New England Journal of Drugs stays true to form

In a recent issue of the New England Journal of Medicine (2004:351:1323-1331), there was a review article on the diagnosis and management of Bell’s palsy. In keeping with the tradition of certain major medical journals of either ignoring or misrepresenting the evidence supporting natural therapies, this article did not mention that intramuscular vitamin B12 appears to be an effective treatment.

In a 1959 report, two patients with Bell’s palsy of 1.5 and 4 years’ duration, respectively, experienced complete or almost complete recovery within 20 days after beginning a series of daily or every-other-day cyanocobalamin injections. More recently, methylcobalamin (500 mcg intramuscularly, 3 times a week) was compared with prednisolone and with the combination of methylcobalamin and prednisolone in a randomized trial. The mean time until complete recovery of facial nerve function was significantly less (p < 0.001) in patients receiving methylcobalamin (1.95 weeks) or methylcobalamin plus prednisolone (2.05 weeks) than in those receiving prednisolone alone (9.60 weeks).

Comment: I sent a letter to NEJM, pointing out the potential importance of this safe and inexpensive alternative to acyclovir and glucocorticoids. While it has been my experience that sending letters to NEJM or JAMA typically results in a polite rejection letter, on rare occasions these journals behave unpredictably and actually publish my letter. So, I keep writing letters, because variable-interval reinforcement is difficult to extinguish, and because if you don’t try to promote an attitude shift, you don’t have a right to complain. Actually, complaining has gotten to be less fun over the years, but the need to set a dysfunctional healthcare system straight remains.

Food additives cause hyperactive behavior

Two hundred seventy-seven children (aged 3 years) living on the Isle of Wight, UK, consumed a diet for four weeks that eliminated artificial colorings and benzoate preservatives. During the second week of the diet, the children were randomly assigned to receive, in double-blind fashion, daily challenges with a drink containing either 1) artificial colorings (20 mg/day total; 5 mg/day each of sunset yellow, tartrazine, carmoisine, and ponceau 4R) and sodium benzoate (45 mg/day) or 2) placebo. During the fourth week, the children were challenged daily with the alternate drink.

During the first week (the elimination phase), a significant reduction in hyperactive behavior was observed. In the challenge phase, significantly greater increases in hyperactive behavior were seen with the food additives than with the placebo. These differences were identified by parents’ ratings but not by objective testing in the clinic. The magnitude of the benefit obtained by avoiding food additives was similar to that for clonidine in the treatment of children with ADHD, but was less than that seen with methylphenidate (Ritalin). The effect of the food additives on hyperactive behavior was not influenced by the presence or absence of hyperactivity at baseline, nor by the presence or absence of atopy, as determined by skin prick tests.

Comment: There have been many studies assessing the effects of food additives. While many of these studies demonstrated an adverse effect of food additives, others found little or no effect. Some of the negative studies suffered from design flaws. For example, one study compared the effect of a chocolate cookie containing artificial food dyes to that of a “placebo” chocolate cookie. Some children in that study may have experienced an adverse reaction to the chocolate “placebo,” which would have masked any effect of the food dyes. In other studies, children underwent challenges with food dyes after they had been on an additive-free diet for at least three months. Tolerance to allergens tends to increase the longer a person avoids them, so the children in those studies may have lost their sensitivity to the additives by the time they were challenged with them. Moreover, most of the previous studies investigated only artificial colors, not sodium benzoate, which appears to be an important symptom-evoking substance.

The present study demonstrates that commonly used food additives contribute to hyperactive behavior in children, and that the effect of these additives is not influenced by prior levels of hyperactivity or by atopy. An earlier study (Lancet 1985;1:540-545) also showed that food dyes and benzoate preservatives are frequent triggers of hyperactive behavior; in that study, however, common foods such as dairy products, chocolate, grapes, wheat, oranges, and eggs also played a significant role.

Considering that more than 1 in 20 children in some areas of the country is on Ritalin or other drugs for hyperactivity, closer attention should be given to the dietary factors that are causing problems for these children.

Bateman B, et al. The effects of a double blind, placebo controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children.

Azelaic acid for rosacea

Two hundred fifty-one patients with papulopustular rosacea with persistent erythema and telangiectasia were randomly assigned to receive, in double-blind fashion, a 15% azelaic acid gel or 0.75% metronidazole gel. The respective treatments were applied topically twice a day for 15 weeks. Azelaic acid gel was more effective than metronidazole gel, as demonstrated by a greater reduction in the mean number of lesions (-12.9 vs. -10.7; p = 0.003) and by a greater mean percent decrease in inflammatory lesions (-72.7% vs. -55.8%; p < 0.001). An improvement in the severity of erythema was seen in 56% of patients receiving azelaic acid and in 42% of those receiving metronidazole (p = 0.02). Neither treatment had an effect on telangiectasia. Both the investigator’s global assessment (p = 0.02) and overall assessment of improvement (p = 0.005) showed a significant advantage for azelaic acid gel. No serious adverse events were reported, although minor skin irritation occurred in
89% and 96% of the patients in the azelaic acid and metronidazole groups, respectively.

Comment: Azelaic acid is a nontoxic 9-carbon dicarboxylic acid that has been shown to be effective as a topical treatment for acne vulgaris, rosacea, and some hyperpigmentary disorders. The results of the present study demonstrate that azelaic acid is at least as effective as, and probably more effective than, standard therapy (topical metronidazole) as a treatment for rosacea. Azelaic acid for topical application is available both by prescription and over the counter; the prescription version costs substantially more than the OTC preparations. While it is generally well tolerated, azelaic acid tends to cause minor skin irritation. It has been said that topical application of azelaic acid can, on rare occasions, cause a loss of pigmentation of normal skin, but some researchers have disputed that statement.


Maternal smoking, iodine, and infant brain development
One hundred-forty healthy pregnant women hospitalized for delivery and their newborn infants were studied. The presence of cotinine in urine and serum was used to classify mothers as smokers (n = 50) or nonsmokers (n = 90). Smoking and nonsmoking mothers had identical urinary iodine levels on day five after delivery, but smoking was associated with reduced iodine content in breast milk (smokers, 26.0 mcg/L; nonsmokers, 53.8 mcg/L; p < 0.001) and in the infants' urine (smokers, 33.3 mcg/L; nonsmokers, 50.4 mcg/L; p = 0.005). In smokers, iodine transfer into breast milk correlated negatively with urinary cotinine concentration. Smoking mothers had significantly higher serum levels of thiocyanate, which may competitively inhibit iodide transport into breast milk.

Comment: Iodine deficiency during the fetal stage or the first years of life may lead to hypothyroidism, resulting in impaired brain development. During the period of breastfeeding, thyroid function of the infant depends on the presence of adequate amounts of iodine in maternal milk. In addition to any other adverse effects smoking may have on infant development, the results of the present study suggest that smoking while breastfeeding increases the risk of iodine deficiency-induced brain damage in the child. Women who breastfeed should not smoke, but if they do, an iodine supplement should be considered.


Soy-derived phosphatidylserine ineffective
One hundred-twenty men and women (mean age, 65 years) with age-associated memory impairment were randomly assigned to receive, in double-blind fashion, either 1) placebo, 2) 300 mg/day of soy-derived phosphatidylserine, or 3) 600 mg/day of soy-derived phosphatidylserine for 12 weeks. Assessments were carried out at baseline, after 6 and 12 weeks of treatment, and 3 weeks after treatment was discontinued. Tests of learning and memory, choice reaction time, and planning and attention functions were administered at each assessment. Delayed recall and recognition of a previously learned word list were the primary outcome measures. No significant differences were found between...

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