

Surgery is better than no surgery for spinal stenosis

Clinical question In adults with spinal stenosis, is surgical treatment more effective than nonsurgical treatment?

Bottom line Most patients with lumbar spinal stenosis treated surgically and nonsurgically improve over time.

However, patients treated surgically have greater improvement in pain management. There are no meaningful differences in disability or in walking capacity. (Level of evidence = 2b)

Synopsis In this unblinded study, 94 adults with at least 6 months of lumbar spinal stenosis symptoms were randomly assigned to receive surgery or nonsurgical treatment. The researchers excluded patients with progressive neurologic deficits, with prior surgery, with severe or minimal symptoms, who were poor surgical candidates, and those having other conditions explaining their symptoms. The patients were evaluated at 6 months, 12 months, and 24 months using intention-to-treat analysis. At the end of the study, approximately 15% of the patients had dropped out. Patients in both groups improved over the course of the study. Although disability scores were more likely to improve in patients treated surgically, the 7.8-point difference on a 100-point scale is not clinically meaningful. However, improvements in pain scores in the patients treated with surgery were clinically better. Finally, there was no significant difference between the groups in self-reported walking ability.

Malmivaara A, Slati P, Heliövaara M, et al, for the Finnish Lumbar Spinal Research Group. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine*. 2007;32(1):1-8.

Delayed tympanostomy tube insertion doesn't impair developmental outcomes

Clinical question Does the delayed insertion of tympanostomy tubes impair



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the long-term outcomes in children with persistent middle-ear effusion?

Bottom line Delayed tympanostomy tube insertion successfully helps many children avoid tubes and does not result in any developmental or other impairment. (Level of evidence = 1b)

Synopsis Many parents and clinicians still believe that there is a significant risk of permanent harm if tympanostomy tubes are not promptly inserted for children with persistent middle-ear effusion. In this study, which is a follow-up to a previously published POEM (*N Engl J Med*. 2005;353(6):576-586), 429 children aged 2 months to 3 years with middle-ear effusion for at least 90 days (bilateral) or 135 days (unilateral) were randomized to receive either prompt or delayed tympanostomy tube insertion. The delay was 6 months for bilateral effusion and 9 months for unilateral effusion. Allocation was concealed, groups were balanced at the start of the study, and analysis was by intention to treat. The researchers did an excellent job of following up: 195 of 216 in the early treatment group and 196 of 213 in the delayed treatment group underwent developmental testing between the ages of 9 and 11 years. At the time of this final evaluation, 86% in the early treatment group had received tympanostomy tubes compared with only 49% in the delayed treatment group. There were no differences between groups in the results of a broad range of tests including evaluation of hearing, reading, oral fluency, auditory processing, phonological processing, behavior, or intelligence. There was also no difference between these groups and a group of children with ear problems that weren't severe enough to qualify them for the study.

Paradise JL, Feldman HM, Campbell TF, et al. Tympanostomy tubes and developmental outcomes at 9 to 11 years of age. *N Engl J Med*. 2007;356(3):248-261.

Acupuncture is ineffective for hot flashes

Clinical question Is acupuncture an effective treatment for perimenopausal and postmenopausal hot flashes?

Bottom line Acupuncture is not an effective treatment for menopausal hot flashes. (Level of evidence = 1b)

Synopsis In this single-blinded study, 103 perimenopausal and postmenopausal women aged 45 to 59 years were randomized to acupuncture or sham procedures twice weekly for 5 weeks. Perimenopausal status was defined as menstrual irregularity or amenorrhea for at least 3 months, and postmenopausal status as amenorrhea for at least 12 months. Women were eligible if they reported at least five hot flashes daily and were not taking estrogen, soy, progesterone, vitamin E, black cohosh, gabapentin, or antidepressants used for treating hot flashes. Other exclusion criteria were the use of Coumadin, certain skin disorders, the presence of a pacemaker or prosthetic joint, diabetic neuropathy, and active chemotherapy. Women used a daily diary to note the number of hot flashes and the severity of each (from 1 [mild] to 3 [severe]). The sum of the severity scores for each hot flash provided a daily hot-flash score. The authors used survival curve statistics with an intention-to-treat analysis and performed an appropriate power analysis. There were no differences between groups at baseline, 6 weeks, or 12 weeks.

Vincent A, Barton DL, Mandrekar JN, et al. Acupuncture for hot flashes: randomized, sham-controlled clinical study. *Menopause*. 2007;14(1):45-52.

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Long-term PPI use increases hip fracture risk

Clinical question Does the long-term use of proton pump inhibitors (PPIs) increase the risk of hip fracture?

Bottom line Long-term use (more than 1 year) of PPIs is associated with an increased risk of hip fracture in adults older than 50 years. Risk is also higher among individuals taking higher doses of PPIs and increases with duration of use. Appropriate use, dose, and duration of therapy should be carefully assessed on an individual basis. (Level of evidence = 3b)

