Reported Sexual Activity and Orgasm Frequency in a Comparative Study of the SERMs Lasofoxifene and Raloxifene in an Osteoporosis Prevention Study

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Introduction
Selective estrogen receptor modulators (SERMs) used for osteoporosis have differential tissue selectivity and may impact various aspects of menopausal health uniquely, including sexual health. Menopausal women often struggle concurrently with both bone health and sexual function issues, and sexual function may remain important to women throughout their lifespans. In one study of 90,000 post-menopausal women 79 years of age, 15.5% reported that they had been sexually active with a partner in the past year.2 A review of published literature revealed 35% of married women 70–79 years of age report that they still have sexual intercourse.2

Demographics, Baseline Characteristics
The study group consisted of women 57 to 74 years of age. The mean age across treatment groups ranged from 59 to 65 years. The majority of participants were white (82.2%). The women were 8 to 14 years post-menopause. The T-scores ranged from -0.32 to 1.79 among the groups. The lasofoxifene 0.5 mg dose was associated with an increase in androgen maturation index (reflecting maturation and androgen reactivity in the vagina) compared to placebo (0.5 mg lasofoxifene vs. 0.3 mg placebo, p = 0.01). This finding was not observed with 1 mg lasofoxifene.

Study Design
A 3-year randomized, double-blind, placebo- and active-treatment controlled study in which subjects were randomized to receive one of the four treatments (see Figure 1): placebo, lasofoxifene 0.25 mg, lasofoxifene 0.5 mg, or raloxifene 60 mg.

Study Population
A total of 618 postmenopausal women were enrolled into the study: 83 women were randomized to lasofoxifene 0.25 mg, 83 to lasofoxifene 1.0 mg, 82 to raloxifene 60 mg, and 83 to placebo.

Results
LUMBAR SPINE BMD RESULTS: Month 12 was the primary statistical analysis period. The mean percentage change from baseline for the lasofoxifene groups was superior to those for raloxifene or placebo. This held true at all time points. At Month 36, the mean percent change in Lumbar Spine BMD for lasofoxifene was significantly higher compared to both placebo and raloxifene (p < 0.001).

VAGINAL HEALTH RESULTS: While not reaching statistical significance likely due to the small sample size, the mean percent change in Lumbar Spine BMD was greater in the lasofoxifene groups than in the placebo groups. The lasofoxifene 0.5 mg dose was associated with a trend toward improvement of vaginal health in the 1 mg lasofoxifene group compared to placebo (p = 0.06).

Additional research is warranted to further characterize the impact of lasofoxifene and other SERMs on sexual function in various populations of postmenopausal women.

Conclusion
Lasofoxifene increased sexual activity and orgasm in postmenopausal women 50 to 74 years of age. A placebo-controlled study in which subjects were randomized to receive one of the four treatments. The results are suggestive that lasofoxifene administered for 4.5 years was effective in preventing bone loss in postmenopausal women with a similar safety profile to raloxifene, and may have potential beneficial sexual effects. Raloxifene, the only SERM that is approved in the U.S. for osteoporosis prevention, had no significant effect on sexual function.

Reference

Figure 1. Study design

Figure 2. Vaginal Health Questionnaire, sexual function portion

Figure 3. Lumbar spine BMD results from Month 6 and Month 12 surveys

Figure 4. Sexual function results from Month 6 and Month 12 surveys

Figure 5. Orgasm results from Month 6 and Month 12 surveys

Figure 6. Sexual activity results from Month 6 and Month 12 surveys

Statistical Analysis
Sexual function was assessed by means of the Vaginal Health Questionnaire, sexual function portion administered at Baseline, Month 6, Month 36, and Month 72. The questionnaire included five subscales: sexual dissatisfaction, dyspareunia, dryness, orgasmic function, and sexual activity. The mean percent change from baseline was greater in the lasofoxifene groups compared to placebo at all time points. At Month 24, the mean percent change in Lumbar Spine BMD for lasofoxifene was significantly higher compared to both placebo and raloxifene (p < 0.001).

Figure 3. Sexual activity results from Month 6 and Month 12 surveys

Figure 4. Sexual function results from Month 6 and Month 12 surveys

Figure 5. Orgasm results from Month 6 and Month 12 surveys

Figure 6. Sexual activity results from Month 6 and Month 12 surveys

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