## Supplementing Vitamin D in Unselected Elderly People through a Yearly Bolus to Reduce the Risk of Fractures: Is this Practice Effective?

## Messori A<sup>1</sup> University of Firenze, Italy

## Abstract

A number of studies have investigated the effectiveness of vitamin D given as an annual dose to unselected elderly people to reduce the risk of fractures, but the results are conflicting. Since new clinical studies have recently been made available, we carried out an updated analysis on this issue.

Our study was aimed at evaluating the effectiveness of this annual dose of vitamin D. Patients were unselected elderly people. Fractures were the endpoint of our analysis. The clinical material was represented by observational and randomized studies that included a patient group given the vitamin D annual bolus and a control group given no such supplementation. Our meta-analysis was based on the randomeffect model of Der Simonian and Laird. Relative Risk (RR) was our outcome measure.

After a standard PubMed search, we identified 5 clinical studies that met the criteria of our analysis (total number of patients: 115,220). The fracture rates were pooled across the studies. The meta-analytical RR was estimated to be 0.81 (95% confidence interval, 0.59 to 1.13). There was a high degree of heterogeneity in this clinical material.Our results indicate that the supplementation of vitamin D based on an annual mega-dose does not reduce the incidence of fractures in unselected elderly people.The effectiveness of vitamin D supplementation in unselected elderly people has been evaluated by numerous clinical studies aimed at improving the clinical outcomes of bone health (e.g. fractures and falls). One important practical criterion to distinguish these supplementation studies from one another is the schedule adopted for the administration of vitamin D.

The great majority of these clinical studies employed a daily administration of vitamin D (or, anyhow, a regular schedule of repeated administrations). According to the systematic review of Newberry et al., and the DIPART pooled analysis of 7 randomized studies, the effectiveness of the daily supplementation appears to be controversial. For example, the DIPART analysis indicated that vitamin D given alone in doses of 10-20 microgram was not effective in preventing fractures; by contrast, calcium and vitamin D given together were shown to reduce hip fractures and total fractures, and probably vertebral fractures. Conflicting results were shown by other clinical

Messori A

University of Firenze, Italy E-mail: luigi.messori@unifi.it

studies as well. So, on the one hand, no firm conclusion can currently be made on the effectiveness of this intervention. More importantly, since the results reported thus far in the literature for the regular regimen of repeated doses are conflicting, it seems very unlikely that this therapeutic controversy will be settled in the near future on the basis of new analyses of published data and/or new data from original studies.

A quite small subset of the clinical studies focused on vitamin D supplementation employed a single mega-dose of vitamin D (single annual bolus scheme) that has generally been administered to unselected elderly patients in conjunction with the influenza vaccination. Also the effectiveness of the annual winter schedule is controversial, but one important advantage in exploring if this dosing schedule works is that the available studies are fewer than in the case of daily administration; therefore this permits an attempt to clarify this question through a new analysis.

The present study was carried out as an original meta-analysis aimed at evaluating if the annual bolus scheme can reduce the incidence of fractures in unselected elderly people in comparison with patients not given any form of vitamin D supplementation.

Keywords: Osteoporosis; Fractures; Vitamin D; Annual bolus; Elderly people