Assessment of serum 25-Hydroxyvitamin D concentrations in post-menopausal osteoporotic women: a retrospective study to evaluate long-term treatment with vitamin D_3

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1 Introduction

- Circulating concentrations of 25-hydroxyvitamin D (25(OH)D) are considered the best indicator of vitamin D status [1].
- However, the optimal concentration of 25(OH)D required for maintenance of skeletal integrity has been a matter of debate.
- Another question yet unanswered is how much vitamin D we need to produce or digest in order to achieve an optimal serum 25(OH)D. The clinical evidence is far from clear [2].
- The aim of this study was to evaluate whether daily treatment with 400 IU vitamin D_3 was sufficient to maintain 25(OH)D concentrations above 60 nmol/L over a three-year period.
- In addition, the study aimed to clarify if any differences existed in serum 25(OH)D between pre-supplemented women and women who already had serum 25(OH)D above 60 nmol/L at screening.

2 Methods

A retrospective single-center study was designed to evaluate 25(OH)D serum concentrations in 251 menopausal women over a three-year period using data collected from a randomized, double-blind, placebo-controlled osteoporosis study.

A comprehensive patient file review was performed to collect patient characteristics and laboratory results. Furthermore, 25(OH)D baseline concentrations were used to classify pre-supplemented women (Group 1) and non-pre-supplemented women (Group 2).

Stored serum samples obtained 6, 12, 24 and 36 months after screening were identified and collected for both groups.

Table 1. Baseline Characteristics of Participants[1]

Characteristic	All Women	Group 1[2]	Group 2[2]	*p*
Participants, n[3]	251 (100%)	79 (31.5%)	172 (68.5%)	-
Age (year)	68.4 ± 6.2	69.2 ± 4.5	68.0 ± 6.9	0.36
BMI (kg/m_2)	25.2 ± 3.8	26.6 ± 4.2	24.6 ± 3.5	< 0.001*
Smoking, yes, n[3]	32 (12.8%)	9 (11.4%)	23 (13.4%)	0.66
Physical Activity, yes, n[3]	176 (70.7%)	54 (69.2%)	122 (71.3%)	0.80
≥ 1 Fracture(s), n[3]	164 (65.3%)	49 (62%)	115 (66,9%)	0.46
≥ 1 Osteoporotic Fracture(s), n[3]	107 (42.6%)	27 (34.2%)	80 (46.5%)	0.07
Triglycerides (mmol/L)	1.14 ± 0.50	1.40 ± 0.62	1.02 ± 0.42	< 0.001*
Total Cholesterol (mmol/L)	5.74 ± 1.03	5.86 ± 0.10	6.69 ± 1.05	0.11
Creatinine (mmol/L)	0.07 ± 0.01	0.07 ± 0.01	0.07 ± 0.01	0.82

Table 1. [1]Except where indicated, data are presented as the mean ± SD with the Mann-Whitney Test or χ^2-test performed where appropriate. [2]Group 1; pre-supplemented women. Group 2; non-pre-supplemented women. [3]Data are listed as n, number of participants with n in percentage of total n in parentheses.

Serum samples stored on site at -20 ° C from the 251 women who completed the study were analyzed for 25(OH)D, parathyroid hormone (PTH), and phosphate. RM-ANOVA was applied to evaluate treatment effect over time.

3 Results

Table 2 presents the results of long-term treatment effects of vitamin D_3 analyzed by RM-ANOVA. The mean concentration of 25(OH)D showed a significant increasing trend throughout the three-year study period and peaked at month 36 at a mean concentration of 103.5 ± 23.0 nmol/L (p<0.001). The average increase in 25(OH)D concentrations over 36 months was 24 nmol/L.

Table 2. Effects of Daily Treatment with 400 IU vitamin D_3 over Three Years

Variable	Baseline	6 months	12 months	24 months	36 months	*p*
25(OH)D (nmol/L)	79.5 ± 17.3	93.0 ± 19.3	99.8 ± 21.8	99.4 ± 22.0	103.5 ± 23.0	< 0.001*
Calcium (mmol/L)	2.33 ± 0.09	2.31 ± 0.10	2.33 ± 0.10	2.33 ± 0.08	2.36 ± 0.09	< 0.001*
PTH (pg/mL)	43.9 ± 12.0	44.7 ± 17.3	44.7 ± 15.5	47.0 ± 16.6	44.2 ± 16.1	0.88
Phosphate (nmol/L)	-	1.1 ± 0.2	1.2 ± 0.6	1.1 ± 0.1	1.1 ± 0.1	0.12
Alk Phos (U/L)	182 ± 59	163 ± 42	159 ± 44	162 ± 45	165 ± 44	< 0.001*

Table 2. All values are mean ± standard variation. *25(OH)D;* 25-hydroxyvitamin D, *PTH;* parathyroid hormone, *Alk Phos;* alkaline phosphatase.

4 Results (cont.)

Pre-supplemented women had a significantly lower mean 25(OH)D concentration compared to non-pre-supplemented women (p<0.001) as depicted in **Fig. 1**. Season significantly interacted with 25(OH)D concentrations over time (p<0.001) and concentrations measured during winter time were significant elevated compared to the remaining seasons (p<0.05, **Fig. 2**). 25(OH)D concentrations were dependent of BMI (p<0.05).

