**Coombes BK, Bisset L, et al. Effect of Corticosteroid Injection, Physiotherapy, or Both on Clinical Outcomes in Patients With Unilateral Lateral Epicondylalgia: A Randomized Controlled Trial. JAMA. 2013;309(5):461-469.**

**PMID: 23385272**

Design: randomized clinical trial

Purpose of study: to test the effectiveness of a corticosteroid injection, with or without physical therapy (PT), on the clinical course of lateral epicondytitis

Population/sample size/setting:

* 165 patients (63 women 102 men, mean age 49.7) treated for unilateral lateral epicondylalgia at a university rehabilitation department in Australia
* Inclusion criteria were age 18 or older with pain over the lateral humeral epicondyle of at least 6 weeks duration and with pain severity of at least 30 mm on a 100 mm VAS, provoked by gripping, palpation, resisted wrist or middle finger extension, or stretching of forearm extensor muscles with reduced pain-free grip
* Exclusion criteria were receipt of an injection during the preceding 6 months, a course of physical therapy during the preceding 3 months, concomitant neck or arm pain preventing participation in usual activities in the past 6 months, symptoms suggesting radicular, neurological, or systemic arthritic conditions, pregnancy, breastfeeding, or contraindication to injection

Interventions:

* Randomization was to one of 4 groups: placebo injection alone (n=41), placebo injection plus PT (n=41), corticosteroid injection alone (n=43), or corticosteroid injection plus PT (n=40)
  + PT program had 8 sessions of 30 minutes duration during an 8 week period, with the physiotherapists individualizing treatment with a mixture of manual therapy and exercises based on the patients’ ability to progress without exacerbating pain
  + A single corticosteroid injection (10 mg triamcinolone plus 1 ml of 1% lidocaine) or a single placebo injection (0.5 ml of normal saline) was given to the two groups which were randomized to receive an injection

Outcomes:

* Followup was done at short term (4 weeks), intermediate term (26 weeks), and long term (52 weeks)
* Comparisons were made between groups which did or did not receive PT, and between groups which received corticosteroid injection or placebo
  + The authors tested for treatment interactions to determine whether the effect of PT depended on whether the patient had had a corticosteroid injection, and whether the effect of a corticosteroid injection depended on whether the patient had had PT
* Primary outcome was global rating of change on a 6 point Likert scale ranging from “complete recovery” to “much worse” at one year
  + Global ratings of “complete recovery” or “much improvement” at one year were combined as counting a successful outcome
  + “Recurrence” was defined as “complete recovery” or “much improvement” at 4 or 8 weeks but not sustained at later outcome measurements (e.g., a patient who was “complete recovery” or “much improvement” at 4 weeks but not at 8 weeks was counted as having a recurrence at 8 weeks)
* Several secondary outcomes were measured, including severity of current resting pain and severity of worst pain over the previous week, the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire for pain and disability, the EQ-5D quality o ife scale, the use of analgesic medication including NSAIDS, and adverse events
* Followup was nearly complete, with 163 of 165 patients having measurement of one-year outcomes (2 deaths from cancer)
* At 1 year, there was no interaction between steroid injection and PT (the effect of PT was the same in patients who had steroid and had placebo injections; the effect of steroid injection was the same in patients who did and did not have PT)
* At 1 year, corticosteroid injection appeared to be detrimental in comparison with placebo injection with respect to the primary outcome
  + Complete recovery or much improvement was reported by 96% of placebo-injected patients and by only 83% of corticosteroid injection patients
  + There was greater recurrence with corticosteroid injection (54%) than with placebo (12%) at one year
* Among the secondary outcomes which differed significantly between groups, the 4 week benefits of corticosteroid injection appeared to be greater than those for steroid injection
  + At 4 weeks, 30/42 patients with corticosteroid injection alone were completely recovered or much better, compared to 4/41 with placebo injection alone
  + At 4 weeks 27/40 with corticosteroid injection plus PT were completely recovered or much better, compared with 16/41 with placebo injection plus PT
  + At 26 weeks, however, the corticosteroid injection demonstrated lower complete recovery of much better (45/82 or 55%) compared to the placebo injection group (69/81 or 85%)
  + The use of analgesics/NSAIDS was the same with corticosteroid injection 26/83)and with placebo injection patients (23/82)
* PT compared to no PT demonstrated no effects on complete recovery or much improvement (73/80 for PT versus 73/83 for no PT) at 1 year
  + However, the PT group had lower rates of analgesic/NSAID use (16/81 with PT compared to 33/84 with no PT)
  + There were benefits of PT observed early on (at 4 weeks); in 82 patients who had a placebo injection, only 4/41 who had no PT had complete recovery or much improvement, compared to 16/41 who did have PT)
* Adverse events were mostly transient and minor, but skin depigmentation (4/83) or subcutaneous atrophy (3/83) was seen only in the corticosteroid injection groups

Authors’ conclusions:

* A single-blinded injection of corticosteroid injection was associated with a poorer one-year outcomes compared to placebo injections; the percentages of complete recovery were lower and the recurrence rates were higher
* The comparative benefits of 8 weeks of PT were seen during early followup, but at 1 year, the comparative benefits of PT were no longer seen; the early benefits were seen in the patients who had had a placebo injection, but there were no comparative benefits of PT in patients who had had a corticosteroid injection
* Soon after the beginning of followup, corticosteroid injections did appear to be more beneficial than placebo injections, but this was reversed by 26 weeks, and at 52 weeks, corticosteroid injection were detrimental compared to placebo
* This evidence does not support the clinical practice of using corticosteroid injections to improve rehabilitation in patients with tennis elbow
* The results may or may not apply to patients who were excluded from the study, such as those with significant neck or other upper limb problems
* Although patients with previous corticosteroid injection were excluded from the study, previous studies have observed that repeat injections yield less favorable outcomes than a single injection

Comments:

* The main outcome of lower rates of complete recovery or much improvement at 1 year in those with corticosteroid injections is likely to be unbiased
* However, the large difference between corticosteroid injection and placebo with respect to “recurrence” is calculated in such a way as to make corticosteroid injection appear more detrimental than they really are
  + In order to have a “recurrence,” a patient needs to have had an early improvement; in placebo-injected patients, whose early improvement rates were lower than for corticosteroid injections, there were fewer opportunities to have a later recurrence; and the large relative risk for recurrence is likely to overstate the real detrimental effects of corticosteroid injections
* Assuming that corticosteroid injections are to be abandoned in patients with tennis elbow, the benefits of PT, seen early during the study, become relevant
  + The later convergence of results in patients with and without PT probably reflect the natural history of the condition, and do not detract from the appropriateness of PT in this setting
* An earlier systematic review (Coombes 2010) presented strong evidence of a similar pattern of results of steroid injections in the setting of tennis elbow, with consistent early benefit followed by later reversal and long-term detriment, whether the comparison intervention was no intervention or was physiotherapy; three studies in that systematic review compared steroid injection to placebo injection, but these studies reported only short term and no long term results

Assessment: High quality study supporting good evidence that in patients with lateral epicondylalgia in one limb, the use of corticosteroid injection shows early benefits which are later reversed, making them detrimental compared to placebo at 6 months and one year. There is good evidence that in patients who do not receive a corticosteroid injection, there are early benefits of an 8 week program of weekly individualized PT, although the natural history of the condition tends to obscure these early benefits at one year from the time therapy begins.

Reference:

Coombes BK, Bisset L, Vicenzino B. Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy: a systematic review of randomised controlled trials. Lancet 2010;376(20):1751-67.