

POEMs

Patient-Oriented Evidence that Matters

We have selected three POEMs for October. The first confirms that, although clopidogrel plus aspirin might be easier to manage for older patients with AF, it doesn't work as well. The second reassures us that we do not need to advise our patients to purchase expensive orthotics for plantar fasciitis and the final POEM reveals that, despite what some of our patients tell us, diphenhydramine (given to infants, not parents) will not reduce the number of times that parents need to get up to their babies at night. It is interesting, to me, that all of these POEMs summarise research that shows that an intervention is unhelpful. There was a time when this sort of research did not get published but the information is often just as useful for GPs as those studies that show positive outcomes! Editor.

Clinical question

Is warfarin better than clopidogrel plus aspirin in preventing strokes in patients with atrial fibrillation?

Bottom line

Warfarin is superior to the combination of clopidogrel (Plavix) plus aspirin in preventing strokes and systemic emboli in high-risk patients with atrial fibrillation. (LOE = 2b)

Reference

ACTIVE Writing Group on behalf of the ACTIVE Investigators; Connolly S, Pogue J, Hart R, et al. Clopidogrel plus aspirin versus oral anticoagulation for atrial fibrillation in the Atrial fibrillation Clopidogrel Trial with Irbesartan for prevention of Vascular Events (ACTIVE W): a randomised controlled trial. *Lancet* 2006; 367:1903–1912.

Study Design

Randomised controlled trial (nonblinded)

Funding

Industry

Allocation

Concealed

Setting

Outpatient (any)

Synopsis

In this study, more than 6700 patients with atrial fibrillation eligible for – and willing to take – oral anticoagulation were included if they had at least one of the following characteristics: more than 75 years of age; treated for hypertension; a previous stroke, transient ischemic attack, or non-CNS systemic embolism; left ventricular ejection fraction less than 45%; or peripheral artery disease. They also included younger patients if they had diabetes or coronary artery disease. Eligible patients were randomly assigned to once-daily clopidogrel (75mg) plus aspirin (75 to 100mg daily) or warfarin titrated to a target international normalised ratio of between 2.0 and 3.0. The primary study outcomes (stroke, non-CNS systemic embolism, myocardial infarction, or vascular death), assessed by researchers masked to treatment assignment, were evaluated by intention to treat. The study was terminated early because of the clear superiority of oral anticoagulation. After 1.3 years of follow-up, bad outcomes occurred in 4.9% of patients taking oral anticoagulation compared with 7.0% in those treated with clopidogrel plus aspirin (number needed to treat = 48; 95% CI, 31–101). They found minimal differences in all individual events, except stroke and non-CNS embolism. The rate of major bleeding complications was comparable in patients taking clopidogrel plus aspirin (2.42% per year) and patients taking warfarin (2.21% per year). However, the rate of minor bleeding was lower in patients treated with warfarin (11.4% vs 13.6%).

Clinical question

Is either a prefabricated orthosis or a custom-manufactured orthosis effective in decreasing pain and improving function in patients with plantar fasciitis?

Bottom line

Specially designed and off-the-shelf orthotics are no more effective than a padded insert, on average, at decreasing pain in patients with plantar fasciitis. Patients reported a small improvement in function, but this benefit was short-lived. (LOE = 2b)

Reference

Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis. *Arch Intern Med* 2006;166:1305-1310.

Study Design

Randomised controlled trial (single-blinded)

Funding

Industry + foundation

Allocation

Uncertain

Setting

Outpatient (specialty)

Synopsis

Participants for this study were drawn from a podiatry clinic and all were diagnosed with plantar fasciitis for at least four weeks. The 135 patients were randomly assigned (concealed allocation uncertain) to receive treatment with one of three foot orthoses: a prefabricated off-the-shelf firm orthosis (Formthotic), a rigid customised orthosis, or a soft sham (placebo) orthosis. All but four subjects participated for the full 12 months of the study, although by the end of the study one in four patients had also received additional treatment. Pain and function were measured using the Foot Health Status Questionnaire. Using intention-to-treat analysis, all three groups experienced an improvement in pain scores at both three-month and 12-month follow-up, and there was no difference among the sham orthotic and the other orthotics. At three months, function was slightly better with both the prefabricated and customised orthoses than with sham treatment, with an adjusted mean difference in function scores of 8.4 and 7.5 of a possible 100 ($P < .05$). However, at 12 months, function scores in patients treated with the sham orthotic had improved and there was no difference among the three groups. The study had the power to find a 15-point difference in pain scores, if one truly existed.

Clinical question

Does diphenhydramine promote sleep in infants whose parents report frequent nocturnal awakenings?

Bottom line

Diphenhydramine was no more effective (and was technically less effective) than placebo in reducing parental attention in infants with frequent nocturnal awakenings. (LOE = 2b)

Reference

Merenstein D, Diener-West M, Halbower AC, Krist A, Rubin HR. The trial of infant response to diphenhydramine: the Tired study – A randomized, controlled, patient-oriented trial. *Arch Pediatr Adolesc Med* 2006;160:707-712.

Study Design

Randomised controlled trial (double-blinded)

Funding

Foundation

Allocation

Concealed

Setting

Outpatient (primary care)

Synopsis

Children aged six months to 15 months whose parents reported at least two nocturnal awakenings were randomized to receive one week of diphenhydramine (1 mg/kg) or placebo 30 minutes before anticipated bedtime. The main outcome was whether the child required parental attention during the night. The study design called for 38 patients in each group. However, after 44 patients completed the study, an independent data monitoring committee unanimously voted to stop the study early because of the dismal results: one of 22 children receiving diphenhydramine showed improvement compared with three of 22 infants taking placebo.