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SERMs in Clinical Practice : New Options for the Management of Postmenopausal Health Risks

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Following menopause, women face the difficult decision of whether to take long-term hormone replacement therapy to attain clear health benefits such as preventing heart disease and osteoporosis, but with potential added risks for uterine and breast cancer. Raloxifene, a selective estrogen receptor modulator (SERM) molecule designed to provide a new choice for women to maintain good health throughout their postmenopausal life.

In phase III clinical trials, raloxifene prevented bone loss and significantly increased bone mineral density in postmenopausal women 2 to 3 per cent more than calcium-supplemented placebo at all skeletal sites (hip, spine and total body) after two years of treatment. Raloxifene also significantly lowered total cholesterol (6 to 7%), LDL-cholesterol (11 to 12%), Lp (a) (4%), and fibrinogen (12 to 13%), and raised HDL-2 cholesterol (15 to 16%) without raising triglycerides or total HDL cholesterol after six months of treatment. In the uterus, raloxifene did not induce bleeding or spotting, nor increase endometrial proliferation (assessed by both transvaginal ultrasonography and conventional biopsy) and was indistinguishable from placebo in all trials. Unlike estrogen, raloxifene did not stimulate breast tissue in postmenopausal women. Raloxifene was similar to placebo with regard to breast swelling, tenderness, and pain, and did not increase the risk for breast cancer. Raloxifene is similar to estrogen regarding an increased risk for thromboembolic events, especially in patients with well-established risk factors for this low-frequency disease. The most commonly observed side effect of raloxifene was hot flashes, occurring in 24% of raloxifene patients *versus* 18% of placebo patients. However, the onset, severity, duration, and drop-out rate for this mild side effect were identical for both placebo and raloxifene. In conclusion, raloxifene prevents bone loss, lowers cholesterol, and is safe in the uterus and breast, thus providing a single solution for the multiple long-term health concerns of millions of postmenopausal women worldwide.