

ORIGINAL RESEARCH COMMUNICATION

Safety of vitamin D₃ in adults with multiple sclerosis^{1, 2, 3}

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Background: Vitamin D₃ may have therapeutic potential in several diseases, including multiple sclerosis. High doses of vitamin D₃ may be required for therapeutic efficacy, and yet tolerability—in the present context, defined as the serum concentration of 25-hydroxyvitamin D [25(OH)D] that does not cause hypercalcemia—remains poorly characterized.

Objective: The objective of the study was to characterize the calcemic response to specific serum 25(OH)D concentrations.

Design: In a 28-wk protocol, 12 patients in an active phase of multiple sclerosis were given 1200 mg elemental Ca/d along with progressively increasing doses of vitamin D₃: from 700 to 7000 µg/wk (from 28 000 to 280 000 IU/wk).

Results: Mean (± SD) serum concentrations of 25(OH)D initially were 78 ± 35 nmol/L and rose to 386 ± 157 nmol/L (*P* < 0.001). Serum calcium concentrations and the urinary ratio of calcium to creatinine neither increased in mean values nor exceeded reference values for any participant (2.1–2.6 mmol/L and <1.0, respectively). Liver enzymes, serum creatinine, electrolytes, serum protein, and parathyroid hormone did not change according to Bonferroni repeated-measures statistics, although parathyroid hormone did decline significantly according to the paired *t* test. Disease progression and activity were not affected, but the number of gadolinium-enhancing lesions per patient (assessed with a nuclear magnetic brain scan) decreased from the initial mean of 1.75 to the end-of-study mean of 0.83 (*P* = 0.03).

Conclusions: Patients' serum 25(OH)D concentrations reached twice the top of the physiologic range without eliciting hypercalcemia or hypercalciuria. The data support the feasibility of pharmacologic doses of vitamin D₃ for clinical research, and they provide objective evidence that vitamin D intake beyond the current upper limit is safe by a large margin.

Key Words: Vitamin D • safety • 25-hydroxyvitamin D • 25(OH)D • multiple sclerosis

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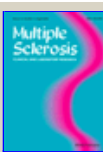
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