POEMs

Patient-Oriented Evidence That Matters

No Short-Term Extra Benefit when Muscle Relaxants Are Added to Ibuprofen for Acute Low Back Pain

Clinical Question

Is treatment for acute low back pain more effective with a combination of ibuprofen and a muscle relaxant compared with ibuprofen alone to improve functional outcomes and reduce pain?

Bottom Line

Adding a muscle relaxant to treatment with ibuprofen does not improve functional outcomes or pain, or lessen the number of people reporting moderate to severe back pain one week after starting treatment. (Level of Evidence = 1b)

Synopsis

The researchers enrolled 320 patients who presented to one of two emergency departments with nonradicular low back pain of two weeks' duration or less (average: 72 hours) with a score of at least 6 of a possible 24 on the Roland-Morris Disability Questionnaire, a self-rated measure of disability due to low back pain. More than 90% of patients had a score of 10 or higher. All patients were given 600 mg of ibuprofen to be taken up to three times per day, as needed. They were also randomized, concealed allocation unknown, to receive identical-appearing capsules containing placebo, 10 mg of baclofen (Lioresal), 400 mg of metaxalone (Skelaxin), or 2 mg of tizanidine (Zanaflex) and were instructed to take one or two capsules up to three times per day, as needed. One week later, using intention-to-treat analysis, questionnaire scores improved in all groups, with improvement ranging from an average 10.1 points to 11.2 points across the groups compared with baseline. At this time, approximately 34% of patients across the groups reported moderate to severe back pain. The study had a power of 80% to find a difference of 5 points on the questionnaire if one existed.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Uncertain

Setting: Emergency department

Reference: *Friedman BW, Irizarry E, Solorzano C, et al. A randomized, placebo-controlled trial of ibuprofen plus metaxalone, tizanidine, or baclofen for acute low back pain.* Ann Emerg Med. *2019;74(4):512-520.*

Allen F. Shaughnessy, PharmD, MMedEd
Professor of Family Medicine
Tufts University
Boston, Mass.

Supplemental MRI Screening in Women with Very Dense Breasts Reduces Interval Cancer Rate but May Cause Overdiagnosis

Clinical Question

Does supplemental magnetic resonance imaging (MRI) screening for women with very dense breasts reduce the number of interval cancers?

Bottom Line

Supplemental MRI screening for women with very dense breasts compared with mammography alone every two years significantly reduces the likelihood of an interval cancer, from 5 per 1,000 to 2.5 per 1,000 in the intention-to-treat population and to 0.8 per 1,000 in the per-protocol population. False-positive results were common, and there were more overall and early-stage cancers detected in the MRI group, raising the concern that many of these cancers may have been present but growing slowly and indolently (so-called overdiagnosed cancers). Subsequent follow-up will hopefully determine whether mortality and not just incidence is affected. (Level of Evidence = 1b–)

Synopsis

Most guidelines recommend mammography every two years, typically in women 50 to 69 or 75 years of age. The only exception is the American College of Radiology, which continues to recommend annual screening. In this Dutch study, women undergoing routine digital mammography who were identified as having very dense breast tissue (grade 4/4) and who had a normal digital mammogram result were randomized in a 1:4 ratio to receive supplemental MRI screening or usual care. After randomization, the women in the MRI group were notified and invited to participate. Obtaining consent after randomization is known as a Zelen design and is thought to reduce protocol violations and anxiety in the women not randomized to MRI. Women with a Breast Imaging Reporting and Data System (BI-RADS) MRI score of 4 or 5 were recalled for further evaluation, including biopsy. Women with a BI-RADS score of 3 had a second reading of the MRI, and if the second reading was also 3, they had a follow-up MRI in six months. The primary outcome was the likelihood of interval cancer, defined as all cancers detected in the 24 months following a negative index digital or MRI mammogram and before the next scheduled mammogram (or within 24 months if aging out of the cohort). A total of 8,061 women were randomized to receive supplemental MRI screening; 4,783 (59%) agreed to the screening. The comparison group had 32,312 women.

Of the 4,783 women who underwent supplemental MRI screening, 79 (1.65%) had breast cancer detected. In the intention-to-screen analysis that included all 8,061 women randomized to MRI, the rate of interval cancers was lower than in the usual care group (2.5 vs. 5.0 per 1,000 women). This is the appropriate comparison because in other mammography trials, women who ignored the invitation to screen had worse health outcomes than those who chose to volunteer. Among women randomized to MRI, the rate of interval cancers was 0.8 per 1,000 women in those who volunteered and 5 per 1,000 women (nearly identical to the control group rate of 4.9 per 1,000) in those who did not. With regard to harms, 9.5% of women undergoing supplemental MRI screening were recalled, and 6.3% of all women had a biopsy. The false-positive rate was 8% among women undergoing supplemental MRI. Of the 79 cancers detected in the MRI group, approximately 80% were invasive, and the remainder were ductal carcinoma in situ. The characteristics of the interval cancers did not differ significantly between groups. At the second round of screening, the rate of invasive cancers was lower in the MRI group than in the digital mammography–only group (2 vs. 7 per 1,000), and they were more likely to be stage 0 or 1 cancers, suggesting that MRI advanced the time of detection. The study was not powered to detect a reduction in mortality.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Population-based

Reference: *Bakker MF, de Lange SV, Pijnappel RM, et al.; DENSE Trial Study Group. Supplemental MRI screening for women with extremely dense breast tissue.* N Engl J Med. *2019;381(22):2091-2102.*

Mark H. Ebell, MD, MS
Professor
University of Georgia
Athens, Ga.

