

POEMs

Patient-Oriented Evidence that Matters

First we have another twist to the calcium supplementation evidence, suggesting that calcium and vitamin D, in combination, reduces the incidence of cancer in women. But does this balance the increased risk of coronary artery disease? The second POEM confirms that warfarin is better than aspirin in preventing strokes in older people who have AF and that it is no more risky. The next POEM will make our ulcer nurses shudder, as it suggests that it does not really matter what type of dressing we use under a pressure bandage when treating venous leg ulcers. Editor

Clinical question

Does supplementation with calcium and vitamin D reduce cancer incidence in postmenopausal women?

Bottom line

Women receiving calcium and vitamin D, but not calcium alone, were less likely to develop a non-skin cancer over four years of supplementation. This is good news, though the study is too small to be definitive – despite enrolling more than 1000 women – since no single cancer incidence was reduced. The dose of vitamin D (1000IU) was higher than what is typically used in research but can be found in several calcium/vitamin D products. (LOE = 2b)

Reference

Lappe JM, Travers-Gustafson D, Davies KM, Recker RR, Heaney RP. Vitamin D and calcium supplementation reduces cancer risk: results of a randomised trial. *Am J Clin Nutr* 2007; 85:1586-1591.

Study Design

Randomised controlled trial (double-blinded)

Funding

Unknown/not stated

Allocation

Uncertain

Setting

Population-based

Synopsis

Both sun exposure and vitamin D status have been linked to reduced cancer mortality. To investigate this asso-

ciation, these US researchers identified a population-based sample of 1180 women older than 55 years without a known cancer. The women, drawn from rural Nebraska, were all of white ancestry. The women were randomly assigned to receive placebo, 1400mg to 1500mg calcium per day, or calcium plus 1000IU vitamin D3 (allocation concealment unknown) for four years. This dose of vitamin D is higher than the typically used dose of 400IU. Health status was assessed every six months and reports of cancer were confirmed. Over the four years of the study, 50 women (4.2%) developed a non-skin cancer. Using intention-to-treat analysis, the incidence of cancer was significantly lower in the vitamin D/calcium-treated women (2.9%) than in calcium-treated women (3.8%) and placebo-treated women (6.9%). One cancer was presented over four years for every 24 women who received calcium/vitamin D instead of placebo (number needed to treat [NNT]=24.3; 95% CI, 18–80; P=.013). Calcium alone did not uniformly change cancer incidence. After giving the treatment 'time to work', cancers in years two to four of the study were also significantly less in the calcium/vitamin D group (NNT=20; 16–37). These results are good news, but, although the authors enrolled more than 1000 patients, this is a relatively small study because of the low number of cancers (n=50). Given that they evaluated at least six different types of cancer in this composite outcome and that no single cancer incidence was significantly reduced, larger studies are necessary to determine whether a specific cancer likelihood is reduced or whether this is simply a statistical artifact.

Clinical question

In patients older than 75 years with atrial fibrillation, is warfarin more effective than aspirin at preventing strokes?

Bottom line

This study confirms that warfarin titrated to a target international normalised ratio (INR) of 2.0 to 3.0 is more effective than 75mg aspirin in preventing strokes without significantly increasing the risk of bleeding complications. (LOE = 1b-)

Reference

Mant J, Hobbs FD, Fletcher K, et al., for the BAFTA investigators; Midland Research Practices Network (MidReC). Warfarin versus aspirin for stroke prevention in an elderly community population with atrial fibrillation (the Birmingham Atrial Fibrillation Treatment of the Aged Study, BAFTA): a randomised controlled trial. *Lancet* 2007; 370:493-503.

Study Design

Randomised controlled trial (single-blinded)

Funding

Government

Allocation

Uncertain

Setting

Outpatient (primary care)

Synopsis

This trial was an open-label trial with masked assessment of the outcomes. The patients, who were at least 75 years of age with atrial fibrillation or atrial flutter, were recruited from primary care practice. They were randomly assigned to receive aspirin (75mg daily; n=485) or warfarin (target INR=2.0-3.0; n=488). The researchers excluded patients with rheumatic heart disease, major hemorrhage within the previous five years, intracranial hemorrhage, proven peptic ulcer disease in the previous year, esophageal varices, allergy, terminal illness, recent surgery, or blood pressure higher than 180/110 mm Hg. The researchers used an intention-to-treat analysis to assess the outcomes. The two groups were similar at baseline and the researchers evaluated them for an average of 2.7 years. The annual rate of strokes in the warfarin group was 1.6% compared with 3.4% in the aspirin group (number needed to treat [NNT]=56 per year; 95% CI, 40-294). The annual rate of total events (stroke, systemic emboli, intracranial hemorrhage including subdural hematoma) in each group was 1.8% and 3.8%, respectively (NNT=51; 37-290). There was no significant difference between the two groups in the rate of extracranial hemorrhage (1.4% and 1.6%). The authors accounted for 100% of the patients at the end of the study.

Clinical question

Which dressing is best when used under a pressure bandage for venous leg ulcers?

Bottom line

In this meta-analysis, no type of product – hydrocolloid, foam, hydrogel, or alginate – was found to be better than a low-adherent dressing or better than one another with regard to healing. Cost, ease of use, and pain on application or removal based on clinical experience can be used to guide product choice. (LOE = 1a)

Reference

Palfreyman S, Nelson EA, Michaels JA. Dressings for venous leg ulcers: systematic review and meta-analysis. *BMJ* 2007; 335:244.

Study Design

Meta-analysis (randomised controlled trials)

Funding

Government

Setting

Various (meta-analysis)

Synopsis

To determine which is the best among the numerous dressings to cover a venous leg ulcer under a compression bandage (e.g. Unna boot), these researchers searched four databases, examined conference proceedings, checked citations, and contacted experts and dressing manufacturers. Two reviewers independently assessed the trials, identifying 42 studies enrolling a total of almost 1000 patients. They did not include studies of diabetic or arterial ulcers. All of the studies were randomised. Allocation concealment was unclear for most of them, as was the masking of the outcome assessor. These design errors could result in an overestimate of benefit of one treatment or another. Studies compared various dressing types and products within specific types, with no studies demonstrating a benefit of one dressing over another or one product over another in terms of healing. As a result, choice of dressing can be based on other factors, such as cost, ease of use, and pain associated with their use, areas that have been poorly studied to date.