

More Isn't Better With Acute Low Back Pain Treatment

Adding cyclobenzaprine or oxycodone/acetaminophen to naproxen for the treatment of acute low back pain does nothing more than increase adverse effects.

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PRACTICE CHANGER

Consider treating patients with acute low back pain with naproxen only, as adding cyclobenzaprine or oxycodone/acetaminophen to scheduled naproxen increases adverse effects and does not improve functional assessment at seven days or three months.

STRENGTH OF RECOMMENDATION

B: Based on a high-quality, randomized controlled trial (RCT).¹

A 46-year-old man presents to the emergency department (ED) with low back pain (LBP) after helping a friend move a couch three days ago. He denies any direct trauma to his back and describes the pain as a "spasm" in his lumbar spinal region with no radicular symptoms. The pain worsens with prolonged standing and position changes. He has tried acetaminophen with no benefit. You diagnose a lumbar muscular strain. What medications should you prescribe to help relieve his LBP and improve his overall function?

Acute LBP prompts nearly 2.7 million ED visits in the United States

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each year.² It leads to persistent subjective impairment and continued analgesic use at seven days (impairment, 70%; analgesic use, 69%) and three months (48% and 46%, respectively) after ED discharge.³ Systematic reviews show that monotherapy with NSAIDs or muscle relaxants is more effective than placebo for pain relief.^{4,5} A secondary analysis of patients (N = 715) from a prospective cohort study showed worse functioning at six months in those who were prescribed opiates for LBP than in those who were not.⁶

Monotherapy or combination therapy for LBP?

Because medications used for LBP have different mechanisms of action, clinicians frequently combine them in an attempt to improve symptoms and function.² Current evidence on combination therapy shows mixed results. A large RCT (N = 867) showed that the combination of cyclobenzaprine and ibuprofen led to lower subjective pain intensity, but it did not result in self-reported pain improvement, compared to cyclobenzaprine alone. However, a small RCT (N = 40) demonstrated improved LBP and spasm with naproxen plus cyclobenzaprine, compared to naproxen alone.^{7,8}

This study sought to determine the benefit of treating acute LBP with cyclobenzaprine or oxycodone/acetaminophen in combination with an NSAID, compared to treatment with an NSAID alone.

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STUDY SUMMARY

Adding second pain reliever provided no significant benefit

This double-blinded RCT enrolled 323 adults presenting to an ED with two weeks or less of nontraumatic, nonradicular LBP.¹ Subjects had a score of > 5 on the Roland-Morris Disability Questionnaire (RMDQ), which measures functional impairment due to LBP (range, 0-24). Patients were excluded if they had radicular pain radiating below the gluteal folds, direct trauma to the back within the previous month, pain lasting > 2 wk, a recent history of multiple LBP episodes per month, or a history of opioid use.

All subjects received 10 days' worth of naproxen (500 mg bid). They were then randomized to receive either oxycodone/acetaminophen (5 mg/325 mg), cyclobenzaprine (5 mg), or placebo, with instructions to take one to two tablets as needed every eight hours for 10 days. All patients also received a 10-minute educational session emphasizing the role of nonpharmacologic interventions.

The primary outcome was change in the RMDQ between ED discharge and a phone call seven days later; a 5-point improvement in the RMDQ was considered

clinically significant. Secondary outcomes included subjective description of worst pain, frequency of LBP, frequency of analgesic use, satisfaction with treatment, median number of days to return to work and usual activities, need for follow-up health care visits, and opioid use. Investigators also asked about any adverse effects.

At seven days, reported RMDQ scores had improved by 9.8 points in patients taking naproxen plus placebo, 10.1 points in those receiving naproxen plus cyclobenzaprine, and 11.1 points in those using naproxen plus oxycodone/acetaminophen. There were no statistically significant between-group differences for placebo vs cyclobenzaprine or oxycodone/acetaminophen (0.3 points and 1.3 points, respectively) or cyclobenzaprine vs oxycodone/acetaminophen (0.9 points).

Secondary outcomes. At seven days, there was no significant difference between study groups in subjective pain assessment, frequency of LBP, or use of as-needed medications in the prior 24 hours. There was also no difference in the median number of days to return to work or need for follow-up health care visits.

Among patients who took more than one dose of the study medication, those who took oxycodone/acetaminophen were more likely to describe their worst pain in the last 24 hours as *mild/none*, compared to patients taking placebo (number needed to treat, 6). About 72% of all subjects reported that they would choose the same treatment option again, with no difference between groups. At three months, there was no difference between groups in subjective pain assessment, frequency of LBP, use of as-needed medica-

tions, or opioid use during the previous 72 hours.

Adverse effects, including drowsiness, dizziness, stomach irritation, and nausea or vomiting, were more common in the oxycodone/acetaminophen and the cyclobenzaprine treatment groups, with a number needed to harm of 5.3 and 7.8, respectively.

WHAT'S NEW

Second med adds nothing

This RCT found that adding cyclobenzaprine or oxycodone/acetaminophen to naproxen for the treatment of nontraumatic, nonradicular acute LBP did not significantly improve functional assessment at seven days or three months after the initial ED visit. But it did increase adverse effects.

CAVEATS

Specific subset studied

This study was performed in a single urban ED and included a very specific subset of LBP patients, which limits the generalizability of the results. However, patients often present to primary care with similar LBP complaints, and the results of the study should reasonably apply to other settings.

The findings may not generalize to all NSAIDs, but there is no evidence to suggest that other NSAIDs would behave differently when combined with cyclobenzaprine or oxycodone/acetaminophen. In this analysis, only about one-third of patients used the as-needed medication more than once daily; another third used it intermittently or never.

CHALLENGES TO IMPLEMENTATION

Patients may expect more

Patients expect to receive prescriptions, and clinicians are

inclined to write them if they believe doing so will help their patients. The evidence, however, does not demonstrate a benefit to these prescription-only medications for LBP. **CR**

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