NO SEVERE HYPERCALCEMIA DURING A HIGH-DOSE VITAMIN D_3 INTERVENTION IN INFANTS

Valkama S, Enlund-Cerullo M, Holmlund-Suila E, Rosendahl J, Hauta-alus H, Helve O, Hytinantti T, Viljakainen H, Andersson S, Mäkitie O.

Children's Hospital, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

Correspondence: saara.valkama@hus.fi

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BACKGROUND

- **The IOM recommendation for adequate daily vitamin D intake is 10 µg.**
- **Vitamin D toxicity is defined as serum 25-hydroxyvitamin D (25-OHD) >250 nmol/L with hypercalcemia, hypercalciuria and suppressed parathormone (PTH).**
- **The effects of higher vitamin D doses on calcium metabolism in infants are incompletely known.**

OBJECTIVE

- **To examine the incidence of hypercalcemia during the first 12 months postnatally as a part of our double-blinded randomized vitamin D intervention in infants trial (VIDI).**

METHODS

- **987 healthy infants were randomized to receive vitamin D_3 supplementation of 10 µg or 30 µg per day from age 2 weeks to 24 months.**
- **Ionized calcium concentration (Ca-ion) was analyzed at 6 and 12 months and 25-OHD and intact PTH (iPTH) at 12 months as a part of the safety protocol.**
- **Severe hypercalcemia was defined as Ca-ion ≥ 1.53 mmol/L, i.e. exceeding the reference range (1.16-1.39 mmol/L) by 10%.**
- **Mild hypercalcemia was defined as Ca-ion 1.40-1.52 mmol/L.**

RESULTS

- **No cases of severe hypercalcemia occurred.**
- **At 6 and 12 months, mild hypercalcemia was present in 26% and 2% of the infants (TABLE 2). At 12 months, iPTH was below the reference range (11.5-78.4 pg/mL) in 11%.**
- **At 12 months, 25-OHD and Ca-ion correlated positively (r= 0.187, p<0.001).**
- **25-OHD did not differ between infants with normocalcemia or mild hypercalcemia (median 96 vs. 106 nmol/L, p=0.127) (FIGURE 1).**

CONCLUSIONS

- **Vitamin D_3 supplementation of 10 µg or 30 µg per day did not cause severe hypercalcemia in infants during the first year of life.**
- **Mild hypercalcemia was more prevalent at 6 months than at 12 months, but did not associate with 25-OHD concentration.**

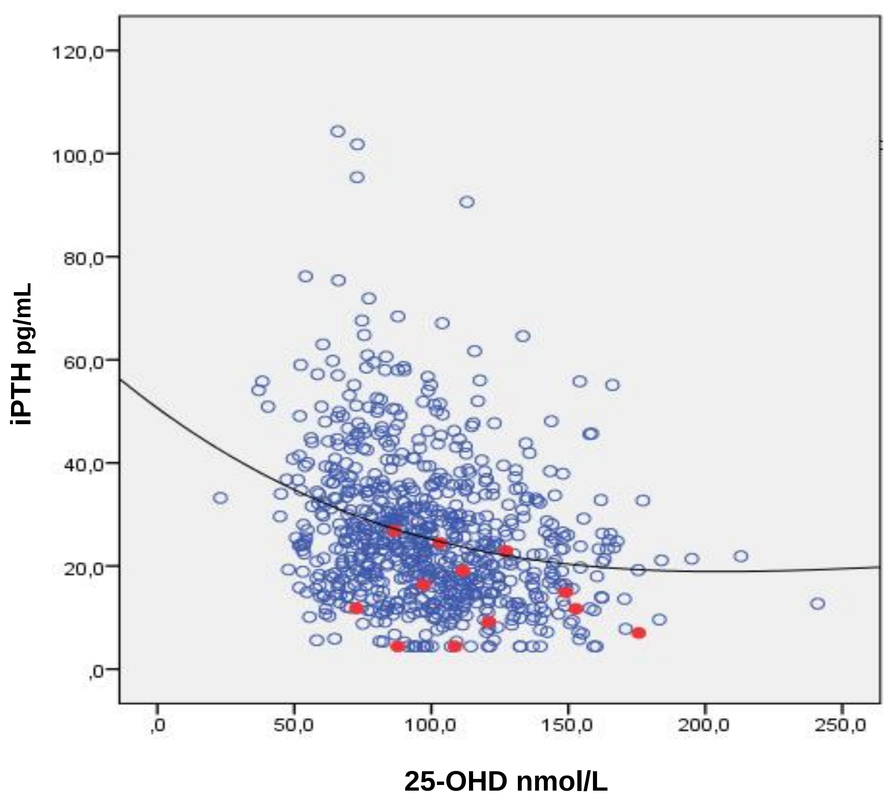

Figure 1. Correlation between iPTH and 25-OHD at 12 months

BLUE= Ca-ion 1.16 -1.39 mmol/L

RED= Ca-ion 1.40-1.52 mmol/L

TABLE 1. Infants' characteristics at 6 and 12 months

	6 MONTHS			12 MONTHS		
	Boys n= 440	Girls n= 448	p value	Boys n= 425	Girls n= 436	p value
Decimal age (yr)	0.5 (0.02)	0.5 (0.02)	0.409[1]	1.0 (0.03)	1.0 (0.03)	0.891[1]
Length (SD)	-0.5 (1.0)	-0.5 (1.0)	0.857[1]	-0.5 (1.0)	-0.6 (1.0)	0.058[1]
Length-adjusted weights (%)	3.3 (9.4)	1.8 (9.0)	0.015[1]	1.9 (8.5)	0.4 (8.3)	0.008[1]
Compliance > 80 %	85%	86%	0.526[2]	85%	86%	0.614[2]
Breastmilk vs. formula milk	27% / 73%	33% / 67%	0.069[2]	10% / 90%	14% / 86%	0.166[2]

All values are presented as means (±SD)

[1] Independent samples T-test. Significant at p< 0.05.

[2] χ^2 test. Significant at p<0.05.

TABLE 2. Ca-ion, S-25-OHD and iPTH concentrations during the first year of life

	6 MONTHS			12 MONTHS		
	Boys n= 441	Girls n=449	p value	Boys n=419	Girls n=431	p value
Ca-ion (mmol/L)	1.37 [1.34-1.40]	1.38 [1.35-1.40]	0.006 [1]	1.33 [1.31-1.35]	1.34 [1.31-1.36]	<0.001[1]
1.16 - 1.39	74%	71%	0.292[2]	99%	97%	0.075[2]
>1.40	26%	29%		1%	3%	
S-25-OHD (nmol/L)				94 [77-117]	99 [78-117]	0.381[1]
<50				1%	1%	0,872[2]
50-75				21%	19%	
75-125				60%	63%	
>125				18%	16%	
iPTH (pg/mL)				23 [16-31]	24 [16-35]	0.255[1]

All values are presented as medians and [IQR]

[1] Independent samples T-test. Significant at p< 0.05.

[2] χ^2 test. Significant at p<0.05.

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Saara Valkama

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