Tveita EK, Tariq R, et al. Hydrodilatation, corticosteroids and adhesive capsulitis: A randomized controlled trial. BMC Musculoskeletal Disorders 2008, 9:53 doi:10.1186/1471-2474-9-53.

Design: Randomized clinical trial

Study question: Does a hydrodilatation procedure including steroids lead to better outcomes of adhesive capsulitis than steroid injection alone?

Population/sample size/setting:

- 76 patients (45 women, 31 men, mean age 51.5) treated for adhesive capsulitis at a university department of physical medicine in Norway
- Eligibility criteria were age between 18 and 70, pain in one shoulder for at least three months but less than two years, willingness to fill out shoulder self-report forms, and limitation of passive movement in the affected shoulder more than 30 degrees compared to the unaffected side (lesser limitation of passive movement was accepted if the patient had a history of adhesive capsulitis in the other shoulder) in two of three movements: forward flexion, abduction, or external rotation
- Exclusion criteria were diabetes, trauma to the shoulder in the past 6 months requiring hospital care, current use of oral steroids, allergies to injection material, cancer, and reduction of glenohumeral ROM for reasons other than adhesive capsulitis, such as dislocation or full-thickness rotator cuff tear with displacement of the humeral head

Main outcome measures:

- All patients were scheduled for three arthrographic injections at two-week intervals, with different volumes of injected fluid designed to distend the joint capsule and rupture the wall of the subcapsular recess
- Allocation of patients was by a minimization method to preserve approximate balance of prognostic factors using the Shoulder Pain and Disability Index (SPADI) as the variable to be balanced between groups
- Randomization was to injection alone (INJ, n=37), or to dilatation of the joint capsule (DIL, n=39)
    - INJ group received up to 10 ml of fluid, containing contrast medium, 20 mg triamcinolone, and 20 mg of bupivacaine, injected slowly and controlled visually by the injecting physician
    - DIL group received the same 10 ml of fluid as the INJ group, and also received 10 ml of saline, again injected slowly into the joint; distention of the capsule was observed until the capsule ruptured, recorded as a loss of resistance and fluoroscopic confirmation of leakage of contrast into the subcapsular recess or adjacent structures

- No specific physiotherapy or manipulative treatment was administered to the patients, who were instructed to follow up with their current treatment program if they wished; their primary care providers were not informed of the group allocation
- Due to unexpected restrictions in treatment capacity, the interventions were delayed for most patients; mean time from treatment allocation to treatment administration was 8.2 weeks for the INJ group and 8.6 weeks for the DIL group
- Rupture occurred in 4 patients in the INJ group, even with the low volumes administered
    - During the course of three injections, the INJ group was injected with an average of 8 ml, 7 ml, and 7 ml
    - The DIL group was injected with an average of 21 ml, 20 ml, and 21 ml
    - 6 patients dropped out prior to receiving treatment because of improvement in their condition; 5 were not able to come to all three appointments; analysis was by intention-to-treat
- Improvement in SPADI scores was the principal outcome measure taken 6 weeks after the final injection; as expected, both groups improved their scores at the time of the 6 week followup measurement
    - At baseline, the mean SPADI for the DIL group was 59 points and the improvement was 39 points
    - The mean SPADI for the INJ group was 63 points and the improvement was 38 points
    - The SPADI improvement was statistically equal between the DIL and INJ groups
- At the end of followup, 5 patients (13%) in the DIL group and 3 (8%) in the INJ group were taking daily analgesics; 11 patients (28%) in the DIL group and 23 (62%) in the INJ group were on sick leave
- Adverse effects were not statistically compared between groups, but the treatment was very painful for 6 patients in the INJ group and for 5 in the DIL group the most frequent complaints were flushing or heat regulation disturbances (13 in the INJ group and 9 in the DIL group)

Authors' conclusions:

- Significant between-group treatment differences were not observed between the DIL and INJ groups, but the confidence intervals do not exclude an important treatment difference for capsular dilatation
- The unexpected delay in implementation of treatment may have meant that many patients had improved during that interval, meaning that there was a smaller margin for improvement as a result of treatment
- The fact that unplanned rupture occurred in 4 patients in the INJ group could obscure some therapeutic benefits arising from distention of the joint capsule

- These results differ from those of Buchbinder et al 2004, who reported benefits from dilatation; they used a mean of 43 ml in the distention group rather than the smaller volumes used in this study
- It is possible that hydrodilatation may be of benefit in some cases, but there is a need for future trials of shoulder injections in patients with adhesive capsulitis

Comments:

- Minimization, which allocates patients in order to balance on known strong predictors of outcome, is generally accepted as being as satisfactory as other methods of randomization (it is widely used in oncology but is rarely used in musculoskeletal literature)
- The eligibility criteria were based on duration of symptoms (between 3 months and 2 years), but this may not ensure that patients are at the same phase in the evolution of the clinical course of adhesive capsulitis
    - As Buchbinder 2004 suggests, the effect of dilatation may be different in the early painful phase of adhesive capsulitis and in the later intermediate stiff phase when pain may be less prominent
- The discussion section is well thought out and concedes that a treatment effect of dilatation cannot be excluded
- The treatment strategy differed from Buchbinder in that the latter study injected up to 90 ml while the placebo group had only 6 ml for purposes of arthrography; the study results are in contrast to, but not necessarily in conflict with one another
- The need for repeated injections (three rather than one as in Buchbinder) is not clear, especially if a single large volume injection is required for a therapeutic effect

Assessment: Adequate for evidence that there is little therapeutic difference between a series of three injections of 10 ml of steroid and three injections of 10 ml of steroid plus 10 ml of saline in the setting of adhesive capsulitis

Reference:

Buchbinder R, Green S, et al. Arthrographic joint distension with saline and steroid improves function and improves pain in patients with painful stiff shoulder: results of a randomized, double blind, placebo controlled trial. Ann Rheum Dis 2004;63:302-309.