

**Buchbinder R, Green S, et al. Oral steroids for adhesive capsulitis (Review). Cochrane Database of Systematic Reviews 2006, issue 4, art # CD006189.**

Design: Systematic Review of randomized clinical trials

PICOS:

- Patient type: patients with adhesive capsulitis, frozen shoulder, stiff painful shoulder, or periarthrititis
- Interventions: Oral steroids
- Comparison: Placebo, no treatment, other treatment, or different dosage of oral steroids
- Outcomes: Pain, range of motion, function, quality of life, treatment success, and adverse effects
- Study types: Only studies described as randomized clinical trials

Study selection:

- Databases included MEDLINE, EMBASE, CINAHL, and CENTRAL, with additional searches of reference lists in review articles and clinical trials
- Search dates were from 1996 through November 2005
- Two reviewers independently extracted data from studies and assessed articles for risk of bias, with four levels of quality of evidence
  - o Platinum level: a published systematic review with at least two RCTs satisfying the following
    - At least 50 participants per group, adequately powered to find a 20% relative difference in the relevant outcome
    - Blinding of patients and outcome assessors
    - Handling of withdrawals with at least 80% follow-up
    - Concealment of treatment allocation
  - o Gold level: at least one RCT satisfying the criteria for platinum level quality
  - o Silver level: a systematic review or RCT which does not meet the above criteria
    - Also includes at least one study of non-randomized cohorts which did and did not receive the intervention, or at least one high-quality case-control study
  - o Bronze level: a high quality case series without controls, or expert opinion based upon known principles of physiology, etc

Results:

- 443 citations were retrieved and screened for inclusion; 5 RCTs with 40, 30, 49, 32, and 28 participants were included as having met all inclusion criteria
- Data from the 5 studies could not be pooled due to different comparison interventions and due to inability to extract necessary data from one placebo-controlled RCT (means were reported without standard deviations)

- 2 studies compared oral steroid with placebo
  - o One study of 30 patients did not find significant differences between 4 weeks of oral steroid versus placebo on either pain or range of movement
  - o The second study with 49 patients found an advantage of 3 weeks of prednisolone over placebo (pain, range of movement, patient-reported success, shoulder-specific disability) at the three week assessment, but after three weeks the prednisolone group did not improve or deteriorated somewhat, while the placebo group continued to improve, such that there were no differences at 6 or 12 weeks
- 1 study with 40 participants compared 6 weeks oral prednisolone with no treatment reported a more rapid initial recovery with oral steroid but by 5 months there were no differences between the two groups
- 1 study with 32 patients gave all patients 2 weeks rest in a sling, followed by manipulation under anesthesia, followed by exercise supervised by a physical therapist. Randomization was to either prednisone or placebo for 4 weeks. The prednisone group had a transient advantage over placebo for external rotation, but at 12 and 18 weeks, the groups did not differ in external rotation, and at all time points, shoulder flexion was not different between groups
- 1 study with 28 patients compared 3 weeks of oral triamcinolone with an intra-articular injection of triamcinolone; the injected group had a transient advantage over oral steroid at 1 week in regaining glenohumeral range of motion, but at weeks 2 and 3, there were no group differences in range of motion
- 3 studies reported adverse effects; one patient in one study had a stress fracture of the foot and three patients in one study had epigastric pain; one patient died from a coronary event in one study, but this was not considered related to treatment

#### Authors' conclusions:

- It is not possible to draw firm conclusions about the efficacy of oral steroids for adhesive capsulitis, but there appear to be short-term benefits
- The effects of oral steroids may not be constant over time; treatment effect may diminish over time
- Most trials were small in size and were poorly reported; inclusion criteria were not well specified, and only one was considered to be of high methodological quality
- There is a lack of reliable evidence to draw conclusions about the effectiveness of oral steroids in comparison with manipulation under anesthesia or steroid injections
- Future trials need to report methods of randomization, sample size determination, means with standard deviations, and a standard set of outcome measures

#### Comments:

- The systematic review included RCTs of low quality, underscoring the authors' concerns about obtaining good evidence for the issue of oral steroids for adhesive capsulitis

- The earliest trial was published in 1954, before current reporting standards were developed, but even one study published in 2004 appeared to have been unclear or lacking on several determinants of study quality
- Even though there may have been some potential for bias in the low-quality studies, the pattern of early and transient benefit appears to be consistent over a variety of steroid drugs and durations of treatment
- The planning of the analysis, done in advance of the data collection, was well thought out, with attention paid to how clinical heterogeneity would be assessed and how the meta-analysis, if it were done, would be conducted

Assessment: A high-quality systematic review supporting good evidence that oral steroids may have very short-term benefits for adhesive capsulitis, but that these benefits are not shown to be present past three weeks, making their benefits of doubtful weight over their potential risks