
Design: Randomized clinical trial

Population/sample size/setting:
- 81 patients (38 women, 43 men, mean age 50) treated for chronic radicular back pain at an orthopedics department in Leicester, UK
- Eligibility criteria included unilateral leg pain at least equal to back pain, completion of at least 6 weeks of NSAID and physical therapy without apparent benefit, and symptoms consistent with MRI diagnosis of nerve root compression due either to herniated disc or foraminal stenosis
- Exclusion criteria included acute back trauma, cauda equina syndrome, prior back operation, periradicular infiltration in preceding 12 months, epidural injection in past 3 months, anticoagulant therapy, pregnancy

Main outcome measures:
- All participants received a periradicular injection under fluoroscopic guidance
- Randomized to 2 ml of 0.25% bupivacaine (n=41) or bupivacaine plus steroids (n=40)
- Primary outcomes were change in Oswestry Disability Index (ODI), change in pain VAS, change in walking distance, and patient satisfaction
- Follow-up observations were done 6 and 12 weeks after the injection by a clinician who was unaware of the treatment assignment
- Modest improvements were observed for both treatment groups for ODI; a 10% reduction was recorded for 55% of the bupivacaine group and for 35% of the bupivacaine plus steroid group; this difference was not statistically significant
- Similarly, a 20 mm reduction in leg pain was recorded for 41.5% of the bupivacaine group and for 45% of the bupivacaine plus steroid group
- Patient satisfaction was similar in the two groups; 49% of the bupivacaine group and 45% of the bupivacaine plus steroid group were satisfied with the results at 12 weeks after injection
- Subgroup analysis showed that disc herniation and foraminal stenosis responded similarly to the two interventions
- The duration of symptoms was correlated with a less favorable functional outcome at 12 weeks

Authors’ conclusions:
- Corticosteroid added no benefit to periradicular injection with bupivacaine for treatment of lumbar radicular pain
- A prolonged duration of radicular pain is associated with a less favorable outcome at 3 months
- Periradicular infiltration of bupivacaine alone provides reduction in pain and improvement in back-related disability at 3 months after injection
- Because the injection of medication did not use contrast, its delivery to the site of therapeutic action is not certain

Comments:
- Sources of bias appear to be well-controlled, and clinically meaningful benefits of periradicular steroid are not likely to have been missed
- The negative correlation between duration of symptoms and the “independent variables” (Table 6) presumably represents the effect on the change in the ODI, which is the disability measure mentioned in the main text, but the table is not clearly described
- The lack of clear units of measurement in Table 6 makes it difficult to determine the clinical interpretation of the decreased effectiveness with duration of symptoms
- Response is reported in terms of means and standard deviations of ODI and pain scores; these outcome measures tend to be bimodally distributed (patients either respond or do not respond); and the percentage of patients with 30% or 50% relief of pain, or with 10 point ODI reductions, are more informative
- The absolute benefit of injection of bupivacaine with or without steroid appears to be limited, since the changes from baseline in Figures 1 through 4 are modest
- Even though the power of the study is not easily estimated, the proximity of the trends in Figures 1 through 3 shows that the responses are close to equivalent, and the area under the curves is similarly convincing of a lack of effect of adding steroid to bupivacaine

Assessment: Inadequate for evidence that periradicular steroid and/or bupivacaine produces decreasing benefits as the duration of symptoms becomes chronic, and adequate for evidence that bupivacaine alone is equal to bupivacaine plus steroid, with no effect of steroid on ODI, leg pain, or back pain