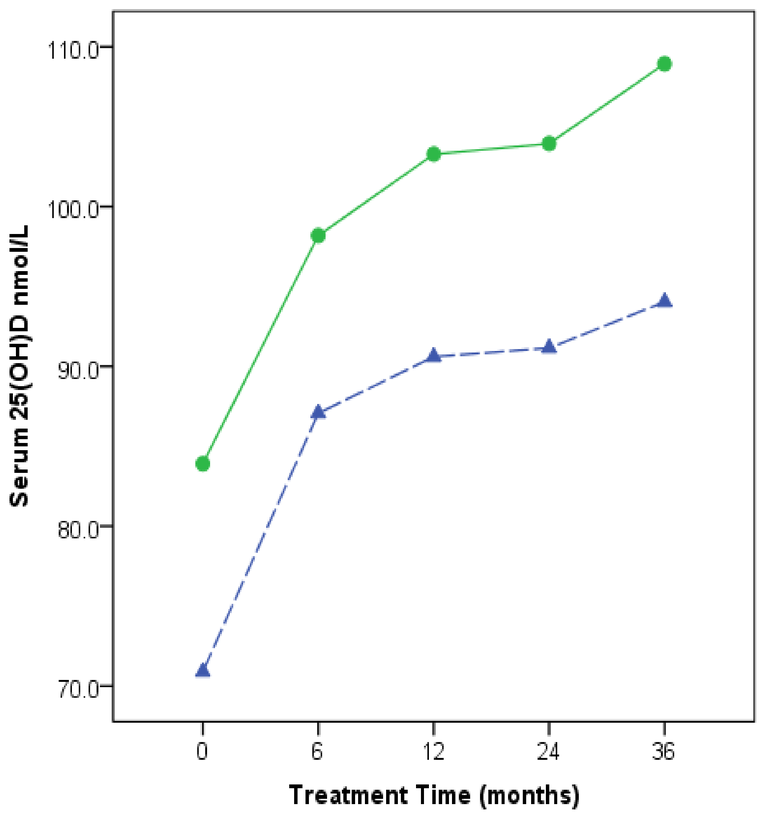

Fig. 1. Serum 25(OH)D in nmol/L for pre-supplemented women (—▲—) and women with adequate serum 25(OH)D above 60 nmol/L prior to baseline (screening) (–●–).

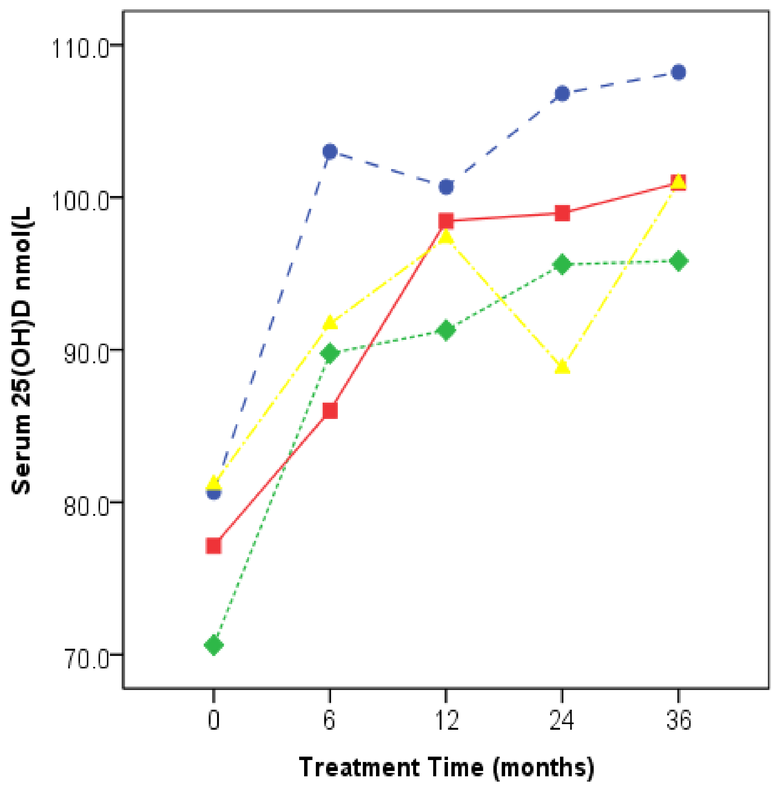

Fig. 2. Serum 25(OH)D in blood samples obtained during winter (---●---), spring (···◆···), summer (—■—) and autumn (– –▲– –) during the three-year period. Note that serum samples taken at month 6 were obtained during the opposite season compared to the yearly samples.

5 Conclusion

In summary, our retrospective study demonstrated that after achieving a serum 25(OH)D of 60 nmol/L, daily treatment with 400 IU vitamin D3 is safe and preserves 25(OH)D serum concentrations above the threshold defined.

6 References & Acknowledgements

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- [2] Bischoff-Ferrari, H.A., et al., Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes. Am J Clin Nutr, 2006. 84(1): p. 18-28.

Conflict of Interest Camilla S. Andersen: affiliated to Aalborg University in Denmark to conduct clinical research and employed by Center for Clinical & Basic Research (CCBR). Peter Vestergaard and Parisa Gazerani: affiliated to Aalborg University in Denmark to conduct clinical research for the Faculty of Medicine. Hans C. Hoeck: employed by CCBR, a private re-search company engaged in contract research with various pharmaceutical and biotech companies.

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