SSRI Escitalopram Rapidly Eases Hot Flashes

BY MARY ANN MOON

THE SELECTIVE SEROTONIN REUPTAKE INHIBITOR ESCITALOPRAM RAPIDLY REDUCES THE FREQUENCY AND SEVERITY OF HOT FLASHES IN MENOPAUSAL WOMEN, according to a report.

In a multicenter, randomized clinical trial comparing 10 or 20 mg per day of escitalopram with placebo, the drug’s benefit “was only modestly less than that reported in a meta-analysis of estrogen therapy,” said Ellen W. Freeman, Ph.D., of the department of obstetrics and gynecology at the University of Pennsylvania, Philadelphia, and her associates.

“Our findings suggest that among healthy women, 10 to 20 mg/d of escitalopram provides a nonhormonal, off-label option that is effective and well tolerated in the management of menopausal hot flashes,” they said.

The double-blind trial involved 205 women who were in the menopausal transition, were postmenopausal, or had undergone hysterectomy with or without ovariectomy. Ninety-five of the women self-reported as African American, 102 as white, and 8 as other. These subjects recorded at least 28 hot flashes or night sweats per week in a daily diary for 3 weeks before enrollment, or hot flashes or night sweats per week in a daily diary showed that every week for the duration of the study, the frequency of hot flashes was significantly decreased in the escitalopram group compared with the placebo group, Dr. Freeman and her colleagues said (JAMA 2010;305:267-74). Escitalopram also diminished the severity of hot flashes by 24%, compared with a decrease of 14% with placebo. Seventy percent of women taking the active drug reported satisfaction with

INDICATION

Prolia® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral, and hip fractures.

IMPORTANT SAFETY INFORMATION

Hypocalcemia: Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®. Hypocalcemia may worsen, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, clinical monitoring of calcium and mineral levels is highly recommended. Adequately supplement all patients with calcium and vitamin D.

Serious Infections: In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®. Endocarditis was also reported more frequently in Prolia®-treated subjects. The incidence of opportunistic infections was balanced and the overall incidence of infections was similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis. Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate in the Prolia® group compared to the placebo group. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia®. An oral exam should

VITALS

Data Source: An 8-week multicenter, randomized, double-blind clinical trial involving 205 women.

Disclosures: This study was supported by the National Institute of Aging, the Eunice Kennedy Shriver National Institute of Child Health and Development, the National Center for Complementary and Alternative Medicine, the Office of Research on Women’s Health, the Indiana Clinical and Translational Sciences Institute, and the National Center for Research Resources. Forest Laboratories provided the escitalopram and placebo pills. Dr. Freeman reported ties to Forest Laboratories, Wyeth, Pfizer, Xanodyne Pharmaceuticals, Pherin Pharmaceuticals, and Bayer Health Care, and her associates also reported ties to numerous drug companies.

Major Finding: Escitalopram decreased the frequency of hot flashes by nearly half, from 9.78 per day to 5.26 per day.

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Prolia® targets and binds to RANK Ligand, inhibiting osteoclast formation, function, and survival1

Prolia® significantly reduced fracture risk at key sites in a phase 3 trial*1,2

 Suppressing Bone Turnover: Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effectiveness of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions: The most common adverse reactions (> 5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia®. The overall incidence of new malignancies was 4.3% in the placebo and 4.8% in the Prolia® groups. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

For more information, visit www.ProliaHCP.com


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