservative strategies comparing individual and group physiotherapy, home exercises, electrotherapies, and steroid injection in different combinations
  - Invasive strategies including distension, manipulation under anaesthesia, and arthroscopic capsular release
- Outcomes—Resolution of pain, improvement of function and quality of life in the short and long term. Patient experience

**How patients were involved in the creation of this article**

We asked two patients with frozen shoulder to comment on the manuscript and incorporated their suggestions. They firmly endorsed individualised strategies over rigid pathways in management of symptoms. A patient contributor also recommended further research on effectiveness of a structured multidisciplinary approach with early involvement of general practitioner, orthopaedic surgeon or rheumatologist, physiotherapist, and pain management specialist.

## Tables

**Table 1 | Summary of evidence for different treatments of frozen shoulder**

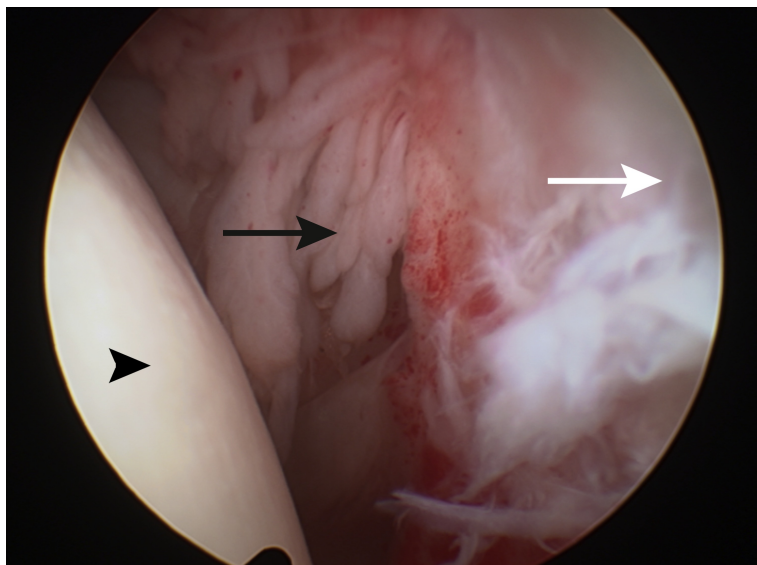
| Intervention                                                                    | Type of evidence                                                                                                   | Summary of evidence                                                                                                                                                                                                          | Evidence of harms                                                                           |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Watchful waiting, with or without oral analgesia                                | Systematic review <sup>15</sup> : 1 non-randomised controlled study (n=77)                                         | Insufficient evidence                                                                                                                                                                                                        | Insufficient evidence                                                                       |
| Physiotherapy (manual therapy and exercises, thermotherapy, and electrotherapy) | Systematic review of manual therapy and exercise <sup>19</sup> : 30 RCTs, 2 quasi-RCTs (n=1836)                    | Insufficient to compare types of manual therapy or exercise with each other or treatment*                                                                                                                                    | No serious harms but insufficient evidence                                                  |
|                                                                                 | Systematic review of electrotherapy (electrical, sound, light, or thermal energy) <sup>20</sup> : 19 RCTs (n=1249) | Moderate evidence* that 8 weeks' low level laser therapy added to exercise benefits pain, function, and range of movement for mixed-stage frozen shoulder populations                                                        | No serious harms but insufficient evidence                                                  |
| Acupuncture                                                                     | Systematic review <sup>15</sup> : 3 RCTs (n=509)                                                                   | Insufficient evidence                                                                                                                                                                                                        | Insufficient evidence                                                                       |
| Oral corticosteroid                                                             | Systematic review <sup>17</sup> : 5 RCTs (n=179)                                                                   | Insufficient evidence to draw firm conclusions, especially compared with other treatments                                                                                                                                    | Minor and short lived in the trials, though the known potential risks need to be considered |
| Intra-articular corticosteroid injection                                        | Systematic reviews <sup>15 19</sup> : 6 RCTs (n=457)                                                               | Moderate evidence* of benefit on pain, function, and disability compared with placebo for mixed-stage frozen shoulder populations, and of enhancement of effects by combination with manual therapy and exercise             | None reported, but insufficient evidence to draw conclusions                                |
| Hydrodilatation with steroid injection (arthrographic distension)               | Systematic review <sup>15</sup> : 3 RCTs (n=144)                                                                   | Moderate evidence of benefit on one of two function and disability outcomes compared with placebo for mixed-stage frozen shoulder populations. Insufficient evidence to draw firm conclusions compared with other treatments | Minor, including procedure related pain                                                     |
| Manipulation of the shoulder joint under general anaesthesia                    | Systematic review <sup>15</sup> : 4 RCTs (n=257)                                                                   | No evidence of benefit though insufficient evidence to draw firm conclusions.                                                                                                                                                | None reported, but insufficient evidence to draw conclusions                                |
| Capsular release                                                                | Systematic review <sup>15</sup> : 2 case series (n=249)                                                            | Insufficient evidence to draw firm conclusions                                                                                                                                                                               | No serious harms, but insufficient evidence to draw conclusions                             |

