**Peters-Veluthamaningal C, Winters J C, et al. Randomised controlled trial of local corticosteroid injections for carpal tunnel syndrome in general practice. BMC Fam Pract. 2010;11;54.**

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Design: randomized clinical trial

Purpose of study: to compare the outcomes of steroid injection versus saline injection in patients with CTS

Population/sample size/setting:

* 69 patients (53 women, 16 men, mean age 57) treated for CTS at 20 general practitioners’ off ices in the Netherlands
* Eligibility required only that the patient present to their primary care doctors with symptoms and signs of CTS
* Exclusion criteria were thenar atrophy, hypersensitivity to corticosteroids, local skin infection, prior steroid or surgical treatment for CTS in the past 6 months, traumatic or neoplastic origins of symptoms, and inability to participate in followup

Interventions:

* Randomization was to corticosteroid injection ( n=36) or saline injection (n=33)
* Steroid injection consisted of 1 ml of a solution containing 10 mg of triamcinolone acetonide (TCA) ; the control group received 1 ml of normal saline
* Injections were done just to the ulnar side of the palmaris longus tendon proximal to the wrist crease at an angle of 10 to 20 degrees; the general practitioners doing the injections had been offered a two-hour course on the technique of injection
  + The injections were done by an independent practitioner other than the one who entered the patient into the study
  + If, one week after the first injection, the results were not satisfactory to the patient, a second injection was done by the independent practitioner
  + One week after the last injection, the patients returned to their own general practitioner for assessment of short term outcomes
* The ethics committee required that if the short-term response to treatment was not satisfactory to the patient and practitioner, blinding would be broken and the course of treatment would be changed
  + If the patient had received TCA, the patient would be referred for operative treatment and not included in the followup analysis
  + If the patient had received saline, the patient would be given one or two TCA injections as a bailout treatment; if, two weeks after the bailout injection, the outcome was unsatisfactory, the patient would be referred for operative treatment and excluded from the followup analysis

Main outcomes:

* Both short-term and longer term outcomes were recorded: by the patients’ general practitioners at 2 weeks and by mailed questionnaire at 1, 3, 6, and 12 months
* Short-term outcome comparison was done at 2 weeks after the intervention by the patients’ primary care physicians, where the primary outcome was assessed as “response” or “non-response”
  + The primary outcome was the direct treatment response with four categories:
    - 0= no response
    - 1= partial response, but not satisfactory, warranting further treatment
    - 2= partial response, satisfactory, not warranting further treatment
    - 3= complete resolution of symptoms and signs
  + The definition of a “responder” was a patient with a score of 2 or 3; a patient with a score of 0 or 1 was designated a “non-responder”
* The authors also followed the “responders” for recurrence of symptoms warranting referral for operative treatment for one year
* Among the 36 patients randomized to TCA, 1 refused further participation, and 35 received TCA: 11 patients had a single TCA injection and 24 patients had two TCA injections
  + In the TCA group, there were 17 responders and 18 non-responders; the 17; responders were entered into followup to determine the rate of recurrence
* Among the 33 patients randomized to saline, 2 refused further participation and did not receive any injection; the other 31 received saline injection (numbers who received two injections not reported)
  + In the saline group, there were 5 responders and 26 non-responders to saline
  + 22 of the 26 saline non-responders received bailout treatment with TCA injection, while the other 4 refused further participation;
  + 18 of the 22 who received bailout injection with TCA became responders and were followed up for recurrence; the other 4 were non-responders to the bailout injection and were referred for operative treatment
* Thus, the short-term (2 week) assessment, determined by the numbers of responders to the first set of injections, favored the TCA group over the saline group (17 responders for TCA versus only 5 for saline)
* The 17 TCA responders, along with the 18 responders to the bailout TCA injections, were followed up for recurrence (n=35)
  + Of these 35 patients who had responded to TCA, there were 17 recurrences resulting in referral to secondary care, while there were 18 who did not have recurrences
  + Among the 17 patients with recurrences, 12 were referred for operative treatment
* The followup process also recorded scores on the Boston Carpal Tunnel Questionnaire, both for the symptom severity scale (SSS) and the functional status scale (FSS), and the authors reported these scores for the 18 who did not have recurrences
  + The average SSS and FSS scores for the patients “free of recurrence” tended to deteriorate during the time of followup, but did not return to the scores which were recorded at baseline
  + The course of the SSS and FSS for the patients with recurrences were not reported, but presumably returned to baseline levels or worse
* There were no serious adverse events during the trial

Authors’ conclusions:

* In the short term, steroid injection is safe and is more effective than saline injection
* Long-term effectiveness of steroid injection is less clear, since long-term data were only available for those patients who were responders to TCA injection
* Deterioration and recurrence were common during the followup of responders to steroid injection
* The response rate to steroid injection was lower than has been reported in other trials of steroid injection
  + This could be because the trial used only 10 mg of TCA, while other studies have used 40 mg of methylprednisolone
  + It could also be due to the fact that the average duration of symptoms was longer in this trial (76 weeks) than in other trials (32 weeks)
  + It is possible that the diagnosis of CTS was less clear, since it was based on clinical criteria alone (even though the Katz hand diagram generally enables general practitioners to diagnose CTS)

Comments:

* The very short-term outcomes are fairly clear: steroid injection is superior to saline injection at 2 weeks of followup
* The longer-term outcome comparisons are clouded by several difficulties:
  + The 5 “responders” to saline injection were not entered into the 12 month followup to detect recurrences
  + The outcomes of operative treatment were not reported, and it was not possible to learn whether surgery was successful in the patients who had it
  + This in turn sheds no light on the question of whether a response to saline injection is correlated with a response to surgery, which remains an important question for the management of clinically diagnosed CTS
  + However, it is clear that even after improvement with steroid injection, short-term success is very often followed by later clinical deterioration and recurrence of symptoms and functional limitations
  + There appeared to be a difference in steroid response rate between those patients who received TCA in the original randomization (17 of 35) and in those who had it as a bailout treatment (18 of 22); this is a curious phenomenon with no clear explanation
    - Table 1 did not compare mean duration of symptoms (which was reported in the discussion section), but did report median duration (13 weeks for saline and 28 weeks for the TCA group)
    - While this would tend to favor the saline group, and therefore would not present problems for the conclusion that steroid is more effective than saline, it could present a possible explanation for the unexplained difference between TCA in the original group and in the bailout injection group
* There is some value in documenting the clinical course of CTS in the year after an initial favorable response to injection
  + There is also some value in reporting that even in the short term, only 17 of the 35 patients who were randomized to steroid injection actually had a good response at two weeks
* Although the vast majority of patients had either classic or probable Katz diagrams, there were 3 patients who were entered into the study with unlikely Katz diagrams
* The methods section inadvertently omitted the minimum age requirement for entry, stating “Exclusion criteria were thenar atrophy, being less than years of age, presence of contraindications for corticosteroid injection" and other criteria, but the age exclusion criterion was left blank; the author has been e-mailed for the answer, but it is not necessary for the assessment of the trial’s suitability for evidence

Assessment: adequate for some evidence that a 10 mg injection of triamcinolone is more effective than a 1 ml injection of saline in the very short term (two weeks after injection), but that a satisfactory short-term outcome may occur in only half of patients who receive it, and that even an initially favorable response to steroid injection leads to recurrence and relapse in more than half of treated patients over the course of 12 months.