

POEMs

Patient-Oriented Evidence That Matters

Acupuncture Effective for Chronic Pain Conditions

Clinical Question

Is acupuncture effective for the treatment of chronic pain?

Bottom Line

Acupuncture, with its meridians, chi, and other concepts that do not seem to line up with anything physiologic, is vexing to most of us who trained in Western medicine. However, this meta-analysis, based on data from almost 21,000 patients, found it to be more effective than no treatment and, to a lesser extent, more effective than sham acupuncture. Given this evidence of benefit and our limited options for chronic pain treatments that do not harm more than help, acupuncture should be added to our armamentarium. (Level of Evidence = 1a-)

Synopsis

To conduct this meta-analysis, the authors identified 44 randomized studies that evaluated the use of acupuncture to treat specific musculoskeletal pain, osteoarthritis, chronic headache, or shoulder pain lasting at least four weeks. The researchers only included studies for which treatment allocation was unambiguously concealed. They combined raw patient data in their meta-analyses for 20,827 patients from 39 trials. For each chronic pain condition, acupuncture was superior to no-acupuncture control, with a moderate

effect size of 0.5. Acupuncture was still more effective than sham acupuncture, with an average effect size of 0.2. Treatment effects persisted over time with only a small decrease. There was significant heterogeneity among the studies, which the authors attribute to differences in the control groups. There was limited evidence of publication bias, meaning that small studies showing no benefit may not have been published. This meta-analysis is an update of a previous meta-analysis that identified slightly better effects (<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1357513>).

Study design: Meta-analysis (randomized controlled trials)

Funding source: Government

Setting: Various (meta-analysis)

Reference: *Vickers AJ, Vertosick EA, Lewith G, et al.; Acupuncture Trialists' Collaboration. Acupuncture for chronic pain: update of an individual patient data meta-analysis. J Pain. 2018;19(5):455-474.*

Allen F. Shaughnessy, PharmD, MMedEd

Professor of Family Medicine
Tufts University
Boston, Mass.

Estrogen No Better Than Vaginal Lubricant for Postmenopausal Vaginal Symptoms

Clinical Question

In women with postmenopausal vaginal symptoms, is local estrogen treatment better than vaginal lubricant or placebo?

Bottom Line

It is time to rethink the idea that vaginal atrophy caused by diminished estrogen is the cause of vaginal symptoms associated with menopause. Vaginal estradiol is no more effective than a non-prescription vaginal lubricant or placebo lubricant in the treatment of women with painful intercourse, vaginal dryness, or other symptoms usually associated with menopause. (Level of Evidence = 1b)

Synopsis

This study evaluated the effect of a vaginal estradiol, 10 mcg, a nonprescription vaginal lubricant,

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and matching placebo tablet and lubricant in 302 postmenopausal women with moderate to severe symptoms of vulvovaginal itching, pain, dryness, irritation, or pain with penetration. Estradiol was used daily for two weeks, then twice weekly; vaginal moisturizer was used every three days for 12 weeks. Results were analyzed using a modified intention-to-treat analysis, including women who returned for evaluation at one month and three months after beginning treatment, regardless of their continued use of treatment. At the beginning of the study, women were asked to identify their most bothersome symptom, which was pain with vaginal penetration (60%) or vaginal dryness (21%) for most women; the main outcome measured was the effect of treatment on this outcome. Treatment with estradiol, lubricant, or placebo produced similar results, decreasing the average score (on a scale of 0 to 3) from 2.4 (moderate severity) at the beginning of treatment to 1.0 (mild). One-half of the women in each group, including the placebo group, had a clinically significant drop in scores with treatment. Sexual function, as measured by the Female Sexual Function Index, improved in all groups, with nearly one-half of the women in all groups improving from being frequently or always distressed about their sex life to rarely or never distressed about their sex life.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (any)

Reference: Mitchell CM, Reed SD, Diem S, et al. Efficacy of vaginal estradiol or vaginal moisturizer vs placebo for treating postmenopausal vulvovaginal symptoms: a randomized clinical trial. *JAMA Intern Med.* 2018;178(5):681-690.

Allen F. Shaughnessy, PharmD, MMedEd

Professor of Family Medicine
Tufts University
Boston, Mass.

As-Needed Use of Budesonide Plus Formoterol As Good As Daily Use of Steroid

Clinical Question

Is as-needed use of budesonide/formoterol (Symbicort) similarly effective to daily maintenance with budesonide (Rhinocort) plus as-needed terbutaline in patients with mild asthma?

