Maine Medical Center
Department of Emergency Medicine
Journal Club Summary Template

Date:10/19/17	**Presenter Name: Andrew Fried**

Article Citation:
ORAL STEROIDS FOR ACUTE RADICULOPATHY DUE TO A HERNIATED LUMBAR DISK: A RANDOMIZED CLINICAL TRIAL Goldberg, H., et al, JAMA 313(19):1915, May 19, 2015

Country(ies): USA

Funding Source(s): This study was supported by grant R01 AR053960 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the US National Institutes of Health to Drs Goldberg and Avins.

☐ None Stated

Purpose

Research Question(s): Is oral prednisone more effective than placebo in improving function and pain among patients with acute sciatica?

☐ None Stated

Hypotheses:
Oral prednisone will be more effective than placebo in improving function and pain among patients with acute sciatica

☐ None Stated

Study Purpose:
To find out if we should be giving these patients steroids for their pain and functionality.

Methods

Study Design: Randomized, double-blind, placebo-controlled clinical trial

Outcome(s) *[or Dependent Variable]:*
Primary: Self reported ODI score 3 weeks after randomization
Secondary:

- Pain (on 0-10 scale) including average, best, and worst levels of pain below the waist over the prior 3 days and average pain levels above the waist
- Short Form 36 Health Survey Physical Component Summary and Mental Component Summary subscale
- Incidence of lumbar spine surgery

Intervention *[or Independent Variable]:*
Three 20-mg capsules of prednisone daily for 5 days, then 2 capsules daily for 5 days, then 1 capsule daily for 5 days

The placebo group got identical appearing capsules and instructions.

Ethics Review: ☐ IRB Review ☐ IACUC Review ☐ Other: ☒ None Stated

Research Setting: Primary care clinic

Study Subjects:
Members of Kaiser Permanente Northern California

Inclusion Criteria:
- 18 to 70
- leg pain extending below the knee in a nerve root distribution
- had a herniated disk **confirmed by MRI**
- Scored 30 points or higher on the Oswestry Disability Index
- Positive straight leg raise (this got removed after 14 months because they weren't enrolling enough people)

Exclusion Criteria:
- onset of radicular pain more than 3 months prior
- previous lumbar surgery
- steroid treatment within the last 3 months (oral or espidural)
- diabetes
- substantial or progressive motor loss
- ongoing litigation or workers comp claim

Study Interventions:
Prednisone as described for the intervention group. Identical placebo pills for the control group.
"Nonsteroidal anti-inflammatory drugs were not allowed for 3 weeks after randomization, but otherwise all patients in both treatment groups received usual care for their symptoms."

Study Groups: 181 patient randomized to prednisone, 88 randomized to placebo

Instruments/Measures Used:
- ODI
- Pain numerical rating scale
- Short Form 36 Health Survey Physical Component Summary
- Mental Component Summary
- Likert scale

Data Collection:
From electronic health record

Data Analysis:

***A priori* sample size calculation?** ☒ Yes ☐ No ☐ Not Described ☐ N/A

Statistical analyses used: *t* Test, Wilcoxon rank sum, Fischer exact, multivariable linear regression models, Poisson regression models.

Done as intention to treat trial

Adjustment for potential confounders? ☒ Yes ☐ No ☐ Not Described ☐ N/A

If yes, list:

- Age, sex, race, ethnicity, study site, presence of positive straight leg raise, elapsed time between symptoms onset and randomization.

Results

Study participants:

	Prednisone	Placebo	
Baseline:	51.2	51.1	
3 weeks:	32.2	37.5	(adjusted difference 6.4, p=0.006)

52 weeks: The difference increased to 7.4 (p=0.005)

Prednisone had a RR 1.7 to decrease ODI by 30 points in 3 weeks, and RR 1.8 to have 50% improvement of ODI score in 3 weeks (NNT 11 and 8)

Secondary outcomes:

- No difference in pain scores
- Improvement by 3.3 in physical component summary short form in 3 weeks by prednisone group, and 3.6 increase in mental component score at 1 year
- No change in likelihood to undergo spine surgery

Adverse events:

"88 participants (49.2%) in the prednisone group reported at least 1 adverse event compared with 21 (23.9%) randomized to placebo (*P* < .001)."

"The majority of these were minor, expected adverse effects commonly associated with short courses of prednisone, such as insomnia, nervousness, and increased appetite"

– (NNH of 4)

Brief answers to research questions *[key findings]:*

There was a modest, significant benefit in ODI scores (decreased by about 6.4 on a scale of 0-100) in 3 weeks.

Additional findings:

No difference in pain or likelihood to need surgery. There was a much higher incident of, mostly minor, adverse effects. The decrease in ODI scores was preserved at 1 year as well.

Limitations:

- No NSAIDS for 3 weeks in the control group, that is not standard of care. I wonder if the NNT to get pt to that 30 point or 50% reduction in 3 weeks would still be 1.7 if patients in the other group were getting NSAIDS.
- Outcomes were self-reported.
- They blinded the patients as well as they could, but the adverse effects revealed to many patients that they were in the treatment arm. (75% thought they had prednisone, compared to 52% in the control arm that thought they were being given prednisone)
- The change seen at 3 weeks was gone at 6 weeks and then back at 52 weeks. With no explanation of why 3 weeks of steroids should be able to change functionality at 1 year, the authors conclude that this was likely due to chance. This casts some doubt on the validity of their conclusions that steroids helped with functionality at 3 weeks as the effect at 1 year was even larger.

Clinical Implications

Applicable?

- This was done in the outpatient setting with MRI proven disk herniation causing radiculopathy, not very applicable to the undifferentiated back pain patients we see in the ED.

Feasible? Yes

Clinically relevant? Yes

Comments:

Level of evidence generated from this study

☐ Ia: evidence obtained from meta-analysis of randomized controlled trials
☒ Ib: evidence obtained from at least one randomized controlled trial
☐ IIa: evidence obtained from at least one well-designed, controlled study without randomization
☐ IIb: evidence obtained from at least one other type of well-designed quasi-experimental study
☐ III: evidence obtained from a well-designed, non-experimental study

☐ IV: expert committee reports; expert opinion; case study; case report

Additional Comments/Discussion/Notes
- Unlikely to be practice changing in the ED environment, however if you chose to prescribe prednisone for pts with sciatic pain, there is some support there.