Maine Medical Center
Department of Emergency Medicine
Journal Club Summary Template

Date: October 2013	**Presenter Name:Kelly Meehan-Coussee**

Article Citation:
Friedman, BW, Dym AA, Davitt M, et al. Naproxen with cyclobenzaprine, oxycodone/acetaminophen, or placebo for treating acute low back pain: a randomized control trial. JAMA. 2015;314(15):1572-80.

Country(ies): USA

Funding Source(s): Presumed: Montefiore Medical Center, Albert Einstein College of Medicine
X None Stated

Purpose

Research Question(s):
Is a 10 day course of muscle relaxants or opioids combined with naproxen more effective than naproxen alone for the treatment of atraumatic, acute lower back pain?
☐ None Stated

Hypotheses:
X None Stated

Study Purpose: To evaluate the difference in pain and functional status following treatment with naproxen vs naproxen plus muscle relaxants or opioids on patients with acute lower back pain

Methods

Study Design:
Randomized double blinded 3 group study

Outcome(s) *[or Dependent Variable]:*
Improvement in RMDQ with a 5 point improvement considered clinically significant

Intervention *[or Independent Variable]:*
Intervention for lower back pain: naproxen + placebo, naproxen + cyclobenzaprine, naproxen + oxycodone/acetaminophen

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

Research Setting: Single urban ED in Bronx, New York

Study Subjects: Adults 21-64 presenting for management of acute lower back pain originating between the lower scapular border and upper gluteal folds with a diagnosis of atraumatic, nonradicular musculoskeletal back pain with functional impairment

Inclusion Criteria:
RMDQ score > 5 (plus location/description/diagnosis as noted above)

Exclusion Criteria:
Radicular symptoms, direct trauma within one month, pain lasting more than 2 weeks, h/o of more than one episode of lower back pain in the past month, currently pregnant or lactating, unavailable for follow up, allergy/contraindication to study medications, history of chronic opioid use, previous enrollment in this study

Study Interventions:
Naproxen + education session + PRN placebo
Naproxen + education session + PRN cyclobenzaprine
Naproxen + education session + PRN oxycodone/acetaminophen

Study Groups:

Instruments/Measures Used:
RMDQ

Data Collection:
Paid reseachers staffed ED 16-24hrs, 7 days a week, collected RMDQ in the ED, and then at day 7 and 3 months following ED visit via phone or mail. Follow ups also included: rating of worst back pain in previous 24hrs, frequency of use of PRN medications, number of days before returning to usual activities, number of provider visits, adverse events (tired, dizziness, irritating to the stomach)

Data Analysis:

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

Statistical analyses used:
Intention to treat analysis with second analysis of only those patients who reported use with 3 pairwise comparisons
Adjustment for potential confounders? ☐ Yes ☒ No ☐ Not Described ☐ N/A
If yes, list:

Results
Study participants: **2588 pts with lower back pain -> 323 meeting inclusion criteria and without exclusion criteria** **107 randomized to placebo (14 lost to follow up)**

108 randomized to cyclobenzaprine (15 lost to follow up)
108 randomized to oxycodone/acetaminophen (12 lost to follow up)

Brief answers to research questions *[key findings]:*
No significant difference in outcomes among groups, but patients in oxycodone/acetaminophen group were more likely to report pain levels of mild or none. No change in improvement in functional outcome or difference in resource utilization across groups.

Additional findings:
At 1 week of follow up, greater than 50% of patients still required medication but greater than 2/3rds reported desiring same medication in the future

Limitations:
Many patients were already using naproxen before ED visit. Patients could titrate doses to balance efficacy with adverse effects, but this does not ensure optimized utilization of medications. There was no evaluation of adequacy of patient blinding regarding patients' assumptions of medications prescribed.

Clinical Implications

Applicable? Yes
Feasible? Not to recreate study, but feasible to implement interventions
Clinically relevant? Yes

Comments: Findings are aligned with my current practice in treatment of atraumatic, nonradicular lower back pain

Level of evidence generated from this study

☐ Ia: evidence obtained from meta-analysis of randomized controlled trials
X 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