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This series is coordinated by Sumi Sexton, MD, Associate Deputy Editor.

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Treating Low Vitamin D Levels Is Ineffective in Postmenopausal Women

Clinical Question

Does vitamin D supplementation in women with low levels of the vitamin affect bone mineral density, muscle mass, strength, or fall risk?

Bottom Line

You do not have to treat a low vitamin D level if your patient is a typical community-dwelling postmenopausal woman younger than 75 years. The usual dosage of vitamin D, 800 IU (20 mcg) daily, will not increase levels even after a year of therapy and has little effect on calcium absorption or bone mineral density. A high dosage, 50,000 IU (125 mcg) twice monthly, will raise levels but is similarly ineffective in improving minimally low bone mineral density, muscle strength, functional status, physical activity levels, or risk of falls. Not checking vitamin D levels will make it easier not to (ineffectively) treat low levels. (Level of Evidence = 1b)

Synopsis

These investigators, through community advertising, enrolled a total of 230 postmenopausal women, 90% of whom were white, with an average age of 61 years and baseline vitamin D levels of 14 to 27 ng per mL (35 to 67 nmol per L). A low 25-hydroxyvitamin D level is typically less than 30 ng per mL (75 nmol per L). The women had low-normal hip T-scores of bone mineral density (average: -1 standard deviation). Using typical tests of balance

and lower extremity strength, the women were at low risk of falls. The women were randomized, using concealed allocation, to receive placebo, daily vitamin D₃ at 800 IU (20 mcg), or twice-monthly vitamin D₃ at 50,000 IU (125 mcg). The twice-monthly, high-dosage group had their vitamin D levels monitored, and the dosage was increased if levels did not increase to at least 30 ng per mL.

After one year, neither vitamin D treatment regimen changed bone mineral density, muscle mass, functional status, or physical activity levels. The number of women reporting at least one fall—almost one-half of the women—was not different among the groups. The study was only one year in length, which should be long enough to see changes in vitamin D levels and muscle mass, although perhaps not long enough to see changes in fall rates (if there is a difference). The U.S. Preventive Services Task Force concludes there is insufficient evidence to recommend for or against screening for vitamin D deficiency; the National Institute for Health and Care Excellence recommends vitamin D supplementation in members of high-risk groups.

Study design: Randomized controlled trials

Funding source: Government

Allocation: Concealed

Setting: Outpatient (any)

Reference: Hansen KE, Johnson RE, Chambers KR, et al. Treatment of vitamin D insufficiency in postmenopausal women: a randomized clinical trial. *JAMA Intern Med.* 2015;175(10):1612-1621.

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Epidural Steroid Not Better Than Placebo Injection for Sciatica and Spinal Stenosis Pain and Function

Clinical Question

Is epidural corticosteroid injection effective for reducing pain and improving function in patients with radicular low back pain or spinal stenosis?

Bottom Line

It is hard to figure out what to do with these results. On the one hand, steroid injection did not provide a significant benefit compared with placebo injection in patients with radicular pain or spinal stenosis. However, part of the reason for this may be the significant and sustained improvement of pain scores seen with the placebo

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injection. This improvement might reflect natural history, but it may reflect the ability of patients treated with either injection to reframe the pain, because short-term improvement in function was (unlike pain relief) quickly lost in patients treated with steroid or placebo injection. (Level of Evidence = 1a-)

Synopsis

To conduct this review, the authors searched two databases, including the Cochrane database, as well as reference lists and a trial registry. Two investigators independently reviewed studies for inclusion, considering randomized trials of epidural corticosteroid injection vs. placebo, other steroid, or other injection techniques for patients with radicular low back pain (sciatica) or spinal stenosis of any duration. They included periradicular injections. One investigator extracted the studies and a second checked the results for accuracy. Of the 63 studies, most ($n = 40$) were of fair quality and five studies were rated as high quality. In six studies of 701 patients, steroid injection provided, on average, immediate pain relief and functional improvement that was not clinically different from placebo treatment. There was no difference in pain and function at short-term (two weeks to three months) or intermediate-term (three months to one year) follow-up. There was no effect on symptoms of spinal stenosis. Pain scores were reduced to a greater degree initially with a steroid, but patients who received the placebo reported pain improvement at short-, intermediate-, and long-term follow-ups, essentially catching up with steroid-treated patients. For function, scores initially improved with steroid injection but then regressed.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Government

Setting: Various (meta-analysis)

Reference: Chou R, Hashimoto R, Friedly J, et al. Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. *Ann Intern Med.* 2015; 163(5):373-381.

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Naproxen Alone May Be Best for Acute Low Back Pain

Clinical Question

What is the optimal medication regimen for treating adults with acute low back pain (LBP)?

Bottom Line

Naproxen alone is as effective as naproxen plus oxycodone/acetaminophen or naproxen plus cyclobenzaprine

(Flexeril) in reducing pain and improving function in adults with acute musculoskeletal LBP without radicular symptoms. Adverse events were significantly more common in patients additionally treated with either muscle relaxants or opioids. Be sure to note the exclusion criteria in the synopsis. (Level of Evidence = 1b)

Synopsis

Clinicians commonly treat acute LBP with a combination of nonsteroidal anti-inflammatory drugs, muscle relaxants, and opioids. These investigators identified adults ($N = 323$), 21 to 64 years of age, presenting to the emergency department for LBP clinically diagnosed as acute musculoskeletal LBP, defined as pain between the lower border of the scapulae and the upper gluteal folds. Exclusion criteria included radicular pain below the gluteal folds, direct trauma to the back within the previous month, pain duration longer than two weeks, and recent history of more than one LBP episode per month. Eligible patients randomly received (concealed allocation assignment) naproxen, 500 mg twice daily for 10 days, plus either placebo, 5 mg of cyclobenzaprine, or 5 mg of oxycodone/32 mg of acetaminophen, all taken as one or two tablets every eight hours. Individuals masked to treatment group assignment assessed pain and functional outcomes seven days and three months after emergency department discharge using a validated scoring tool. Complete follow-up occurred for 96% of participants at seven days and 87% at three months.

Using intention-to-treat analysis, there were no significant differences in pain and function scores between the three treatment groups at seven days and at three months of follow-up. Use of additional health care resources was uncommon but not significantly different between the three groups. However, adverse effects, including drowsiness, dizziness, dyspepsia, and nausea or vomiting, were significantly increased for oxycodone/acetaminophen (number needed to treat to harm [NNTH] = 5.3; 95% confidence interval [CI], 3 to 14) and cyclobenzaprine (NNTH = 7.8; CI = 4 to 129) compared with naproxen plus placebo.

Study design: Randomized controlled trial (double-blinded)

Funding source: Unknown/not stated

Allocation: Concealed

Setting: Emergency department

Reference: Friedman BW, Dym AA, Davitt M, et al. Naproxen with cyclobenzaprine, oxycodone/acetaminophen, or placebo for treating acute low back pain: a randomized clinical trial. *JAMA.* 2015;314(15):1572-1580.

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