Bottom Line

As-needed use of budesonide/formoterol is as effective as the daily use of maintenance budesonide plus as-needed terbutaline at preventing severe exacerbations, and results in a much lower cumulative steroid dose. (Level of Evidence = 1b-)

Synopsis

This industry-sponsored noninferiority trial included 4,215 patients, of whom 4,176 had data available for analysis. Their mean age was 41 years, and approximately 50% controlled their asthma by using a daily inhaled glucocorticoid during the previous year; the other half had uncontrolled asthma using a short-acting beta-agonist (SABA) alone. Fully 22% had a severe exacerbation during the previous year, defined as the need for at least three days of systemic steroids, hospitalization, or an emergency department visit, which seems high for mild asthma. As in the similar SYGMA 1 trial published in the same issue of this journal, mild asthma was defined as asthma that is uncontrolled using only a SABA as needed, or well controlled using a low-dose steroid inhaler. After a run-in period during which patients used only an as-needed SABA (terbutaline, 0.5 mg), the patients were randomized to receive: (1) placebo inhaler twice daily plus budesonide, 200 mcg/formoterol, 6 mcg, as needed; or (2) budesonide, 200 mcg twice daily plus as-needed use of terbutaline, 0.5 mg. This trial was initially designed as a superiority trial to show that one of the interventions was better than the other. However, a lower-than-expected rate of exacerbations and a higher-than-expected rate of adherence to the daily inhaled steroid hurt the power, so the authors moved the goalposts midgame and declared it a noninferiority trial. Noninferiority was defined as no more than a 20% increase in the number of severe exacerbations. Although it is not good research practice to change goals midstream, in some ways this is a more interesting research question, and the noninferiority margin the authors chose seems clinically reasonable. After one year, there was indeed no difference between the groups regarding the likelihood of a severe exacerbation (0.11 for as-needed use and 0.12 for daily steroid inhaler per patient per year). There were also no differences between groups regarding the time to a first severe exacerbation or regarding different types of severe exacerbations (i.e., hospitalization or emergency department visit). Adverse events between groups were similar.

Not surprisingly, patients in the as-needed inhaler group had only about one-fourth the total steroid dose during the study period.

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Outpatient (any)

Reference: Bateman ED, Reddel HK, O'Byrne PM, et al. As-needed budesonide-formoterol versus maintenance budesonide in mild asthma. *N Engl J Med.* 2018;378(20):1877-1887.

Mark H. Ebell, MD, MS Professor

University of Georgia
Athens, Ga.

Breast Cancer Screening with MRI: More False-Positives, More Biopsies

Clinical Question

Does breast cancer screening with magnetic resonance imaging (MRI), alone or with mammography, improve diagnostic yield?

Bottom Line

Screening with MRI is not for everyone. Women who undergo breast cancer screening with MRI are much more likely to be referred for biopsy—that will ultimately be negative—than if they have screening mammography alone. This is even true of women with a personal history of breast cancer. The benefit of possible early detection of breast cancer with MRI has to be carefully weighed against unnecessary additional diagnostic maneuvers. (Level of Evidence = 2b)

Synopsis

This study analyzed data collected in six Breast Cancer Surveillance Consortium registries throughout the United States, comprising 812,164 women undergoing a total of 2,048,994 digital mammographies, breast MRIs, or both between the years of 2003 and 2013. Most women had no history of breast cancer; those who did have a personal history of breast cancer received their diagnosis at least six months prior. In women without a personal history of breast cancer, age-adjusted biopsy rates were much higher following MRI than mammography alone: 8.47% vs. 1.49%. Ductal carcinoma in situ and invasive biopsy yield were significantly higher following mammography in women with a history of breast cancer. High-risk benign lesions (lobular carcinoma and atypical hyperplasia) were more commonly identified by MRI, regardless of personal history of breast cancer.

Study design: Cohort (prospective)

Funding source: Government

Setting: Outpatient (any)

Reference: Buist DS, Abraham L, Lee CI, et al.; Breast Cancer Surveillance Consortium. Breast biopsy intensity and findings following breast cancer screening in women with and without a personal history of breast cancer. *JAMA Intern Med.* 2018;178(4):458-468.

Allen F. Shaughnessy, PharmD, MMedEd

Professor of Family Medicine
Tufts University
Boston, Mass. ■