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Clinical Question: Is Diazepam + Naproxen better than Naproxen alone for acute low back pain?

Introduction: Nonsteroidal anti-inflammatory drugs are recommended as first-line therapy for patients with acute low back pain. However, it is not clear whether the addition of other classes of therapeutic agents to nonsteroidal anti-inflammatory drugs can further improve low back pain outcomes.

Benzodiazepines are often mentioned as useful for these patients and are used in 300,000 US ED visits for low back pain annually, although scant evidence exists to determine the appropriateness of this approach. Specifically, they evaluated the following hypothesis: A daily regimen of naproxen+diazepam would provide greater relief of functional impairment caused by low back pain than naproxen+placebo, as measured by improvement in the Roland Morris Disability Questionnaire score 1 week after an ED visit.

Methods: Randomized, Double blinded study, in urban healthcare system. Patients were included that had acute, nontraumatic, nonradicular low back pain of no more than 2 weeks duration and a score >5 on Roland-Morris Disability Questionnaire. The higher the score the greater the disability. Primary outcome is improvement in score between ED discharge and 1 week later. Secondary outcome included pain intensity 1 week and 3 months after ED discharge. All patients received 20 tabs naproxen BID for pain, randomized to receive 28 tabs of diazepam 5 mg or identical placebo. N of 50 in both groups.

Results: 545 patients screened for eligibility. 114 patients met selection criteria and were randomized. 112 provided 1 week outcome data. The mean Roland-Morris Disability Questionnaire score of patients randomized to naproxen+diazepam improved by 11 CI 95%, as did the mean score of patients randomized to naproxen+placebo CI 95%. At 1-week follow-up, 18 of 57 diazepam patients reported moderate or severe low back pain versus 12 of 55 placebo patients. At 3-month follow-up, 6 of 50 diazepam patients reported moderate or severe low back pain versus 5 of 53 placebo patients. Adverse events were reported by 12 of 57 diazepam patients and 8 of 55 placebo patients.

Conclusion: Among ED patients with acute, nontraumatic, nonradicular low back pain, naproxen+diazepam did not improve functional outcomes or pain compared with naproxen+placebo 1 week and 3 months after ED discharge.

Limitations: Strict inclusion criteria, 1 urban health care system serving a socioeconomically depressed population, no testing of diazepam alone vs naproxen, medications were prn so patients receiving diazepam may have had insufficient dosing, presence or absence of muscle spasm on clinical not inclusion criteria.