Synopsis Significant hypochlorhydria as a result of PPI therapy may cause calcium malabsorption, resulting in a higher risk of bone fractures. These investigators analyzed data obtained from the United Kingdom General Practice Research Database relating to prescription use and subsequent diagnoses and hospitalizations for hip fracture. Previous studies validate information obtained in this manner from the same source. Cases consisted of individuals older than 50 years with first occurrence of hip fracture at least 1 year after the beginning of their standard follow-up period. Up to 10 controls were selected for each case matching for multiple variables, including sex, year of birth, and duration of follow-up. The exposure of interest was the effect of cumulative duration of PPI therapy for up to 4 years. The authors performed a statistical analysis of the data to control for other potential confounders, including body mass index, smoking history, alcoholism, impaired mobility, atherosclerotic vascular disease, peptic ulcer disease, renal failure, among others. There were 13,556 hip-fracture cases and 135,386 controls. PPI use for more than 1 year was associated with a significantly increased risk of hip fracture (adjusted hazard ratio = 1.44, 95% CI, 1.30-1.59; number needed to harm/person-years

= 1,266; 944-1,856). The associated risk was further increased among patients taking higher doses of PPI and with increasing duration of use. Histamine-2 receptor antagonist therapy (eg, ranitidine, cimetidine) did not significantly increase hip fracture risk.

Yang YX, Lewis JD, Epstein S, Metz DC. Long-term proton pump inhibitor therapy and risk of hip fracture. *JAMA*. 2006;296(24):2947-2953.

Presence of risk factors doesn't predict acute coronary syndrome

Clinical question In the emergency department (ED), how useful is knowing the patient's risk factors when predicting the likelihood of an acute coronary syndrome (ACS)?

Bottom line The presence or absence of cardiac risk factors does not help to determine whether a patient with symptoms will have ACS. In patients older than 65 years, even the presence of four or five risk factors does not predict the likelihood of ACS (likelihood ratio = 1.2). Although their risk of having a cardiac event was higher over time because of their risk factors, at the time of symptom presentation these patients were no more likely to have an ACS than people with fewer or no risk factors with similar symptoms. In patients younger than 40 years, the presence of four or more risk factors is moderately predictive of ACS (likelihood ratio = 7.4). (Level of evidence = 1b)

Synopsis To answer this question, the researchers used an Internet tracking system that collected data on 10,806 eligible patients presenting to EDs with possible acute coronary syndromes. Data were entered using a convenience sample of patients prospectively enrolled in eight EDs in the United States. ED-recorded positive risk factors—diabetes, hypercholesterolemia, hypertension, smoking, and family history—were each given equal weight. A

thirty-day follow-up was performed to determine the diagnosis and was completed in more than 95% of patients. ACS occurred in 8.1% of the patients in the study. For patients younger than 40 years, the area under the receiver operating characteristic curve was 0.763, indicating fair diagnostic performance. The presence of risk factors had little diagnostic utility in patients older than 40 years, and the estimated likelihood of ACS in patients older than 65 years was no better than that occurring by chance. For example, the positive likelihood ratio for four or five risk factors in patients aged 40 to 65 years was only 2.13; in patients older than 65 years it was only 1.09. Negative likelihood ratios for these aforementioned age groups were 0.92 and 1.00, respectively.

Han JH, Lindsell CJ, Storrow AB, et al, for the EMCREG i*trACS Investigators. The role of cardiac risk factor burden in diagnosing acute coronary syndromes in the emergency department setting. *Ann Emerg Med*. 2007;49(2):145-152.

Montelukast plus salmeterol is inferior to steroids plus salmeterol in asthma

Clinical question Is montelukast plus salmeterol more effective than the combination of beclomethasone plus salmeterol in moderate asthma?

Bottom line Patients with moderate asthma have fewer treatment failures when treated with inhaled beclomethasone plus inhaled salmeterol than those treated with oral montelukast plus inhaled salmeterol. (Level of evidence = 1b)

Synopsis In this study, 192 patients aged 12 to 65 years with moderate asthma completed a 4-week run-in period during which they received inhaled beclomethasone and oral montelukast. To be eligible, the patients had to have at least one of the following: 1-second forced expiratory volume (FEV₁) of at least 40% of predicted; demonstrated hyperrespon-

siveness to methacholine; or a 12% or greater improvement in FEV₁ after a beta-agonist (if FEV₁ was less than 55% of predicted). Those who passed the run-in period (ie, had the capacity to attain reasonable asthma control) were enrolled into a crossover trial. These patients were randomly assigned to 14 weeks of inhaled beclomethasone (80 mcg twice daily) plus inhaled salmeterol (50 mcg twice daily) plus oral placebo or inhaled placebo plus salmeterol plus oral montelukast (10 mg at bedtime). After this, the patients went through an additional 4-week period identical to the initial

run-in period, and then crossed over for 14 weeks of the alternate therapy. The main outcome, assessed via intention to treat, was treatment failure, defined primarily by a variety of spirometric measures, increased use of rescue albuterol, symptoms resulting in emergency department treatment, or use of nonstudy medications for worsening symptoms. A total of 98 of the 192 patients did not complete the study; 75 of those 98 were dropped when the data monitoring and safety committee terminated the study. There were no differences in the numbers or reasons for withdrawal

between the treatment arms. Ten patients (9%) failed therapy while taking the beclomethasone-based regimen compared with 29 (26%) of those taking the montelukast-based therapy (number needed to treat = 6; 95% CI, 4-13). Finally, this study was stopped by the data safety and monitoring board because of convincing evidence of the superiority of inhaled corticosteroids.

Deykin A, Wechsler ME, Boushey HA, et al, for the National Heart, Lung, and Blood Institute's Asthma Clinical Research Network. Combination therapy with a long-acting beta-agonist and a leukotriene antagonist in moderate asthma. *Am J Respir Crit Care Med.* 2007;175(3):228-234.