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Effects of 8 years of treatment with tibolone 2.5 mg daily on postmenopausal bone loss.

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The objective of this study was to assess the long-term effects of tibolone 2.5 mg daily (Livial; Organon) on bone mineral density in recently postmenopausal women. An 8-year, open, nonrandomized, prospective study was designed to compare the effects of tibolone 2.5 mg daily (n = 59) with an untreated control group (n = 51). The subjects of this study were 110 recently postmenopausal women (6-36 months since last menstrual period). The main outcome measures were bone mineral density of the spine and femur, measured by dual-energy X-ray absorptiometry, and assessment of biochemical markers of bone metabolism. After 8 years of tibolone use, the mean (\pm SEM) increase in bone mineral density compared with baseline was 4.1% \pm 0.8% ($p < 0.0001$) in the spine and 4.6% \pm 1.8% ($p = 0.015$) in the femoral neck. Over the same period, bone mineral density in the control group decreased in the spine by -7.5% \pm 1.1%, ($p < 0.0001$) and in the femur by -6.7% \pm 1.2% ($p < 0.0001$). The bone resorption marker, calcium/creatinine ratio, decreased in the tibolone group but not in the control group. Serum bone formation markers decreased (alkaline phosphatase) or stayed approximately the same (osteocalcin) in the tibolone group. Adherence was high, with 58% (34 of 59) of the tibolone group continuing treatment for 8 years. We conclude that tibolone 2.5 mg daily prevents bone loss in the lumbar spine and femoral neck over 8 years and adherence to treatment is high. The greater bone density compared with untreated women would be expected to reduce the risk of bone fractures.

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