# POEMs

## *Patient-Oriented Evidence That Matters*

## Chronic Sinusitis: Saline Irrigation Helps Somewhat; Steroid Does Not Add More Benefit

### Clinical Question

In patients with chronic rhinosinusitis, does the addition of budesonide (Rhinocort) to a saline irrigation solution result in further improvement in symptoms?

### Bottom Line

This study showed that patients with chronic rhinosinusitis who continue to use a saline nasal wash (NeilMed) will often experience an improvement in symptoms that can be clinically meaningful, but the addition of the corticosteroid budesonide has yet to show an extra benefit. (Level of Evidence = 2b)

### Synopsis

These researchers recruited 80 patients with chronic rhinosinusitis (two or more symptoms, including mucopurulent drainage, nasal obstruction, facial pain, and decreased sense of smell for at least 12 weeks) to be randomized, allocation concealment unknown, to receive treatment using a large-volume saline sinus irrigation with placebo or budesonide, 1 mg once daily, for 30 days. The patients, average age 51 years, had a Sino-Nasal Outcome Test score of 44.1 out of a possible 110. A significant number of patients dropped out (23%), leaving 61 to be evaluated. The average decrease in scores was 20.7 points in the treated group and 13.6 points in the control group, which was not statistically significant. More participants in the treated group (79%) received a clinically important benefit of at least a 9-point improvement than in the saline-only group (59%; not statistically different). This small study, with a significant drop-out rate, did not have the power to find a difference if one exists. The authors did not give specific data to judge the degree of benefit beyond a 9-point improvement for the responders.

**Study design:** Randomized controlled trial (double-blinded)

**Funding source:** Self-funded or unfunded

**Allocation:** Uncertain

**Setting:** Outpatient (specialty)

**Reference:** *Tait S, Kallogjeri D, Suko J, Kukuljan S, Schneider J, Piccirillo JF. Effect of budesonide added to large-volume, low-pressure saline sinus irrigation for chronic rhinosinusitis: a randomized clinical trial.* JAMA Otolaryngol Head Neck Surg. *2018;144(7):605-612.*

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## Clopidogrel Plus Aspirin Provides More Net Benefit Than Aspirin Alone After Minor Stroke or TIA

### Clinical Question

Does adding clopidogrel (Plavix) to aspirin following a transient ischemic attack (TIA) or minor stroke safely improve outcomes?

### Bottom Line

This study provides support for a strategy of adding clopidogrel to aspirin for the first week or so after a minor ischemic stroke or TIA because this is when the greatest benefit occurs. Harms were spread fairly evenly throughout the study period. (Level of Evidence = 1b)

### Synopsis

The CHANCE trial was a Chinese study that found improved outcomes with no increase in bleeding risk for patients with minor ischemic stroke or TIA who were given aspirin

plus clopidogrel for three weeks. This current study broadens the population to include non-Chinese patients, uses a higher loading dose of clopidogrel (600 mg instead of 300 mg), and continues the combined clopidogrel plus aspirin for 90 days. The investigators identified patients with a minor stroke (National Institutes of Health Stroke Scale score of 1 to 3 points) or high-risk TIA (ABCD2 score of at least 4 points) and randomized them to receive either aspirin alone or a 600-mg loading dose of clopidogrel, then 75 mg clopidogrel daily plus aspirin. The aspirin dose varied by site from 50 mg to 325 mg per day based on physician preference, but the recommended dosage was 162 mg daily for five days, followed by 81 mg daily. All patients were recruited within 12 hours of symptom onset. The primary outcome was a composite of ischemic stroke, myocardial infarction, or vascular death, and the secondary outcome was recurrent ischemic stroke within 90 days. A total of 4,881 patients were recruited and randomized, but the trial was stopped early because it reached a prespecified level of increased intracranial hemorrhage. Rates of loss to follow-up were similar between groups (6% to 7%) and more than one-fourth of patients in each group stopped taking the study medication prematurely. The mean age of participants was 65 years, 45% were women, 20% were black, 43% had a TIA, and 57% had a minor stroke. At the end of the 90-day study period, there was no difference in the likelihood of vascular death, myocardial infarction, or all-cause mortality between groups. Although the composite outcome was less common with clopidogrel, this was due to a reduction in ischemic stroke only. Patients who received both clopidogrel and aspirin were less likely to have an ischemic stroke (4.6% vs. 6.3%; $P = .01$; number needed to treat [NNT] = 59) but were more likely to experience a major hemorrhage (0.9% vs. 0.4%; $P = .01$; NNT = 200); most of the difference in the latter outcome was due to nonncerebral hemorrhages. The excess strokes in the aspirin-only group largely occurred in the first week, whereas hemorrhagic events occurred throughout the study period.

