Efficacy of Vitamin D3 Supplementation in Elevating Circulating 25(OH)D Concentration in Individuals with Chronic Spinal Cord Injury (VitD-SCI): Evidence from a Randomized, Double-Blind, Placebo-Controlled Trial

Project: 567

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Introduction:

Individuals with spinal cord injury (SCI) are at increased risk for insufficient 25(OH)D levels, a serum 25(OH)D level \leq 75 nmol/L. Vitamin D is important for secondary health conditions in SCI such as bone density, pressure injuries, and respiratory infections. Vitamin D supplementation can correct insufficient 25(OH)D levels, but there is a lack of evidence regarding the optimal dose and duration of vitamin D supplementation for long- term management of vitamin D status in the context of SCI. We evaluated the efficacy of medium-dose and high- dose vitamin D3 supplementation in raising 25(OH)D levels above the sufficiency threshold of 75 nmol/L in individuals with SCI.

Methods:

This was a randomized, double-blind, placebo-controlled trial. Individuals living with SCI for at least three years (chronic SCI) and having insufficient 25(OH)D levels at the first study visit (baseline) were included. Participants were randomly assigned to the placebo group, medium-dose intervention (24'000 IU D3/4 weeks), or high-dose intervention (24'000 IU D3/2 weeks) for 12 months. Serum 25(OH)D levels were assessed every three months. The tolerability and safety of vitamin D3 supplementation were also evaluated. Forty-two participants were included in the analyses, consisting of seven females, with a mean (standard deviation) age of 48 (10) years, 27 with a complete lesion, and 32 with paraplegia.

Results:

All participants tolerated the vitamin D3 supplementation well and 25(OH)D levels remained well below toxic ranges. At baseline, there was no difference in 25(OH)D levels between the three groups (placebo 45 (19) nmol/L; medium dose 41 (14) nmol/L; high dose 43 (15) nmol/L; p = 0.8). At 12 months, a dose-response effect on 25(OH)D levels was observed (placebo 47 (19) nmol/L; medium dose 61 (19) nmol/L; high dose 74 (14) nmol/L; p = 0.001). In the high dose group, 46% of the participants reached sufficient levels. Participants having an incomplete lesion, higher baseline 25(OH)D levels, lower body mass index, higher sun exposure scores, or those receiving supplementation during summer, autumn, or winter were more likely to reach sufficient 25(OH)D levels.

Conclusions:

Vitamin D3 supplementation effectively increased 25(OH)D concentration to sufficient levels in participants with specific characteristics. However, 25(OH)D levels remained insufficient, also in participants receiving 48'000 IU per month. Higher supplementation doses are needed to successfully increase 25(OH)D levels in all individuals with chronic SCI