Riew KD, Yin Y, et al. The Effect of Nerve-Root Injections on the Need for Operative Treatment of Lumbar Radicular Pain. JBJS Am 2000;82-A(11):1589-1593.

Design: Randomized clinical trial

Population/sample size/setting:

- 55 patients (27 men, 28 women, age not reported) treated for degenerative lumbar radicular pain in a university orthopedics department in St. Louis

- Eligible if they were at least 21 years old and had confirmation of disc herniation or central/foraminal spinal stenosis by MRI or CT, provided they had six weeks of nonoperative therapy including anti-inflammatory medication, physical therapy, and activity modification without benefit
    - An exception to the six week rule was made if the patient had intractable pain with maximum anti-inflammatory medication plus narcotics
- Exclusion criteria were acute trauma, cauda equina syndrome, progressive neurologic deficit, Workers Compensation claim, lack of radiographically detectable abnormalities, or symptomatic degenerative changes at more than two spinal levels which would necessitate three separate injections
- All patients were considered to be strong surgical candidates, who would be recommended for operative treatment if they did not have any spinal injections

Main outcome measures:

- All patients had selective nerve-root injection under fluoroscopic guidance with 1 ml of 0.25% bupivacaine
- Randomization was to either bupivacaine alone (n=27) or bupivacaine plus 1 ml containing 6 mg betamethasone (n=28)
- Most results (for pain and for disability) are reported in terms of p values without numerical data and are not worth discussing
- The principal outcome for which numerical data are reported is whether or not the patient had surgery during the observation period of the trial
    - There was a minimum of 15 months of observation (mean was 23 months; maximum was 28 months)
- Repeated injections were allowed; injection therapy was not considered to have failed if the patient received two or three additional injections
    - Failure of injection was defined only as the patient opting for operative treatment
- 26 of the 55 patients opted to have an operation; 29 opted not to have an operation
    - More patients in the bupivacaine plus steroid group opted out of surgery than was the case in the patients who had bupivacaine alone

    - Of the 27 patients who had bupivacaine only, 18 opted for an operation, and 9 did not
    - Of the 28 patients who had bupivacaine plus betamethasone, 8 had an operation and 20 did not
- 19 patients had more than one injection; 10 had 2 injections, 6 had 3 injections, and 3 had 4 injections
    - The minimum interval between injections was 6 days; the longest was 10.5 months
    - 13 of the 19 patients avoided an operation and the other 6 had an operation

Authors' conclusions:

- Nerve root injections were successful in avoiding surgery in over half of the operative candidates who entered the study
- The data do not give a good explanation as to why so many patients did not have operations
- Some patients had disc herniation and some had spinal stenosis, but the sample size was too small to determine whether injections are equally effective in both groups
    - Since spinal stenosis, in contrast to disc herniation, does not have a natural history of spontaneous resolution, it is difficult to say that postponing surgery is in the best interests of patients with spinal stenosis
- The study supports having a treatment algorithm for patients with one or two-level radiculopathy without motor or sensory deficits; surgery should be deferred until selective nerve-root injections with bupivacaine plus betamethasone have been tried up to three or four times

Comments:

- Several interesting points are raised by the authors; unfortunately, they did not report the data needed to asses them
    - In the patients who avoided surgery, the change in neurological symptoms was not significant
        - P values alone are not enough to interpret the changes in scores on the pain VAS and on the NASS questionnaires
    - It is highly plausible that patient-completed paper and pencil questionnaires do not tell decision-makers everything they need to know about the effectiveness of an intervention, and that additional valuable information is obtained from such outcomes as opting for surgery
    - Mention was made about the role of expectations of improvement on the part of the patients, but no information was reported concerning these expectations

    - The differences between disc herniation and spinal stenosis could not be determined because of the limited sample size, but the note of caution about postponing surgery for spinal stenosis patients does seem reasonable
- The patients in the study appear to have been those for whom a surgical intervention was highly likely in the clinical setting where they were treated, and the same degree of difference in surgical intervention may not apply in other settings
- The fact that many patients needed repeat injections raises concerns about how many injections should be done before an operation is done
- The fact that many outcomes were inadequately reported does not by itself invalidate the conclusion that the nerve root injections allowed many patients to avoid surgery during the study period

Assessment: Adequate for evidence that the addition of a steroid to an anesthetic selective nerve root injection enables surgery to be avoided for more than one year and possibly longer

Riew KD, Park JB, et al. Nerve Root Blocks in the Treatment of Lumbar Radicular Pain. A Minimum Five-year Follow-up. JBJS Am 2006;88A:1722-1725.

