

P301. Effect of isolated vitamin D supplementation on the bone turnover markers in younger postmenopausal women: randomized, double-blind, placebo controlled trial.

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Context: Most randomized and controlled studies that evaluated the effect of vitamin D (VD) supplementation on bone mass included the association with calcium, a fact that makes it difficult to identify the effects specifically attributable to VD.

Objective: to evaluate the effect of supplementation of VD alone on the bone turnover markers in postmenopausal women.

Methods: This is a double-blind, placebo-controlled trial. Serum levels of total calcium, parathormone(PTH), alkaline phosphatase(AP) and 24h-urine calcium were determined. Serum C-terminal telopeptide of type I collagen(s-CTX) and procollagen type 1 amino-terminal propeptide(P1NP) as markers of bone resorption and formation, respectively, were measured by immunoassay. Plasma 25(OH)D concentrations were measured by HPLC. Intention-to-treat analysis was performed using t-test, Gamma distribution, ANOVA and Tukey test.

Participants: Women aged 50-65years with amenorrhea \geq 12months and normal bone mineral density, were included. Those with previous use of VD or of drugs that could interfere with bone metabolism (bisphosphonate, estrogen, testosterone, corticosteroids, tamoxifen, calcitonin); primary hyperparathyroidism or hypercalciuria; renal failure; liver disorders were excluded. **Interventions:**The intervention time was 9months, with assessments at baseline and endpoint. A total of 160 postmenopausal women randomized into two groups: VD group, vitamin D3 supplementation 1,000IU/day/orally(n=80) or placebo group(n=80).

Main Outcome Measures: Effect of isolated VD supplementation on bone turnover markers.

Results: After 9 months, 25(OH)D concentrations increased from 15.0 ± 7.5 to 27.5 ± 10.4 ng/ml in VD group and decreased from 16.9 ± 6.7 to 13.8 ± 6.0 ng/ml in placebo group($p < .001$). There was a decrease (-21.3%) of PTH values in VD group with a significant difference between groups at the end of the study($p < .001$). No significant differences were observed in the other laboratory parameters (total calcium, AP, and calciuria) in either group($p > 0.05$). Comparison of bone turnover markers showed a significant reduction in s-CTX(-24.2%, $p < .0001$) and P1NP(-13.4%, $p = 0.003$) levels in VD group. No significant variations in bone turnover markers were observed in the placebo group.

Conclusion: In postmenopausal women with VD deficiency, isolated supplementation with 1,000IU of vitamin D3 for 9months associated with a reduction in bone turnover markers.

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