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.

Design: Randomized clinical trial

Population/sample size/setting:

- 46 patients (37 women, 9 men, mean age 57) treated for painful stiff shoulder at community-based rheumatology practices in Australia
- Eligible if they had pain & stiffness in one shoulder for at least 3 months, restriction of passive ROM of at least 30° in two planes of movement
- Excluded if they had severe pain at rest, previous arthrographic distension, inflammatory joint disease, suspicion of complete rotator cuff tear, joint calcification, XR evidence of osteoarthritis or fracture

Main outcome measures:

- All had contrast arthrography; randomized into distension group with 40 mg methylprednisolone and saline up to 90 ml total injectate (n=25) or placebo, which was arthrography alone with 6 ml injectate
- Distension injections continued until (1) filling of subcapsular bursa, (2)capsular rupture, (3) 90 ml of injectate had been given, (4) patient requested end of procedure, (5) severe pain developed, (6) complete rotator cuff tear was diagnosed
- Median volume injected was 43 ml (range was 21-80 ml)
- Shoulder Pain and Disability Index (SPADI) is self-administered pain and disability instrument (100 is maximum disability); it was measured at baseline and at 3, 6, and 12 weeks after intervention
- Problem Elicitation Technique (PET) is a patient preference disability measure administered by interviewer; it asks patients which of their problems they most want to see improved from treatment using Likert scales; higher score indicates greater disability and/or importance (maximum score 500)
- Pain VAS and ROM for flexion, abduction, external rotation, and position of hand behind back were also assessed by blinded examiner
- At 3 weeks, distension group had significantly greater improvement than placebo group in SPADI, PET, pain VAS, abduction, and hand behind back ROM
- 4 patients withdrew from trial after 3 weeks, all from placebo group; 3 crossed over to distention treatment and 1 began antidepressant treatment
- At 6 weeks, distension group had advantage over placebo only on PET using intention-to-treat analysis; when crossovers were excluded, distension group also had advantage over placebo for improvement in SPADI and in pain VAS
- At 12 weeks, distension group had advantage over placebo group for PET score for both analyses, intention to treat and excluding crossovers

Authors' conclusions:

- Shoulder joint distension with saline and steroid significantly improves function, pain, and range of motion after 3 weeks, and this is maintained at 6 weeks
- Because crossovers were all from placebo to distension groups, it is informative to use both the intention to treat and the analysis excluding the crossovers
- Steroid is unlikely to account for the group differences, since 25% of the patients had received steroid injections prior to entry into study
- Appropriateness of intervention may depend on stage of disease; the first stage (early painful phase) may not tolerate distension of capsule, but second phase (intermediate stiff phase with less pronounced pain) may be better candidates
- SPADI is a fixed item questionnaire and may have a ceiling effect, since it measures basic activities of daily living; PET has advantage of relevance to patient perceived needs and has less ceiling effect. Even though SPADI was primary outcome measure, PET is pertinent and showed group differences at 12 weeks

Comments:

- Overall design and execution of study is satisfactory; authors provide thoughtful discussion which sheds light on which phase of disease is likely to be most appropriate for distension (at least 3 months of symptoms, past the phase where pain predominates and where stiffness is the greater problem for the patient)
- Study was terminated early because of lack of success in recruitment of participants; the authors appear to have adjusted their significance levels to avoid the problems which can lead to concluding that results are statistically significant when this conclusion is not warranted
- Numerous analyses were undertaken in addition to those summarized above; without access to study protocol, it is not possible to determine which of these were originally planned
- Group comparisons and tabular summaries are of score changes from baseline tested with independent sample t-tests; the actual SPADI and PET scores during follow-up are not reported but would be helpful in understanding results
- Most patients do non-manual work; only 3 patients (all in the distension group) performed manual work
- The treatment groups differed not only with respect to the volume of fluid injected; the dilatation group also had Depo-Medrol while the control group did not have any steroid to produce a treatment effect; an effect of the steroid cannot be excluded, but the authors may well be correct to think that this is not a likely explanation of the observed effects

Assessment: Adequate for evidence that arthrographic distention of up to 90 ml of fluid is better than injection of only 6 ml of placebo in improving function and pain for patients with painful stiff shoulder lasting more than three months