RCT=randomised controlled trial. \*GRADE system applied in this review.

Table 2| Ongoing trials of different treatments of frozen shoulder

| Name of trial                                                                                                                          | Population<br>(target sample size)                                                                                                                                                                                                 | Intervention and comparison                                                                                                                                                                     | Primary outcome                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UK Frozen Shoulder Trial (UK FroST), <sup>24</sup> UK                                                                                  | Adults ≥18 years old with primary frozen shoulder, including diabetics (n=500)                                                                                                                                                     | 1. Early structured physiotherapy (12 weeks)<br>2. Manipulation under anaesthesia without arthroscopic capsular release<br>3. Manipulation under anaesthesia with arthroscopic capsular release | Oxford Shoulder Score (OSS) at 12 months after randomisation                                                                                                                 |
| Acupuncture for treatment of Frozen shoulder Syndrome (SMART), <sup>25</sup> Taiwan                                                    | Adults 20-65 years old with frozen shoulder, (n=60)                                                                                                                                                                                | 1. Electroacupuncture and physical therapy<br>2. Sham electroacupuncture and surgery                                                                                                            | Disabilities of the Arm Shoulder and Hand (DASH); Shoulder Pain and Disability Index (SPADI); passive and active range of motion; and musculoskeletal ultrasound at one year |
| Corticosteroids and/or Arthrographic Distension in the Treatment of Adhesive Capsulitis (CADAC), <sup>26</sup> Belgium                 | Adults ≥18 years old with pain and stiffness in predominantly one shoulder for ≥4 weeks and restriction in passive range of movement >30° in ≥2 planes of movement, (n=132)                                                        | 1. Arthrographic distension plus intra-articular corticosteroid<br>2. Arthrographic distension<br>3. Intra-articular corticosteroid                                                             | SPADI at 4 weeks                                                                                                                                                             |
| Treatment of Adhesive Capsulitis Arthrographic Joint Distension with Local Anaesthetic Alone, <sup>27</sup> Canada                     | Adults 19-70 years old with frozen shoulder of ≥3 months' duration, (n=108)                                                                                                                                                        | 1. Arthrographic distension with triamcinalone plus lidocaine<br>2. Arthrographic distension Lidocaine                                                                                          | SPADI at one year                                                                                                                                                            |
| Manipulation under Anaesthesia versus Capsular Release in the Treatment of Adhesive Capsulitis, <sup>28</sup> USA                      | Adults ≥18 years old in the frozen or thawing phase of frozen shoulder who have tried and failed three months of non-operative treatment or who demand a quicker return to function and will not try non-operative therapy, (n=50) | 1. Manipulation under anaesthesia<br>2. Arthroscopic capsular release                                                                                                                           | DASH 12 months post-operation                                                                                                                                                |
| Adhesive Capsulitis: Prospective Analysis of Efficacy and Financial Impact for Use of Physical Therapy in Treatment, <sup>29</sup> USA | Adults ≥18 years old with frozen shoulder as defined by American Academy of Orthopaedic Surgeons, (n=260)                                                                                                                          | 1. Physiotherapy plus steroid injection<br>2. Watchful waiting with steroid injection                                                                                                           | American Shoulder and Elbow Surgeons Standardized Questionnaire one year after enrolment                                                                                     |

## Figure



Arthroscopic view of frozen shoulder, showing the humeral head (black arrowhead), glenoid (white arrow), and rotator interval with inflamed and proliferative tissue (black arrow) and site for injection