

Clinical News

Serum Estradiol and Cognitive Function With Aging

Findings from a recently published study (Yaffe K, Lui L-Y, Grady D, et al. Cognitive decline in women in relation to non-protein-bound estradiol concentrations. *Lancet* 2000;356:708-12) suggest a sparing effect of estrogen replacement therapy on cognitive loss with aging in women. Investigators measured total and free testosterone, and free and bioavailable estradiol concentrations in 425 women age 65 or older, who were enrolled in the Study of Osteoporotic Fractures. Cognitive function was tested with a modified Mini Mental Status Examination (mMMSE) at baseline and at 6 years.

Cognitive function scores were similar for all tertiles of free estradiol at baseline. After 6 years, cognitive impairment (decrease of 3 or more points on the mMMSE) was observed in 5 of the 94 women in the highest tertile for free estradiol, and in 17 of the 106 women in the lowest tertile. Similar results were obtained for bioavailable estradiol levels. The investigators reported finding no association between the risk of cognitive impairment and serum testosterone levels. Repeat analyses conducted after excluding the 61 women taking estrogen at the time the blood samples were drawn did not substantially change the results.

Multiple Factors Contribute to Menopause-Related Symptoms

Findings from a recently published study (Gold EB, Sternfeld B, Kelsey JL, et al. Relation of demographic and lifestyle factors to symptoms in a multi-racial/ethnic population of women 40-55 years of age. *Am J Epidemiol* 2000;152:463-73) suggest that the incidence and severity of menopause-related symptoms in the 40- to 55-year-old age group are affected by a combination of factors, including lifestyle, men-



strual status, race/ethnicity and socioeconomic status.

The investigators analyzed data from the ongoing Study of Women's Health Across the Nation (SWAN). Among the findings reported were the following:

Hot flashes were the most commonly reported menopause-related symptoms. Most symptoms were reported less frequently by Japanese and Chinese women than by Caucasian women. African-American women reported hot flashes and vaginal dryness more often than Caucasians, while Caucasian women reported urine leakage and difficulty sleeping more often than did African-Americans. Hispanic women were the most likely to report urine leakage, vaginal dryness, heart pounding and forgetfulness; these symptoms were found to be affected by factors unrelated to menopause, including body mass index, ability to pay for health care, smoking and physical activity.

Product News

Once-Weekly Alendronate Approved

The FDA has approved two new strengths of Merck & Co., Inc.'s alendronate (Fosamax) for once-weekly dosing; the 70-mg tablet is approved for osteoporosis treatment and the 35-mg tablet for osteoporosis prevention. Merck notes that the FDA approval makes alendronate "the first and only oral medication approved for the

treatment and prevention of postmenopausal osteoporosis in a once-weekly dosing regimen."

In the primary analysis of 770 postmenopausal women with osteoporosis who completed a year-long, double-blind, multicenter study, the mean increases from baseline in lumbar spine bone mineral density (BMD) were therapeutically equivalent after 1 year, with a 5.1% increase in the once-weekly (70 mg) group and a 5.4% increase in the once-daily (10 mg) group. Hip and total body BMD increases were also similar in the two treatment groups. (All participants received calcium and vitamin D supplements with treatment.)

The safety and tolerability profiles of the 70-mg and 10-mg regimens were similar, with no statistically significant differences between the groups in adverse upper gastrointestinal (GI) events leading to discontinuation with the study. No significant difference was found between the once-weekly and once-daily treated groups with respect to the incidence of adverse upper GI events on the day of dosing.

Further information is available at www.fosamax.com.

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