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

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Spinal Stenosis: Physical Therapy **Before Surgery**

Clinical Ouestion

Is surgery more effective than physical therapy in patients referred for surgery for spinal stenosis?

Bottom Line

Assigning patients to six weeks of physical therapy is as effective as initially sending them for decompression surgery, with fewer complications, even in patients who have a strong preference for surgery. A trial of six weeks of physical therapy makes sense for many patients with confirmed spinal stenosis before getting out the scalpel. (Level of Evidence = 1b-)

Synopsis

The investigators enrolled 169 patients (average age: 66 to 69 years) with image-confirmed lumbar stenosis who consented to surgery. This approach to enrollment eliminated many patients, presumably those with milder symptoms. The patients were randomly assigned (allocation concealed) to surgery or physical therapy. The decompression surgery was the typical procedure used in research and practice. Physical therapy, administered twice weekly for six weeks, consisted of lumbar flexion exercises and conditioning to identify the issues of strength and flexibility identified at enrollment. Analysis was by intention

to treat, meaning that patients assigned to physical therapy were analyzed as being in that group even if they eventually received surgery, which 57% of them did over the two years of follow-up (most of them within the first 10 weeks of the study).

Approximately 20% in each group sought additional physical therapy. Two years after identification, general quality of life (as measured by the 36-Item Short Form Health Survey, a typical measure of quality of life) improved equally in both groups, to an average score of 48 to 50 from a baseline of 26 to 28 out of a possible 100. Analyzing by actual treatment rather than by intention to treat yielded similar results, although the study may not have had enough power to find a difference if one existed. Pain, disability, and neurogenic symptoms improved similarly in both groups. Complications were common in the back surgery group, including the need for reoperation. Many patients were not returned to "normal" but continued to visit a back surgeon or primary care physician for back pain two years after the intervention.

Study design: Randomized controlled trial (single-

blinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (specialty)

Reference: Delitto A, Piva SR, Moore CG, et al. Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial. Ann Intern Med.

2015;162(7):465-473.

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Prednisone Speeds Recovery, **Shortens Stay in Patients** Hospitalized with CAP

Clinical Question

Does adding prednisone to antibiotics improve outcomes in adults hospitalized with community-acquired pneumonia (CAP)?

POEMs

Bottom Line

Among patients hospitalized with CAP, adjunctive prednisone speeds time to recovery by 1.5 days and shortens hospital length of stay by approximately one day, but produces no difference in pneumonia complications at 30 days, (Level of Evidence = 1b)

Synopsis

In this Swiss study, patients admitted to the hospital with CAP randomly received 50 mg of prednisone daily for seven days (n = 402) or placebo (n = 400). Each day, a researcher unaware of treatment assignment assessed the patients' clinical status. Patients treated with prednisone reached clinical stability (at least 24 hours of stable vital signs: afebrile, no tachycardia or tachypnea, normotensive, normal mental status, no hypoxia) approximately 1.5 days faster than patients treated with placebo. The average length of stay was one day longer in patients treated with placebo. The patients taking prednisone were more likely to have hyperglycemia treated with insulin.

Study design: Randomized controlled trial

(double-blinded)

Funding source: Foundation

Allocation: Concealed

Setting: Inpatient (any location)

Reference: Blum CA, Nigro N, Briel M, et al. Adjunct prednisone therapy for patients with community-acquired pneumonia: a multicentre, double-blind, randomised, placebo-controlled trial.

Lancet. 2015;385(9977):1511-1518.

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Real-World Study Finds Lower Mortality and Stroke Risk with Dabigatran, but More GI Bleeds

Clinical Question

In a real-world setting, how do the harms of dabigatran (Pradaxa) and warfarin (Coumadin) compare?

Bottom Line

In this well-designed observational study, older patients given an initial prescription of dabigatran had lower all-cause mortality ▶

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(number needed to treat [NNT] = 192 for one year) and fewer ischemic and hemorrhagic strokes, but a higher risk of gastrointestinal (GI) bleeding, than a matched group of patients given warfarin. Benefits and harms were greater at the higher dose (150 mg) and varied by age and sex. Specifically, women 85 years and older had higher all-cause mortality with dabigatran. (Level of Evidence = 2b)

Synopsis

The comparative safety of the novel oral anticoagulants is important knowledge, because they are being widely adopted at great cost to the health system. Although they are clearly more convenient than warfarin, are they also safer? This study identified Medicare patients 65 years and older who were given an initial prescription for warfarin or dabigatran for the treatment of nonvalvular atrial fibrillation. It is important to include only new users, because the first few months are when patients are at the highest risk of bleeding complications. Each dabigatran user was matched to a warfarin user via propensity score matching, which matches patients based on factors associated with the likelihood of being prescribed dabigatran, using logistic regression. The result was two groups that looked very similar: 59% were 75 years and older, 51% were women, 92% were white, 33% had diabetes mellitus, and approximately 50% had ischemic heart disease. Their CHADS₂ score, a measure of stroke risk, was 2 or higher for 71%, and the HAS-BLED score, a measure of bleeding risk, was 2 or 3 for 82%. Ultimately, there were 67,207 patients in each

group; slightly more than one-half in each group filled only a single prescription for their anticoagulant, and there were slightly more than 19,000 person-years of follow-up in each group. Thus, the outcomes largely reflect harms accrued soon after beginning each medication.

There were several important differences between groups. Patients given dabigatran had significantly fewer ischemic strokes (11.3 vs. 13.9 per 1,000 person-years; NNT = 607 per year), fewer intracranial hemorrhages (3.3 vs. 9.6 per 1,000 personyears; NNT = 158 per year), and lower all-cause mortality (32.6 vs. 37.8 per 1,000 person-years; NNT = 192 per year). However, they had a significantly higher risk of major GI bleeding (34.2 vs. 26.5 per 1,000 person-years; number needed to treat to harm = 129 per year). The increased GI bleeding risk was primarily in women 75 years and older and in men 85 years and older. All of the benefits and harms were greater with a dabigatran dosage of 150 mg twice daily, and were statistically significant only for the reduction in the risk of intracranial hemorrhage at the 75-mg dose.

Study design: Cohort (retrospective)

Funding source: Government **Setting:** Population-based

Reference: Graham DJ, Reichman ME, Wernecke M, et al. Cardiovascular, bleeding, and mortality risks in elderly Medicare patients treated with dabigatran or warfarin for nonvalvular atrial fibrillation. Circulation. 2015;131(2):157-164.

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