Clinical Update
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relief for those children using the herbal eardrops compared to those taking the anesthetic ear drops.

Criticisms of this trial include the lack of an antibiotic-only group as well as the lack of clear reporting on follow-up otoscopic examinations by the attending physician. As noted in the previous review of the earlier trial, any practitioner would expect successful outcomes to be based at least partially on follow-up evaluation of the child’s affected ear and not based solely on subjective feedback of patients or parents. In addition to evaluation at 3 days, follow-up evaluation of the tympanic membrane to rule out fluid build-up in the middle ear (otitis media with effusion) would be critical to determining success with or without antibiotic therapy.

Finally, as was the case with the earlier trial, the children included in the current study are older (5 years and over) and more likely to spontaneously recover from AOM without antibiotics. Hopefully, the investigators will extend their findings to younger children in future trials to see if the NHEP work as effectively in managing pain in that patient population—a group that makes up the majority of AOM cases.8

The herbs used in the Israeli product and similar products in the U.S. are based on traditional use. Marigold flowers have been traditionally used topically as an anti-inflammatory and for wound healing.9 Mullein flowers and leaves, because of high mucilage content, act as a demulcent to soothe irritated mucous membranes internally and as an emollient topically to treat skin irritations and minor burns.5 Although more commonly associated with its use as an antidepressant, St. John’s Wort flowering tops have been used topically to reduce “nerve pain” and inflammation.6 Garlic bulbs are thought to have topical antimicrobial effects—an action that has been shown in vitro.7

Practice Implications: The results of this trial support the notion that the wait-and-see approach to AOM in older children may be the most prudent. It also suggests that, although modest, the use of traditional herbal eardrops is a therapeutic option for pain during this waiting period. Herbal eardrops containing a combination of mullein, marigold (calendula), St. John’s wort, lavender, and garlic in an olive oil base reduce ear pain associated with AOM as effectively as standard anesthetic eardrops. However, recommendation of these drops should only be made following otoscopic examination of the tympanic membrane and the absence of any rupture that would allow the drops to enter the middle ear. Persistence of symptoms beyond 3 days would suggest the need for antibiotics.

References:

Cardiovascular Benefits of a Theaflavin-Enriched Green Tea Extract


Summary: This double-blind, placebo-controlled trial included 240 men and women (18 years or older) with mild to moderate hypercholesterolemia (high cholesterol characterized in this trial by subjects with low density lipoprotein cholesterol [LDL-C] in the range of 130-190 mg/dL). The subjects were consuming a low-fat diet (less than 32% of total calories from fat) and were randomized to receive a daily dose of either 375 mg of theaflavin-enriched green tea (Camellia sinensis [L.] Kuntze, Theaceae) extract (Nashai Biotech, LLC, Nashville, Tennessee) or placebo for 12 weeks. Subjects were recruited from 6 urban hospitals in China. They were administered one green tea extract capsule per day, which contained 75 mg theaflavins, 150 mg of green tea catechins, and 150 mg of other tea polyphenols. The main outcome measure was the change from baseline for total cholesterol (TC), LDL-C, high density lipoprotein cholesterol (HDL-C) and triglycerides. Lipid and lipoprotein concentrations were measured after a 12-hour fast at weeks 2 (2 weeks prior to treatment), week 0 (beginning of treatment), week 4, and week 12.

After 12 weeks, there was a statistically significant decrease in TC of 11.3% (P < 0.01) and LDL-C of 16.4% (P < 0.01) in the green tea group. No significant changes were seen in TC or LDL-C in the placebo group at any point during the study. After 12 weeks, HDL-C and triglycerides increased by 2.3% and 2.6%, respectively in the green tea group, while HDL-C fell by 0.7% and triglycerides increased by 5.6% in the placebo group. The mean TC to HDL-C ratio fell from 4.61 to 4.05 (P < 0.001) from baseline to week 12 in the green tea group, but did not change significantly in the placebo group (from 4.55 to 4.57, P = 0.85). There were no significant differences in adverse events between the two groups (specific adverse events are not listed).

Comments/Opinions: Already the second most popular beverage in the world next to water, tea is enjoying a resurgence based on population studies linking it to decreased risk of cardiovascular disease and cancer.1,3 Interestingly, these data have included both green tea and black tea consumption and have been based on tea consumption in populations as diverse as the Japanese and the Dutch. Additionally, tea drinking has been associated with an improved lipid profile in some4 but not all5 observational studies. These data have led to not only a large increase in tea consumption in the North America but also a preponder-
ance of encapsulated green tea supplements.