Useful Signs and Symptoms for Diagnosing Hip Osteoarthritis

Clinical Question

What clinical signs and symptoms are useful for diagnosing radiography-based hip osteoarthritis (OA) in adults?

Bottom Line

Although plain radiographs are often used to diagnose hip OA, the correlation between radiographic indicators of hip arthritis and hip pain is low. The accuracy of clinical symptoms and signs for diagnosing hip OA in this study is based on radiography as the diagnostic standard. (Level of Evidence = 4)

Synopsis

In the absence of a more reliable diagnostic standard, the investigators wished to evaluate the accuracy of clinical findings in determining the prevalence of radiographic OA among adults presenting with hip or groin pain. Two individuals independently searched multiple databases, including PubMed, MEDLINE, and CINAHL, as well as reference lists of previous review articles for studies describing clinical findings in patients with hip or groin pain. Studies were assessed for risk of bias using a standard scoring tool, and ▶

only level one and two studies (N = 6, reporting data from 110 patients) were included. Discrepancies were resolved by consensus agreement with a third reviewer.

Clinical findings associated with the presence of hip OA included a family history of OA (positive likelihood ratio [LR+] = 2.1; 1.2 to 3.6), a personal history of knee OA (LR+ = 2.1; 1.1 to 3.8), pain when climbing stairs or walking down slopes (LR+ = 2.1; 1.6 to 2.8), and the worst pain located in the medial thigh (LR+ = 7.8; 1.7 to 37). Findings associated with the absence of OA included being younger than 60 (negative likelihood ratio [LR–] = 0.11; 0.01 to 0.78), morning stiffness lasting less than 60 minutes (LR– range, 0.22 to 0.65), the absence of pain on walking (LR– range, 0.25 to 0.58), and the absence of pain improved by sitting (LR– = 0.24; 0.06 to 0.92). Physical findings associated with OA included posterior hip pain caused by squatting (LR+ = 6.1; 1.3 to 29), groin pain on hip abduction or adduction (LR+ = 5.7; 1.6 to 20), abductor weakness (LR+ = 4.5; 2.4 to 8.4), decreased hip adduction (LR+ = 4.2; 3.0 to 6.0), and decreased internal rotation (LR+ = 3.2; 1.7 to 6.0). The absence of normal hip passive adduction (LR– = 0.25; 0.11 to 0.54) or abduction (LR– = 0.26; 0.09 to 0.77) was useful in excluding OA.

Study design: Systematic review

Funding source: Foundation

Setting: Various (meta-analysis)

Reference: *Metcalfe D, Perry DC, Claireaux HA, et al. Does this patient have hip osteoarthritis?: the rational clinical examination systematic review.* JAMA. *2019; 322(23):2323-2333.*

David C. Slawson, MD
Professor of Family Medicine
UNC Chapel Hill
Charlotte, N.C.

For Three-Vessel Disease, but Not Left Main Disease, CABG Is Preferred over PCI

Clinical Question

For patients with three-vessel disease or left main disease, is percutaneous coronary intervention (PCI) with a drug-eluting stent noninferior to coronary artery bypass graft (CABG)?

Bottom Line

For patients with left main disease, PCI with a drug-eluting stent and CABG had similar all-cause mortality rates at 10 years. For those with three-vessel disease, CABG is associated with lower 10-year mortality (21% vs. 28%; number needed to treat = 14). (Level of Evidence = 1b)

Synopsis

This is the 10-year follow-up to a trial that initially randomized 1,800 patients with three-vessel coronary artery disease or left main disease to receive either PCI with a drug-eluting stent or CABG. Groups were balanced at the beginning of the trial, and analysis was by intention to treat. The average age of participants was 65 years, 25% had diabetes mellitus, 33% had a previous myocardial infarction, and 9% had a previous stroke or transient ischemic attack. Left main disease was present in 40% and three-vessel disease in 60% of the patients. The primary outcome was all-cause mortality, ascertained primarily from national death registries. Median follow-up was 11.2 years. At 10 years, 27% of patients in the PCI group had died compared with 24% in the CABG group (hazard ratio = 1.17; 95% CI, 0.97 to 1.41). Analyzing the period from five years to 10 years separately, the authors again found no significant difference (13% for PCI vs. 12% for CABG). There was a difference between groups based on their initial lesion. In those with three-vessel disease, all-cause mortality was significantly higher in the PCI group (28% vs. 21%; hazard ratio = 1.41; 95% CI, 1.10 to 1.80), whereas there was no difference in mortality for those with left main disease (26% for PCI vs. 28% for CABG). Results were similar for patients with and without diabetes.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (any)

Reference: *Thuijs DJ, Kappetein AP, Serruys PW, et al. Percutaneous coronary intervention versus coronary artery bypass grafting in patients with three-vessel or left main coronary artery disease: 10-year follow-up of the multicentre randomised controlled SYNTAX trial.* Lancet. *2019;394(10206):1325-1334.*

Mark H. Ebell, MD, MS
Professor
University of Georgia
Athens, Ga.

Editor's Note: Dr. Ebell is deputy editor for evidence-based medicine for *AFP* and cofounder and editor-in-chief of Essential Evidence Plus, published by Wiley-Blackwell. Dr. Shaughnessy is an assistant medical editor for *AFP*. ■