

**Alvarez CM, Litchfield R, et al. A Prospective, Double-Blind, Randomized Clinical Trial Comparing Subacromial Injection of Betamethasone and Xylocaine to Xylocaine Alone in Chronic Rotator Cuff Tendinosis. Am J Sports Med 2005;33:255-262.**

Design: Randomized Clinical Trial

Population/sample size/setting:

- 62 patients (31 men, 27 women, 4 withdrawals not described, mean age 48) treated for rotator cuff disease (RCD) at a sports medicine clinic in Ontario
- Patients identified by history of pain in shoulder and/or lateral deltoid area with overhead activity, and by physical exam findings of (1) tenderness at insertion of cuff, (2) decreased or painful ROM in active forward elevation, external rotation, internal rotation, and (3) a positive Neer impingement sign
- All had failed 2-week trial of NSAIDs and minimum 6 weeks of PT strengthening program; all had ultrasound imaging, and full-thickness was an exclusionary criterion

Main outcome measures:

- 77 patients were randomized to subacromial injection of 5 ml of 2% lidocaine or 4 ml of 2% lidocaine and 1 ml (6 mg) betamethasone; after 10 minutes, pain was re-assessed, and 15 were excluded if they did not have a 50% reduction in their VAS, leaving 62 patients (31 betamethasone + lidocaine, 31 lidocaine only) for followup
- First 10 patients had contrast-enhanced radiographic confirmation of needle placement; all of these confirmed that injection was subacromial
- Western Ontario Rotator Cuff Index (WORC) was primary outcome; this is a questionnaire covering domains of physical symptoms, work, sports, social well-being, and emotional well-being
- WORC done at baseline, 2 weeks, 6 weeks, 3 months, and 6 months
- 58 completed the study; 4 dropped out (3 lidocaine, 1 steroid)
- Over 6 months, both groups improved in quality-of-life; no significant differences observed between groups; lidocaine group improved WORC from baseline of 35 to 6 months score of 59; steroid group from 38 to 51
- Good to excellent outcomes (defined as increase of WORC score from baseline of greater than 61%) was seen in only 18% of lidocaine group and 13% of steroid group at 6 months

Authors' conclusions:

- Addition of betamethasone to lidocaine did not improve health-related quality-of-life scores 6 months after injection
- Modest improvement in both groups might be due to placebo effect, to natural history of rotator cuff disease, to distension of subacromial space with 5 ml injectate, or to carryover effect of lidocaine

Comments:

- Mean duration of symptoms was 3.8 (SD=3.9) years in steroid group and 2.5 (SD=3.1) in lidocaine group; this is a markedly skewed distribution, but range is not given. Minimum and maximum durations are probably very wide apart; entry criterion did not identify duration of symptoms, which would be helpful in applying results to another population
- Several secondary outcomes (including active range of motion) were measured in addition to WORC, the primary outcome; no group differences were found, but it is not stated whether ROM measurement was blinded
- Analysis of covariance was used to compare group outcomes, but it is not specified which variables were entered as covariates. Presumably baseline scores and group assignments were entered, but other variables may or may not have been entered. ANCOVA is the most appropriate analysis of outcomes, but more description of the model would have helped
- Three findings were documented on physical exam, but it is not clear whether all patients had all three positive, or whether all three were required for entry
- It appears that a positive Neer impingement test (in addition to the physical finding of Neer sign) was required for inclusion into follow-up sample; 15 patients were excluded from further analysis based on a negative impingement score. This appears to be a lost opportunity to analyze patients with chronic rotator cuff symptoms likely to occur in clinical practice, since the Neer test results were not known until the purported therapeutic injection had been done
- 5 ml injectate is much less than is generally done in studies of distension arthrography (20 ml is a modest volume); this is unlikely to explain outcome
- In spite of the lack of clarity on these points, a dramatic effect of steroid injection is not likely to have been missed
- Betamethasone has glucocorticoid potency 5-6 times (and a longer half-life) than that of the more commonly used triamcinolone; the 6 mg dose would be equivalent to 30-36 mg triamcinolone, which is about in the dose range of many studies using triamcinolone in Cochrane review

Assessment: adequate