The choice of the green tea extract for this trial was based upon what is assumed to be beneficial in both green and black teas. As is widely known, catechins (e.g., (-)-epigallocatechin gallate [EGCG]) are the predominant flavonoids in green tea and are associated with increased antioxidant activity in the body. After fermentation from green tea to black tea, about 15% of catechins remain unchanged and the rest are converted to theaflavins (polyphenol pigments) and thearubins.

Despite favorable epidemiological evidence for both green and black teas, this is the first trial to actually demonstrate that a tea extract lowers LDL-C. According to the authors, the rationale to enhance the level of theaflavin is based on a previous trial of daily consumption of 3.6 g of encapsulated green tea polyphenols in which no effect on lipids was found. It should be noted that this earlier trial was with smokers. Also notable is the fact that human tea-drinking trials have tested exposure to 0–35 mg of theaflavins and 50–850 mg of catechins per day, with no significant effect on lipids. As noted by the authors, more research is needed on this new proprietary theaflavin-enriched green tea extract to better understand its potential for reducing risk of cardiovascular disease. At the time of writing, the extract was rapidly making its way into products in the U.S. market. However, more clinical trials are needed to support the positive effects of theaflavins.

**Practice Implications:** The Third Report of the National Cholesterol Education Program Adult Treatment panel states that diet therapy is the initial recommendation for lowering LDL-C. These guidelines have included increasing fiber and plant stanols and sterols to assist in lowering LDL-C. According to data from previous observational studies as well as trials conducted on conventional statin drugs, it is estimated that each 1% reduction in LDL-C results in approximately a 1.0% to 1.5% reduction in the relative risk of major cardiovascular events. Extrapolating the results above suggests a decreased risk of 16% to 24% with regular consumption of the theaflavin-enriched green tea extract in persons with mild to moderate hypercholesterolemia.

**References:**


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*Note: For an excellent overview of clinical trials on green and black teas, please see the chapter on tea in *The ABC Clinical Guide to Herbs.*

**Is Black Cohosh a Selective Estrogen Receptor Modulator?**


**Summary:** In a double-blind, placebo-controlled trial, 97 peri- and postmenopausal women (40–60 years), who were experiencing at least three hot flashes per day, were randomized to receive either one tablet of 20 mg of black cohosh (*Actaea racemosa* L., Ranunculaceae; syn. *Cimicifuga racemosa* [L.] Nutr.) extract corresponding to 20 mg of the rhizome, 0.3 mg of conjugated estrogens (CE), or placebo 2 times per day for 3 months. The final analysis contained 62 postmenopausal women: 33 perimenopausal patients were excluded from the statistical analysis as well as 2 dropouts. The black cohosh (BC) extract used in the trial (BNO 1055, sold as Klimadynon® and Menofem®, manufactured by Bionorica AG, Neumarkt, Germany) is a dried aqueous/ethanolic extract (58%, v/v) of the rhizome (standardization specifics are not provided in the paper). The change from baseline in the Menopause Rating Scale (MRS) was the primary efficacy endpoint. Subjects completed the MRS at baseline and at weeks 4, 8 and 12. The MRS covers 10 climacteric (menopausal) symptoms — hot flashes and sweating, heart palpitations, sleep disturbances, mood swings, tension and nervousness, mental fatigue and memory loss, loss of sexual drive, urinary incontinence, vaginal dryness, and joint pain. Patients were instructed to report the intensity of each symptom on a 10-point scale (0 = no symptoms, to 10 = severe symptoms). Patients were also instructed to complete a diary of symptoms each day, which included information on the number of hot flashes, the occurrence (intensity, duration) of vaginal bleeding episodes, and sleep disturbances. Blood samples were collected at baseline and at weeks 4, 8, 12, and 12, and used to measure luteinizing hormone (LH), follicle-stimulating hormone (FSH), estradiol, and progesterone. Additionally, the levels of CrossLaps (a marker of bone degradation) and bone-specific alkaline phosphatase (a marker for bone formation) were measured by immunoassays and enzymatic assay, respectively. At baseline and at week 12, all subjects had complete gynecological examinations, including transvaginal ultra-
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