UAMS Journal Club Summary, January 2018
Drs. Lauren Evans and Tyler Griffin
Faculty Advisor: Dr. C Eastin

Clinical Bottom Line

Among patients with acute, nontraumatic, nonradicular LBP presenting to the ED, adding cyclobenzaprine or oxycodone/acetaminophen to naproxen alone did not improve functional outcomes or pain at 1-week follow-up. These findings do not support use of these additional medications in this setting.

PICO Question

P Patients who presented to the ED with nontraumatic, nonradicular LBP of 2 weeks' duration or less
I 10-day course of naproxen + cyclobenzaprine or naproxen + oxycodone/acetaminophen.
C Naproxen + placebo
O Improvement in RMDQ between ED discharge and 1 week later.

Trial 1

Benjamin W. Friedman, MD, MS, et al. "Naproxen With Cyclobenzaprine, Oxycodone/Acetaminophen, or Placebo for Treating Acute Low Back Pain A Randomized Clinical Trial." *JAMA*. Volume 314, Number 15, 1572-1580
https://www.ncbi.nlm.nih.gov/pubmed/26501533

Validity Rating:
Low risk of bias

The Basics
This randomized, double-blind, 3-group study was conducted at one urban ED in the Bronx, New York City. N=107. The study looked at patients age 21-64 with nontraumatic, nonradicular LBP of 2 weeks or less duration. Patients were discharged home with combination therapy of naproxen + either placebo, Tylenol/oxycodone, or cyclobenzaprine. Results were based on improvement in the Roland-Morris Disability Questionnaire (RMDQ).

Exclusion criteria

- Low back pain duration >2 weeks or more frequent than 1 × /mo
- Age >65 years
- Direct trauma
- Refused participation
- Medication contraindication or allergy
- Radicular pain
- Medical cause of low back pain
- Unable to consent
- Previous enrollment

- Chronic opioid use
- Admitted to hospital

Primary Outcome
- RMDQ score at 1 week follow up

Secondary Outcomes
- RMDQ score at 3 month follow up

Follow Up
- Research assistants contacted patients by telephone 1 week and 3 months after ED visit to asesess RMDQ scores

Results
- The authors assumed a mean change in RMDQ between baseline and 1 week of 5.6 and a minimum clinically important difference on the RMDQ of 5.0. There was no significant difference in the RMDQ score between the groups.

Limitations/Biases
- Single center study
- 3 patients of 107 lost to 1 week follow-up. 11 lost to 3 month follow-up
- Did not look at any secondary outcomes such as return to function
- Lack of standard doses and much was left to physician discretion
- Did not evaluate the adequacy of patient blinding.
- Did not determine whether participants were using NSAIDs at the time of enrollment

Trial 2

Turturro, Michael A. et al. "Cyclobenzaprine with ibuprofen versus ibuprofen alone in acute myofascial strain: A randomized, double-blind clinical trial." *Annals of Emergency Medicine*, Volume 41 , Issue 6 , 818 – 826
https://www.ncbi.nlm.nih.gov/pubmed/12764337

Validity Rating:
Low risk of bias

The Basics
A randomized, prospective, double-blind study with n=102. The study looked at patients age 18 – 70 with acute myofascial strain caused by minor trauma within the past 48 hours who were discharged home with ibuprofen 800mg q6h and either cyclobenzaprine 10mg q8h or a placebo q8h who then rated their pain using a VAS scale.

Exclusion criteria

- Unable/unwilling to consent
- Analgesic use within prior 4 h
- Known pregnancy/lactation
- Acute intoxication
- Altered mental status
- Hypersensitivity to ibuprofen or cyclobenzaprine
- Taking TCAs, MAO inhibitors, CNS depressants
- History of urinary retention, BPH, Cardiac dysrhythmias, narrow angle glaucoma, peptic ulcer disease, renal insufficiency
- Required opioid and/or parenteral analgesic in the ED

Primary Outcome

- Pain, using a 100-mm VAS scoring system, at time = 0, 30, 60, 90, 120, and 180 minutes and 24 and 48 hours.

Secondary Outcomes

- None

Follow Up

- Research assistants contacted patients by telephone 24 and 48 hours after enrollment and assisted with VAS scales.

Results

- There was no significant difference in the mean pain score between the groups. Prior to the study the authors determined that samples of 38 patients in each group would be sufficient to detect a difference of 15 mm with 90% power. The final results of the study showed a difference in VAS scores of -3.0 to 2.7 mm with sufficient group size. At 24 h the difference in mean pain score was 0.2 mm with a CI of -11.4 to 11.8.
- The cyclobenzaprine group had an increased CNS side effects (42% vs 18%).

Limitations/Biases

- Excluded any patient who had taken analgesia < 4 hours prior to arrival and only included patients with acute trauma causing the myofascial strain
- 25 patients of 101 lost to follow up
- Follow up was limited to a 48 hour time window
- Did not look at any secondary outcomes such as return to function