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complications due to the infection. The researchers correctly point out that children older than 6 years old have a greater chance of spontaneous recovery from AOM without using antibiotics. However, any practitioner would expect that this be based 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.

Concerns with study design aside, the clinical trial does provide some support for a clinical tool used widely by practitioners of herbal medicine (including naturopathic physicians and medical doctors using complementary and alternative therapies) for the management of pain associated with AOM. During my seven years of pediatric practice, I frequently recommended that parents administer a similar herbal ear drop preparation (Mullein Garlic Compound, HerbPharm, Williams, Oregon) for children during the first 48 hours of an AOM episode. In addition to the older age group in the Israeli trial, I found the drops to be equally effective for pain reduction in younger children. The upside of the pain reduction was not only happier kids, but also reduced use of acetaminophen (not to mention more relaxed parents).

The herbs used in the Israeli product and similar products in the U.S. are based on traditional use. Calendula (marigold) flowers have been traditionally used topically as an anti-inflammatory and for wound healing.¹ 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.² Although more commonly associated with its use as an antidepressant, St. John’s wort flowering tops have also been used topically to reduce “nerve pain” and inflammation.³ Garlic bulbs are thought to have topical antimicrobial effects — an action that has been demonstrated in vitro.⁴

While the herbal combination used in this trial apparently provides symptomatic relief of ear pain associated with AOM, the investigators in the discussion section of the paper fuel the controversy surrounding the rampant use of antibiotics for AOM. The authors of the study suggest that in children older than 6 years, initial antibiotic treatment at the diagnosis of AOM be withheld until follow-up (exact amount of time is not given). If no improvement is noted, they suggest then using antibiotics.

Practice Implications: Herbal ear drops containing a combination of mullein, calendula (marigold), St. John’s wort, and garlic in an olive oil base may reduce ear pain associated with AOM as effectively as standard anesthetic ear drops. However, recommendation of these drops should be made only following otoscopic examination of the tympanic membrane and the absence of any rupture that would allow the drops to enter the middle ear. It should be noted that these drops are only for symptomatic treatment and do not exclude the potential need for antibiotic treatment and/or other supportive therapies.

—Donald J. Brown, N.D.  

References

Low-Fat Diet, Supplemented with Flaxseed, May Influence Prostate Cancer Progression


Summary: In a pilot study, 25 men (average age 64 years) with prostate cancer and awaiting prostatectomy (removal of the prostate gland), were instructed to add 30 g (approximately 3 rounded tablespoons) of ground flaxseed (Linum usitatissimum L., Linaceae) to their daily diet. Additionally, they were given instructions for a low-fat diet (20 percent of kilocalories or less). Subjects were instructed to tally the number of fat grams they consumed each day; however, these did not include fat from high omega-3 fatty acid sources such as fish or fish. Blood was drawn at baseline and one to three days before surgery to measure prostate-specific antigen (PSA), testosterone, free androgen index, and total serum cholesterol. Following surgery, the tumors of these diet/flaxseed treated men were compared with historic controls (men with prostate tumor removal who did not alter their diet) matched by age, race, biopsy Gleason sum⁵, and PSA at the time of diagnosis. Tumor tissue samples were used to determine the degree of either apoptosis

Flaxseed Linum usitatissimum. Photo © 2002 stevenfostercom

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The average duration of the diet and flaxseed supplementation was 34 days (range of 21 to 77 days). Compared to baseline, there were significant (all p < 0.05) decreases in total testosterone (422 + 122 ng/dL to 360 + 128 ng/dL), free androgen index (36.3 percent + 18.9 percent to 29.3 percent + 16.8 percent), and total serum cholesterol (201 + 39 mg/dL to 174 + 42 mg/dL). Overall, there were no significant effects on PSA levels. However, using Gleason sum as a differentiating point, it was found that in men with less histopathologically aggressive disease, the low-fat diet and flaxseed supplementation led to slight but non-significant decrease in PSA levels compared to historic controls. PSA continued to rise in men with more aggressive disease. The apoptotic scores (TUNEL scores) were significantly different between the two groups (p = 0.01) with a higher score for those in the diet/flaxseed group. The proliferation index (MB-1 index) was significantly lower for those in the diet/flaxseed group (p = 0.05). Decrease in proliferation and higher rates of apoptosis were significantly associated with the number of days on the diet and flaxseed supplement (p = 0.049 and p = 0.017, respectively).

Comments/Opinions: Less an herbal medicine study and more nutritional in scope, this pilot study completed by researchers at Duke University provides further evidence that dietary factors may play a role in the progression and possibly prevention of prostate cancer. Some epidemiological studies have linked prostate cancer risk to increased consumption of foods high in saturated fats (primarily from meat and dairy sources) while some, but not all, preliminary clinical trials have found this link. Typically, as saturated fat is reduced in the diet, most people are likely to increase fruits and vegetables, which are higher in fiber and other nutrients linked to prostate cancer prevention. Among these are lycopene, a carotenoid abundant in tomatoes. Cruciferous vegetables, which are high in substances such as indole-3-carbinol, glucaric acid (calcium D-glucarate), sulforaphane, and the carotenoids lutein and zeaxanthin, have been linked with prostate cancer prevention in a preliminary study. Other foods linked to decreased risk of prostate cancer in preliminary research include fish and soymilk.

Flaxseed is a source of dietary fiber that is especially rich in dietary lignans (the authors of this study suggest it has “75 to 800 times more than any other food”). One study found that 50 to 60 g per day of fiber from mixed sources decreased PSA levels in 14 healthy men. Lignans (typically classified as phytoestrogens) have been found to influence both estrogen and androgen metabolism. A study with premenopausal women suggests that flaxseed supplemen-

* Biopsy Gleason sum is a scoring or sum based on tissue biopsy that allows for staging of the disease. The higher the score, the more aggressive the disease.
** TUNEL is an abbreviation for terminal deoxynucleotidyl transferase-mediated dUTP-biotin nick end-labeling and is used to determine an index of apoptosis. Apoptosis is a type of cell death programmed into a cell at birth and that triggers its death at old age or under conditions where cell death benefits the host (e.g. cancer). MB-1 is an abbreviation for murine MB-1 hybridoma clone and is used to determine the rate of tumor proliferation.
likely through a hormonal mechanism. This study sets the stage for larger clinical trials that should investigate the role of this intervention as either (or both) a preventive or complementary therapy for prostate cancer. Future trials should also add groups taking only flaxseed without a low-fat diet and a control group using only a low-fat diet for comparison. Clinicians wishing to recommend this regimen for their patients should consider the potential risks of drops in serum testosterone levels over a long period of time (e.g., decreased muscle mass, lowered libido, depression) as well as the difficulty of compliance with the diet used in this study.

—Donald J. Brown, N.D.

Reference: