Ginger, Vitamin B6 Can Help Nausea in Pregnancy

BY SHERRY BOSCHERT

San Francisco Bureau

SAN FRANCISCO — Multiple clinical trials have shown that both ginger and vitamin B_6 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 per day of vitamin B_6 (with no placebo arm in those studies).

The most common dose was 1 g per 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 B₆. Two randomized, controlled trials (with 59 and 342 patients, respectively) found that vitamin B₆ supplements worked significantly better than placebo to decrease severe nausea and vomiting in pregnancy or to decrease over-



"There is quite a bit of evidence in clinical trials" to support the safety of ginger in pregnancy, says Dr. Cathi Dennehy.

all nausea scores and vomiting in the first 3 days of use.

Bendectin, a product that combined vitamin B_6 , 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 ${\rm B}_6$

with doxylamine. A meta-analysis of 170,000 exposures to Diclectin found no adverse effects on fetuses. "Overall, it looks like vitamin B_6 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.

Peppermint oil also decreases lower esophageal sphincter tone, increases bile flow, and can worsen gastroesophageal reflux disease, "which can get problematic during pregnancy," she said. "You wouldn't want to give this to someone who already was complaining of those types of symptoms."

Peppermint "likely is safe as a tea formulation in pregnancy," Dr. Dennehy concluded.

Three separate studies in the past decade suggest that 7%-13% of women use herbal preparations during pregnancy for a variety of indications, a practice that is more common in Australia and some European countries than in the United States. However, a year 2000 survey of certified nurse-midwives in North Carolina found that 73% recommended herbal products in pregnancy, most commonly for nausea and vomiting, Dr. Dennehy noted.

Intake of Nicotine in Breast Milk May Disrupt Infant Sleep

BY TIMOTHY F. KIRN
Sacramento Bureau

A mother who smokes and breast-feeds appears to be giving her infant a dose of nicotine that significantly interferes with the baby's sleep, according to the results of a study.

Infants spent an average of about a third less time sleeping after their mothers smoked just prior to breast-feeding, compared with when the mothers refrained, wrote Julie A. Mennella, Ph.D., and her associates at the Monell Chemical Senses Center in Philadelphia.

Nicotine is not listed as a drug that is contraindicated during breast-feeding because the benefits of breast-feeding are considered to be so great, Dr. Mennella and her associates noted.

But the presence of nicotine in breast milk could have many adverse consequences.

Mothers who smoke are known to wean their children earlier than are mothers who do not. It might be that sleep-deprived infants tend to be fussier and, if the sleep deprivation occurs because of smoking, the fussiness may stop when the mother stops breast-feeding. That in turn may reinforce a smoking mother's decision to wean, they suggested.

Sleep also is known to be important for learning and development, and therefore disruption of sleep caused by smoking

could have lasting consequences, they said.

Lastly, adolescents whose mothers smoked during their early life are more likely to smoke, and this may sometimes be because they recognize the tobacco-related flavors from breast milk, and come to appreciate them.

The study was conducted with 15 volunteer mother-infant pairs. The average age of the infants was 4 months.

The mothers were brought into a testing center twice, and told to refrain from smoking for 12 hours before each testing session, with the last breast-feeding done about 2.5 hours before the session.

During one testing session, they were allowed to smoke at least one cigarette, in a separate room from the infant, and during one session they were not (Pediatrics 2007;120:497-502).

Nicotine levels in breast milk were measured at baseline and after smoking. The infants' sleep and awake times were monitored using an ambulatory monitor for 3.5 hours.

During the session when the mothers smoked, the estimated dose of nicotine delivered to the infants was a mean of 549 ng/kg. That compared with a mean dose of 127 ng/kg during the nonsmoking sessions.

During the nonsmoking sessions, the infants slept a mean of 84.5 minutes. That compared with a mean of 53.4 minutes during the smoking sessions. All but two

of the infants slept less during the smoking session.

Both active sleep and quiet sleep were reduced with smoking, and the duration of the longest bout of sleep declined from a mean of 60 minutes during the non-smoking session to a mean of 37 minutes during the smoking session.

With greater doses of nicotine, the reduction in active sleep was greater, Dr. Mennella and her associates said.

Mothers often cut back on their smoking during pregnancy. But then they tend to relapse to more smoking once their infants are born, the investigators said. And, this information may give them an added incentive to continue to curb their smoking while breast-feeding.

Nicotine that is stored in breast milk reaches peak levels about 30-60 minutes after the mother's smoking and then declines fairly rapidly.

