

# Ginger, Vitamin B<sub>6</sub> Ease Nausea in Pregnancy

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SAN FRANCISCO — Multiple clinical trials have shown that both ginger and vitamin B<sub>6</sub> can safely help reduce the nausea and vomiting of "morning sickness" in pregnancy.

Cathi Dennehy, Pharm.D., reviewed the evidence for the efficacy and safety of the two supplements at a meeting on antepartum and intrapartum management sponsored by the University of California, San Francisco.

► **Ginger.** Six randomized, controlled trials found significant reductions in nausea and vomiting during pregnancy in women who took powdered ginger, ginger syrup, or ginger extract products for 4-21 days. Four trials found greater reductions in nausea and vomiting, compared with placebo, and two trials found effects that were equivalent to treatment with 30 mg or 75 mg/day of vitamin B<sub>6</sub> (with no placebo arm in those studies).

The most common dose was 1 g/day of powdered ginger, which comes in capsules containing 250-500 mg each. Patients took divided doses b.i.d. or q.i.d. depending on the capsule size.

The studies included 26-291 women each. Four trials that included a total of 265 women found no increased risk of negative birth outcomes in the ginger groups. Most of the women in these studies used ginger during the first trimester of pregnancy, but some studies included women up to the 20th week of gestation and after the critical developmental stages, which might have diluted the findings regarding safety. A separate observational study that focused strictly on ginger use during the first trimester also found no increase in adverse events.

Side effects are rare but may include GI upset, heartburn, flatulence, or bloating. Much higher doses of ginger (2.5 g/day or higher) can produce antiplatelet effects.

Two previous studies—one in rats and the other an in vitro study—had raised some concerns about possible mutagenic properties or some increase in early embryonic loss. However, "there is quite a bit of evidence in clinical trials" to support the safety of ginger in pregnancy, said Dr. Dennehy of the university's School of Pharmacy.

► **Vitamin B<sub>6</sub>.** Two randomized, controlled trials (with 59 and 342 patients, respectively) found that vitamin B<sub>6</sub> supple-

ments worked significantly better than placebo to decrease severe nausea and vomiting in pregnancy or to decrease overall nausea scores and vomiting in the first 3 days of use.

Bendectin, a product that combined vitamin B<sub>6</sub>, an antihistamine, and an anticholinergic, was pulled off the U.S. market in the early 1980s after lawsuits alleged that it caused limb deformities in children. Plaintiff victories on those charges were overturned on appeal. Moreover, late last

year, the FDA took the unusual step of publishing a notice in the Federal Register stating that Bendectin had not been withdrawn from the market for safety or health reasons. The move was widely seen as an invitation for a pharmaceutical manufacturer to begin selling the drug again.

Today, a similar product called Diclectin is sold in Canada and combines vitamin B<sub>6</sub> with doxylamine. A meta-analysis of 170,000 exposures to Diclectin found no adverse effects on fetuses. "Overall, it

looks like vitamin B<sub>6</sub> is a safe product to use" in pregnancy, Dr. Dennehy said.

Dr. Dennehy also reviewed the prospect of peppermint tea as a morning-sickness palliative. There are no trials of peppermint tea either in general use or during pregnancy, she said, but a small randomized controlled study of peppermint oil for postoperative pain found it to be more effective than placebo. Peppermint oil relaxes GI smooth muscle, and commonly is used for irritable bowel syndrome. ■

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**References:** 1. Food and Drug Administration, Center for Drug Evaluation and Research. Approval package for: application number NDA 21-928; statistical review(s). Food and Drug Administration Web site. Available at: [http://www.fda.gov/cder/foi/nda/2006/021928\\_s000\\_Chantix\\_StatR.pdf](http://www.fda.gov/cder/foi/nda/2006/021928_s000_Chantix_StatR.pdf). Accessed August 25, 2006. 2. Data on file. Pfizer Inc. Post hoc analysis of data from final study reports. 3. Gonzales D, Rennard SI, Nides M, et al, for the Varenicline Phase 3 Study Group. Varenicline, an  $\alpha_4\beta_2$  nicotinic acetylcholine receptor partial agonist, vs sustained-release bupropion and placebo for smoking cessation: a randomized controlled trial. *JAMA*. 2006;296:47-55. 4. Jorenby DE, Hays JT, Rigotti NA, et al, for the Varenicline Phase 3 Study Group. Efficacy of varenicline, an  $\alpha_4\beta_2$  nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release bupropion for smoking cessation: a randomized controlled trial. *JAMA*. 2006;296:56-63. 5. CHANTIX [package insert]. New York, NY: Pfizer Inc; May 2007.

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