
Design: Randomized clinical trial

Population/sample size/setting:
- 27 patients (17 men, 10 women, mean age 42.6) who presented with new onset back pain in the adult primary care or emergency departments at Kaiser Permanente in Santa Rosa, CA
- Eligible for inclusion if they had a diagnosis of acute sciatica, age between 20 and 60 years, and recruitment into the study within one week of symptom onset
  - Diagnosis of sciatica was based on unilateral leg pain below knee and a positive straight leg raising sign between 0° and 60°
- Excluded if there was a history of diabetes, renal failure, upper GI bleed, major psychiatric disease, pregnancy, or “red flag” symptoms such as unexplained weight loss, fever, night sweats, saddle anesthesia, bowel/bladder incontinence, etc

Main outcome measures:
- 29 patients were originally randomized on a sequential even-odd number basis to prednisone (n=15) or placebo (n=14); 2 prednisone patients dropped out because of scheduling conflicts, leaving 27 patients with outcome data
  - Medication was taken for 9 days: 3 days at 60 mg, then 3 days at 40 mg, then 3 days at 20 mg
- Outcomes were measured at intake and then weekly for 4 weeks, followed by monthly evaluations for 5 month; the total duration of the study was 6 months
- Roland-Morris pain scores showed improvement in the prednisone group earlier than in the placebo group, but statistically significant pain differences were not recorded at any time point during the study
- A similar pattern was observed for other outcomes: statistically significant improvement in the prednisone group being reported before similar improvement in the placebo group, but no significant group differences during the 6 months of observation
  - These other outcomes included mental health scores, Roland-Morris disability scores, and return to work
  - Medication use (NSAID, narcotics) did not differ between groups
- Many patients were not referred for imaging, but 14 patients (7 in each group) had MRI scanning due to progressive pain or neurological involvement; all patients referred for MRI had disc and nerve root abnormalities
- Epidural injection was administered to 2 of the 13 prednisone patients and to 6 of the 14 placebo patients; one of the placebo patients later had an L5 discectomy
  - The sample size precluded these differences from being statistically significant

Authors’ conclusions:

- Patients with acute sciatica showed no significant differences between responses to prednisone and placebo, even though the prednisone patients had a slightly faster relief of symptoms and had fewer epidural injections
- There are no dramatic effects of giving prednisone
- However, the prednisone patients may have had subtle advantages over placebo, such as fewer epidural steroid injections, which were not statistically significant because of sample size
- Patients with back and leg pain do not always have lumbosacral radiculopathy; patients considered for prednisone should be selected on the basis of clear-cut signs and symptoms of sciatica
- The possibility that a short course of prednisone may reduce work disability, the need for injections, and overall health costs deserves evaluation with a larger randomized trial

Comments:

- Even-odd allocation of treatment has a risk of bias due to a lack of allocation concealment, even though it appears that all consecutive eligible patients were randomized and selection bias may not bias the results
- The differences in the use of epidural injections raise the possibility that oral steroids may be effective, even though the study does not rise to the level of evidence

Assessment: Inadequate for evidence supporting prednisone for acute sciatica