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Manipulation or intra-articular steroids in the management of adhesive capsulitis of the shoulder? A prospective randomized trial

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Background: The management of adhesive capsulitis (frozen shoulder) is controversial. The authors present a prospective randomized study comparing the outcome, at a two-year follow-up period, of two groups of patients treated either by manipulation of the shoulder under anaesthetic or by intra-articular shoulder injections using steroid with distension.
Methods: Fifty-three patients suffering from Idiopathic ''Primary'' Frozen Shoulder were prospectively randomized into two treatment groups and followed up for two years from the start of treatment. Patients were assessed using the Constant score, a Visual Analogue Score, and the SF36 questionnaire.
Results: No statistical differences were found between the two groups of patients with regards to the outcome measures.
Conclusion: Treatment using steroid injections with distension as an out-patient is therefore recommended for the treatment of Idiopathic ''Primary'' Frozen Shoulder. This has the same clinical outcome as a manipulation under anaesthetic with less attendant risks.
Level of evidence: Level 1; Randomized controlled trial, therapeutic study.

Keywords: Frozen shoulder; adhesive capsulitis; manipulation under anesthesia; distension injection; brisement

Perhaps the least understood of the shoulder's many problems is adhesive capsulitis, or frozen shoulder, which Codman[7] first described in 1934. The American Academy of Orthopaedic Surgeons defines frozen shoulder as, ''A condition of varying severity characterized by the gradual development of global limitation of active and passive shoulder motion where radiographic findings other than osteopenia are absent.''[44] Lundberg[19] suggested that this condition should be subdivided into 2 groups:

1. primary frozen shoulder as the idiopathic group where no identifiable cause can be determined, and
2. secondary frozen shoulder as a painful, stiff shoulder where there is an identifiable cause such as the following commonly accepted precipitating factors: shoulder immobilization[26] local shoulder conditions, including

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rotator cuff injuries, tendonitis and trauma[24,26]; surgery to the torso[39]; and a multitude of different medical conditions,[5,32,42] including diabetes.[6]

Primary frozen shoulder is said to be self-limiting over a period of 12 to 24 months, during which time disability can be considerable. The untreated shoulder is described as passing through 3 distinct phases consisting of ''freezing,'' ''frozen,'' and ''thawing,'' with most shoulders regaining full function.[14,23,33,36] However, long-term studies have shown that although the patient subjectively feels that the condition has resolved after 12 to 24 months, careful assessment reveals that pain and reduction in passive and active movements are present for many years after the onset of symptoms.[4,29,34,36] The aim of any treatment is to interrupt the natural history of the condition to reduce the period of disability to a minimum.

To this end, a variety of treatment modalities have been advocated, including manipulation under anesthesia (MUA)[2,10,13,15,17,25,30,38] and distension of the shoulder joint (brisement), which can be undertaken with or without arthrography or steroid injections.[11,12,16,24,31,43] MUA has been accepted as the gold standard of treatment for this condition because it is most commonly used by all surgeons. More recently, some surgeons recommend the more aggressive surgical approach with open or arthroscopic release of the coracohumeral ligament[27,28,41]; however, this is usually reserved for the more recalcitrant cases, especially in diabetic patients.

Few published prospective studies have assessed the effect of these different therapeutic modalities, and direct comparison is difficult because of differing patient groups and assessment of outcome.[22] No studies reported to date have been prospective, randomized, or controlled. For this reason, we undertook a long-term prospective randomized study to compare the results after MUA and injections using steroids with distension.

Patients and methods

The study cohort comprised 53 consecutive patients, aged 40 to 75 years, who presented to the upper limb service at the Royal Oldham Hospital with primary frozen shoulder. A closed envelope method was use to randomize patients to MUA or injection. The MUA group received treatment with a manipulation under general anesthesia, followed by physiotherapy as an outpatient. The injection group was treated by distension with local anaesthetic and a steroid, followed by physiotherapy. Ideally, the study would have included a control group undergoing no treatment; however, initial discussions with the Local Research and Ethics Committee during the planning stage revealed that this would not have been an ethically acceptable study design because previous studies showed both of the treatment modalities proposed in this study had a benefit over conservative management.[12,38]

Every patient was assessed by the senior author (L. G. J.) before entry into the study. Additional or alternative pathologies were excluded by taking a comprehensive history coupled with a thorough clinical examination. Radiographs indicated osteopenia in some patients but no further additional findings. Excluded were patients with medical conditions such as diabetes type 1 or 2, known to be associated with frozen shoulder, and patients who had received a steroid injection into the affected shoulder before referral.

Full Local Research and Ethical Committee approval was obtained before commencement of the study (ref: 3/96/1[a]). Each patient gave full informed consent before entry into the study. Patients were followed up on the intent-to-treat basis,[3] even if circumstances changed.

All patients were assessed at each outpatient visit using the Constant-Murley Shoulder Function Assessment Score (CS),[8] a straight-line visual analog score (VAS) to assess pain levels (range, 1-100 points),[1] and the Short-Form 36-Item Health Survey questionnaire[20,40] (SF-36), which was performed at the beginning and end of the 2-year follow-up.

Those in the MUA group underwent the procedure on the next available list. All shoulder manipulations were undertaken by the senior author. The anesthetized patients were positioned on the opposite side to that being manipulated. The assistant placed the heel of the hand on the lateral border of the ipsilateral scapula to stabilize it. Using a short lever arm, the patient's arm was manipulated into full adduction and forward flexion, full external rotation, full internal rotation, and finally, full abduction.[9,10] All patients were treated as day cases and discharged after the MUA, with exercises shown by a physiotherapist.

Patients in the injection group received 3 injection treatments with a steroid and distension, at 6-week intervals, in the outpatient clinic. The injection, consisting of 40 mg of triamcinolone (in 1 mL), 5 mL of 2% lignocaine, 10 mL of 0.25% bupivacaine, and 5 mL of air, was given by the posterior route.[10] The affected shoulder was held between the long finger on the coracoid process and the thumb on the posterior corner of the acromion. The needle was then inserted 1 to 2 cm below the corner of the acromion into the ''soft spot'' and directed towards the index finger, thereby entering the glenohumeral joint. The air provides a palpable and occasionally an audible ''squelch,'' confirming that the injection is indeed in the glenohumeral joint[16] and that the joint capsule has not been ruptured by the injection. Patients were given a sheet detailing the same exercises that the MUA group had been shown by the physiotherapist.

All patients were reviewed at 2, 6, and 12 weeks, and then at 6, 9, 12, 18, and 24 months. At each visit, the CS and the VAS were repeated. The SF-36 was repeated at the final visit at 2 years.

A sample size of 20 patients in each group would be required for the power of 80% at a 5% significance level (α error = 0.05, β error = 0.20) calculated from a pilot study of the CS and shoulder function. Incorporating a dropout rate of 15% increased the patient number in each group to 23 to achieve this. To recruit at least these numbers, a 4-year study period was required.

Data was input into SPSS software (SPSS Inc, Chicago, IL) for statistical analysis. Statistical analysis incorporated the duration of symptoms before presentation to allow for the natural history of the disease. During statistical analysis it was noted that due to missing data, an area under the curve analysis could not be performed. In view of this, cases were selected where information was recorded for at least 3 of the first 4 time points and the method suggested by Matthews et al[21] was used.

Results

The MUA group contained 28 patients, of which 15 (54%) were women, with a median age of 56.5 years. The