Brief summary of results:

- The 29 patients who had avoided surgery in the 2000 study were asked to participate in a 5 year follow-up study
    - 20 of these patients had been in the steroid group, and 9 had been in the bupivacaine group
- 21 responded to the request to participate
    - 8 patients were lost to follow-up; all 8 had received the steroid injection in the 2000 study
- Among the 21 patients who responded, only 4 had opted for surgery in the past 5 years; 17 had continued not to have surgery
- Of the 20 steroid patients, 3 had opted for surgery; of the 9 bupivacaine patients, 1 had had surgery
    - The numbers were too small to reach statistical significance
- Among the 21 patients, 14 had spinal stenosis and 7 had a herniated disc
    - 3 stenosis patients had surgery while 11 did not; 1 herniated disc patient had surgery and 6 did not; again, the numbers were too small for statistical significance
- Among the 17 patients who had no surgery at 5 years, there were decreases in neurological symptoms and in back pain

    - These results are reported only as p values less than 0.05, and no effect sizes are reported
- 9 patients had more than one block; none of these went on to have surgery

Authors' conclusions:

- The initial study showed a significant difference between the steroid and bupivacaine groups with respect to avoiding surgery; this difference was not seen in the follow-up study, perhaps due to the small numbers available
- Of the 29 patients who avoided surgery in the first study, only 4 had an operation in the current study; even if all 8 patients lost to follow-up had had surgery in that period, there would still be 17/29 patients (59%) of apparent surgical candidates who could avoid surgery in the longer term
- Even if the 8 patients who were lost to follow-up had continued to avoid surgery, the difference between steroid and bupivacaine groups would not be significant
- Injections blocking the lumbar nerve root are likely to be effective in preventing surgery in otherwise surgical candidates, and are an attractive first option prior to surgery

Comments:

- The improvements in symptoms were reported only as p values, and these have no direct clinical meaning without reporting the actual pain and disability scores; they cannot be interpreted
- The authors stated that even if the 8 patients lost to follow-up had continued to avoid surgery, there would not be differences between steroid and bupivacaine groups in the outcome of surgery avoidance
    - However, this is not correct
    - The authors' analysis looked only at the 29 patients who avoided surgery in the first study
        - 12 of these were in the steroid group; if they assume that the 8 lost patients had avoided surgery, then there would be 20 steroid patients to analyze, and of these, 3 would have surgery and 17 would not have surgery
        - These numbers (3:17) would be compared to the 9 bupivacaine patients, only one of whom had an operation, and the comparison of 3:17 to 1:8 would indeed not be significant
    - However, the analysis ought to be in terms of all 55 patients originally randomized to steroid or bupivacaine, 28 of whom had steroid and 27 had bupivacaine
        - In this case, the comparative success of steroid and bupivacaine depends on how the 8 lost patients are assumed to have fared

        - If all 8 had had surgery, then the five year operative rate among the 28 steroid patients would be 19 operated and 9 not operated
        - The 5 year rates for the bupivacaine group would be 19 operated and 8 not operated; in this scenario, the surgical rates for both steroid and bupivacaine would be almost identical
        - However, if the 8 lost patients did not have an operation, then there would be 17 non-operated and 11 operated patients in the 28 steroid patients (the rates in the bupivacaine group would not change, since none of them were lost to follow-up)
        - Under this scenario, the relative risk of surgery for the bupivacaine group would be 1.8 compared to the steroid group, and would have a p value of 0.03
    - It seems likely that the 8 lost patients did not have an operation; if they had done poorly and had needed an operation, it seems likely that the authors' attempts to find them would have met with success; it seems likely that steroid injection is more successful than bupivacaine in avoiding surgery long term
    - The comparative success of steroid and bupivacaine with respect to surgery avoidance therefore cannot be determined without resort to speculation
    - However, the authors have shown that if a patient headed for surgery can get through the first year with only a nerve block, there is a good chance that a later operation will not be necessary
    - The patient population for Riew was specifically made up of patients for whom an operation was the next likely step
        - This is in contrast to the Pinto 2012 meta-analysis, whose patient mix was not composed of clear surgical candidates but of a more general mix of sciatica patients
        - Therefore, there is no conflict between Riew reporting that steroid injection may prevent surgery in operative candidates and Pinto reporting that steroids have no important effect on sciatica patients in general

Assessment: Adequate for some evidence that in patients who are clear candidates for surgery, a nerve root block with either steroid or bupivacaine may prevent the need for an operation, and that either kind of block is likely to prevent an operation for five years