

**Gialanella B, Prometti P. Effects of Corticosteroids Injection in Rotator Cuff Tears. Pain Med 2011;12:1559-1565.**

Design: Randomized clinical trial

Population/sample size/setting:

- 60 patients (5 men, 55 women, mean age 78) treated for symptomatic rotator cuff tears at a rehabilitation medicine facility in Italy
- Eligibility criteria were age over 75, full thickness rotator cuff tear diagnosed with imaging, and not having surgery considered the first treatment choice
- Exclusion criteria were inflammatory disease, fracture or operations around the shoulder, neurological diseases that can cause shoulder pain, pregnancy, diabetes, and intra-articular injections of the affected shoulder in the past 12 months

Main outcome measures:

- All patients had 15 sessions of 20 minute duration of passive glenohumeral joint mobilization
- Randomization was into one of three groups, each with n=20: Group TA1 had one intra-articular injection of 40 mg triamcinolone (TA), group TA2 had 2 injections of 40 mg TA 21 days apart, and a control group received no injection
  - o Neither injection group received local anesthetic with the TA
- Outcomes were ascertained at 3 and 6 months by the physician who did the injections; a one-month ascertainment of pain was done by telephone at one month
- Pain was determined in three ways: rest pain, activity pain, and night pain
  - o For activity and night pain, groups TA1 and TA2 had greater relief at one and three months than the control group, but were equal to one another at one and three months
    - At 6 months, Groups TA1 and TA2 did not have significantly different activity and night pain compared to the control group
  - o Activity and night pain improved from baseline at all time points for groups TA1 and TA2, however, the control group did not improve from baseline on either pain measure
- Function was determined by the Constant score at 3 and 6 months
  - o Groups TA1 and TA2 reported improvement from baseline in Constant scores, but did not differ from one another
  - o The control group did not improve its Constant scores from baseline at either 3 or 6 months

- However, with respect to Constant scores, the TA1 and TA2 groups did not differ significantly from the control group at baseline, 3 months, or 6 months
- The use of NSAIDs in the two TA groups was less than the use of NSAIDs by the control group at 1 and 3 months, but not at 6 months

Authors' conclusions:

- Intra-articular injection of TA improves pain relief in full thickness rotator cuff tears for up to three months
- Additional injections of TA 21 days after the first injection do not lead to better outcomes
- Therefore, a single dose is to be preferred to two doses of TA
- The study was not blinded, since the same physician who did the injections measured the study outcomes

Comments:

- The study results are generally consistent with what is reported elsewhere: injected corticosteroids produce a benefit for up to several months in rotator cuff pathology
- The study was restricted to elderly patients who would not be expected to be in a workers' compensation population
- The lack of blinding creates a risk of bias that could inflate the treatment effect in the injected groups, and the Constant scores are especially at high risk of bias
  - The strength component of the Constant scores was omitted from the followup examinations due to "difficulty of patients to perform this test," but it is not clear if the omission was planned in advance or if it arose at the time of the followup examinations
  - The effect of steroids on patients who will be placing significant physical loads on their treated shoulders cannot be estimated
- On the other hand, the use of analysis of variance (ANOVA) to compare the outcomes is less useful than other methods of analysis when repeated measurements are done, and this could have minimized the group differences in the Constant scores
  - The Constant scores in the control group were higher than for the TA groups
  - There appears to be improvement in the Constant scores between baseline and 3 months for the TA scores, but not for the control group
  - An analysis which used the followup scores as outcomes, but used the baseline scores as covariates, might have shown a treatment effect of the injections at 3 and possibly at 6 months
  - The small sample sizes (20 in each group) mean that the comparisons are likely to be underpowered, especially with respect to the equivalence of single and repeated doses of TA, but the outcome scores in Tables 2 and 3 do appear to be quite similar for TA1 and TA2

- An effect on rest pain was not found, but because the baseline scores are low, this could have led to floor effects (not much room for improvement)
- There is a very sparse mention of adverse effects, “No adverse events were reported during the study;” but this does not provide a good estimate of risk of injections

Assessment: Adequate for some evidence that intra-articular triamcinolone provides pain relief for up to 3 months in elderly patients with full thickness rotator cuff tears, and that a single injection is likely to be as beneficial as two injections.

Inadequate for any evidence regarding function (high risk of bias from lack of blinding)