

Tafazal S, Ng L et al. Corticosteroids in peri-radicular infiltration for radicular pain: a randomised double blind controlled trial. One year results and subgroup analysis. Eur Spine J 2009;18:1220-1225.

Design: Randomized clinical trial

Population/sample size/setting:

- 150 patients treated for radicular lumbar pain in an orthopedics department in the UK, of whom 124 (53 women, 71 men, mean age 52) had complete data for analysis 3 months after entering a randomized clinical trial
 - o Of the 124 patients, 76 had disc herniation and 48 had foraminal stenosis
- Eligibility criteria were unilateral leg pain (at least as intense as any back pain) and MRI confirmation of nerve root compression due to either disc herniation or foraminal stenosis, with at least 6 weeks of conservative treatment with analgesics and physical therapy and no apparent benefit
- Exclusion criteria were acute trauma, cauda equina syndrome, previous back operation, peri-radicular infiltration in preceding 12 months, epidural injection in past three months, pregnancy, local skin infection, allergy to treatment agents, anticoagulation treatment, and inability to complete questionnaires

Main outcome measures:

- The 150 patients who entered the trial were randomized to peri-radicular injection, under fluoroscopic guidance, of one of two mixtures: (1) 2 ml of 0.25% bupivacaine alone, or (2) 2 ml of 0.25% bupivacaine plus 40 mg methylprednisolone
 - o The syringes were prepared by an assistant who placed masking tape in order to conceal the solutions from the injecting physician
 - o For 3 patients, leakage of the solution occurred, unblinding the injector, resulting in exclusion of the patient from the analysis of results
 - o Additional exclusions occurred before the primary analysis at 3 months, either because of surgery or through failure to attend the clinic for the follow-up appointment, leaving 124 patients for the main analysis
- The principal outcomes were changes in VAS pain scores for leg and back, and in the Oswestry Disability Index (ODI) at the 3 month follow-up examination
 - o Additional measurements were taken of a low back outcome score, the modified somatic perception questionnaire, and the modified Zung depression score

- At 12 months, two other outcomes were measured: the need for surgery and the need for further nerve root blocks
- Subgroup analyses were done with the disc herniation and foraminal stenosis patients being analyzed separately, in order to determine whether the source of radicular pain predicted the success of treatment
- At 3 months, the improvements in pain VAS and in ODI were not different between the groups which did and did not receive the steroid injection in addition to the local anesthetic; the bupivacaine group improved the ODI by 10.7 points and the bupivacaine plus steroid group improved the ODI by 9.3 points
 - Similarly, both treatment groups had an equal improvement in the 100 mm VAS scores at 12 weeks (22.6 mm for bupivacaine alone versus 24.5 for the steroid group)
- For the subgroup analyses between disc herniation and stenosis, group differences were inconclusive, but not greatly different between subgroups for most measures
 - The mean ODI decreased significantly more in the disc herniation group (15.0 points) versus only 3.3 points in the spinal stenosis group
 - However, the percentage of patients with at least a 10 point change in the ODI was 54% for the herniation group versus 44% in the stenosis group
 - The mean pain VAS decreased by 26 mm in the disc herniation group and by 21 mm in the stenosis group
 - The percentage of patients with at least a 20 point drop in VAS was 58% in the disc herniation group and 52% in the stenosis group
 - An excellent or good subjective outcome was reported by 54% of patients in the disc herniation group and by 42% of the patients in the stenosis group
- The rates of subsequent surgery were not significantly different between the bupivacaine group at the 12 month follow-up (14/65) and the bupivacaine plus steroid group (9/64)
 - Similarly, there were no significant differences in the rates of further root blocks in the two groups: 10/65 for the bupivacaine group and 8/56 for the steroid group