**Study design:** Randomized controlled trial (double-blinded)

**Funding source:** Government

**Allocation:** Concealed

**Setting:** Outpatient (any)

**Reference:** *Johnston SC, Easton JD, Farrant M, et al.; Clinical Research Collaboration, Neurological Emergencies Treatment Trials Network, and the POINT Investigators. Clopidogrel and aspirin in acute ischemic stroke and high-risk TIA.* N Engl J Med. *2018; 379(3):215-225.*

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## Digital Media Use Associated with ADHD Symptom Development Among Adolescents

### Clinical Question

Is frequent use of digital media associated with the development of attention-deficit/hyperactivity disorder (ADHD) symptoms in high school students?

### Bottom Line

High school students who reported a high frequency (many times per day) of digital media use (e.g., social networking, streaming movies or music, texting) were significantly more likely to self-report symptoms of ADHD over two years of follow-up (10% higher symptom reporting rate). It remains uncertain whether the association is causal and whether efforts to reduce exposure can result in less symptom development. (Level of Evidence = 1b)

### Synopsis

The investigators analyzed data obtained from a longitudinal cohort survey of adolescents enrolled in 10 high schools in the Los Angeles, Calif., area. Beginning in the fall of 10th grade, eligible students (n = 2,587) initially classified as not having ADHD symptoms based on a previously validated evaluation tool, provided follow-up self-reported symptom scores at six, 18, and 24 months. At baseline and at 12 and 24 months, students also indicated how frequently they engaged in various digital media activities in the past week (none, one to two times per week, one to two times per day, or many times per day). The authors performed various analyses to address potential confounders, including age, sex, family income, history of delinquent behavior, race/ethnicity, depressive symptoms, substance use, and family history of substance use.

More than one-half (54.1%) of the students reported high frequency of checking social

media, which was the most common media activity. High-frequency engagement in digital media activity at baseline was significantly associated with a higher odds of reporting symptoms of ADHD at follow-up (odds ratio = 1.10; 95% confidence interval, 1.05 to 1.15). In addition, the mean rate of having ADHD symptoms at follow-up was significantly increased among the 51 students who reported 14 high-frequency media use activities and the 114 students who reported seven high-frequency media use activities at baseline compared with the 495 students who reported no high-frequency media use over the preceding week (10.5% and 9.5% vs. 4.6%, respectively).

**Study design:** Cohort (prospective)

**Funding source:** Government

**Setting:** Population-based

**Reference:** *Ra CK, Cho J, Stone MD, et al. Association of digital media use with subsequent symptoms of attention-deficit/hyperactivity disorder among adolescents.* JAMA. *2018;320(3):255-263.*

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## Decompression Surgery No More Effective Than Exercise for Shoulder Impingement Syndrome

### Clinical Question

In patients with symptoms of shoulder impingement syndrome, is subacromial decompression surgery more effective than sham arthroscopy or exercise therapy to decrease pain and improve function?

### Bottom Line

Despite being one of the most common orthopedic surgeries performed, subacromial decompression is not significantly better than physical therapy to treat patients with pain and limited function caused by shoulder impingement. This study is backed up by a meta-analysis that found the same results (*Disabil Rehabil*. 2015;37(1):1-8). Another meta-analysis (*Br J Sports Med*. 2017;51(18):1340-1347) demonstrated the benefit of shoulder exercises over other physical therapy modalities. (Level of Evidence = 1a)

### Synopsis

Finnish researchers enrolled 210 adults 35 to 65 years of age with a clinical presentation of shoulder impingement syndrome, who had no evidence of rotator cuff tear on magnetic resonance imaging and who had not responded to three months of conventional treatment. The patients were first randomized to receive surgery or physical therapy using concealed allocation. Patients in the surgery group underwent diagnostic arthroscopy to rule out tears or other pathology and then, in the operating room, were randomized again to receive arthroscopic subacromial decompression or no further intervention (to keep treatment assignments concealed, the latter group was kept in the operating theater for the length of time of a typical decompression). After two years, patients in all three groups had a large decrease in reported pain, from approximately 75 points to between 20 and 30 points on a 100-point visual analog scale. Decompression was statistically better than exercise therapy, but the result would not be clinically relevant (a difference of at least 15 points) and was no different than diagnostic arthroscopy. There was also no difference in pain or function scores at earlier time points. The researchers did not attempt to stratify patients by degree of joint narrowing or by the presence of osteoarthritis or other morphology, and targeted therapy aimed at specific changes may have found a difference in treatment outcomes.

**Study design:** Randomized controlled trial (double-blinded)

**Funding source:** Government

**Allocation:** Concealed

**Setting:** Outpatient (specialty)

**Reference:** *Paavola M, Malmivaara A, Taimela S, et al.; Finnish Subacromial Impingement Arthroscopy Controlled Trial (FIMPACT) Investigators. Subacromial decompression versus diagnostic arthroscopy for shoulder impingement: randomised, placebo surgery controlled clinical trial.* BMJ. *2018;362:k2860.*

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**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*. ■