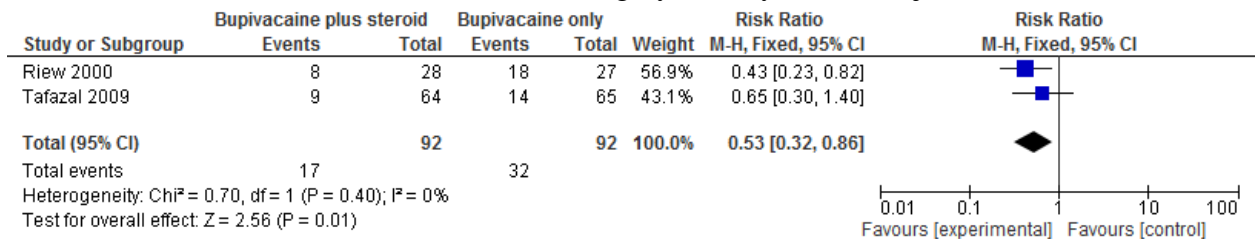
Authors' conclusions:

- Peri-radicular infiltration of steroids appears not to produce any additional benefit compared with bupivacaine alone in patients with sciatica
- Subgroup analysis showed a trend, but did not appear to show a statistically significant difference in effect of ESI between disc herniation and foraminal stenosis
 - Multiple subgroup analyses may have led to a Type I error (incorrectly identifying a statistically significant difference) in the greater ODI reduction for herniated discs than for spinal stenosis

- In contrast to Riew 2000, addition of steroid to bupivacaine did not appear to reduce the need for surgery at one year
 - o The overall rate of surgery for Riew (47%) was much greater than for the current study, in which only 18% of patients had surgery in the first year
- Peri-radicular infiltration of bupivacaine is effective for sciatica due to a herniated disc, and adding steroid appears to confer no added benefit

Comments:

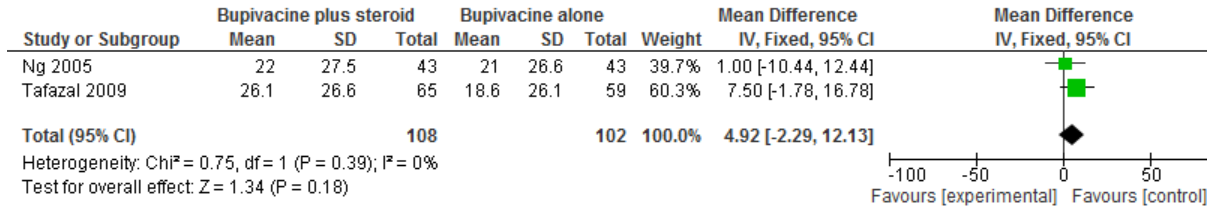
- The numbers are too small to make reliable comparisons of herniated disc and spinal stenosis responses to peri-radicular infiltration of anesthetic with or without steroid
 - o The text does report that the mean change in the ODI was greater for the disc herniation group than the stenosis group (mean change of 15.0 versus 3.3), but the standard deviations (SD) were very different in relation to the means; the SD for the stenosis group was 14.0; with a mean of only 3.3, the data were too skewed to make the t-test useful
 - o The similarity in clinically important ODI changes (10 points or more) is more appropriate for comparing the subgroups; the smaller improvement in the stenosis group is only suggested, not demonstrated, given the sample size
- There is an error in Table 6, which does show that the treatment groups had similar distributions of subjective patient satisfaction ($p=0.488$ using SPSS for chi-square trend); the number of patients with disc prolapse is 76 in the table and in the text, but the numbers in the left column of Table 6 add up to 83, not 76
- Although the rates of surgery were much lower than in the study by Riew et al 2000, the effect sizes (reduction in rates of surgery) were fairly similar; pooling the two studies estimates that ESI decreases rates of surgery in the year after injection:



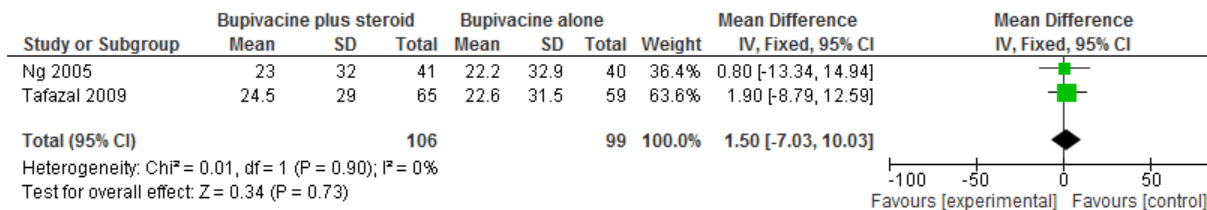
- o The pooled data suggests that patients with steroid were 53% as likely to have surgery in the year after injection than patients with anesthetic alone
- o It is still possible that ESI is a good option for patients with sciatica who have preferences not to be operated on, or who wish to delay surgery, even though the pooled estimate of 0.53 could easily be materially changed by further research with larger sample sizes
- For short term changes in leg pain, Ng and Tafazal have both 6 week and 12 week data (subject to some guesswork as to the exact numbers in each group); for both

studies, it is possible to pool the differences in pain VAS responses between the groups receiving anesthetic plus steroid versus anesthetic alone

- For the six week estimate, the pooled pain response is only 5 mm on a 100 mm scale

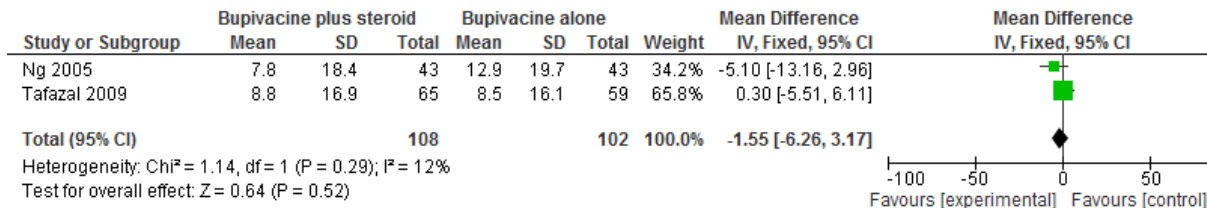


- For the 12 week estimate the pooled pain response is only 1.5 mm on a 100 mm scale

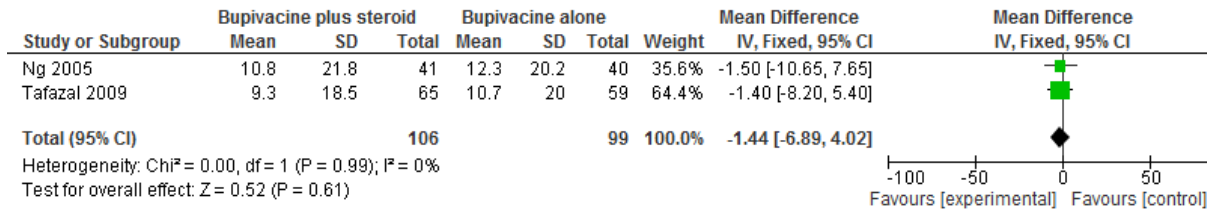


- For short term changes in ODI, Ng and Tafazal have 6 and 12 week data with pooled results showing small differences between treatment groups

- The 6 week pooled ODI difference is 1.55 points



The 12 week pooled ODI difference is 1.44 points



- Pain VAS and ODI are both based upon patient-completed questionnaires; differences in rates of surgery are based on what actually happened in the first year of treatment
- Rates of having surgery probably provides information which is not completely captured by the VAS and ODI questionnaires
- The effects of adding steroid to bupivacaine are open to some interpretation; effects on patient-reported pain and disability are small at both 6 and 12 weeks, and the effect on avoiding surgery within 12 months may be large enough to warrant further attention
 - Because of the small sample sizes and the fact that only Riew 2000 estimated that adding steroid reduced the need for surgery, it is appropriate to say that

there is “some” evidence that a steroid injection may reduce the 12-month need for surgery in patients with radicular pain

- Both Ng and Tafazal reported only small effects of adding steroid to anesthetic; these studies add up to good evidence that adding steroids has only a small effect on patient-reported improvements on pain and disability

Assessment: Adequate for some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment, and good evidence that adding steroids has only a very small effect on patient-reported pain and disability