[SaO013] NATIVE VITAMIN D IN DIALYSIS PATIENTS: SAFETY AND BIOLOGICAL EFFECTS

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INTRODUCTION AND AIMS:
Native vitamin D (VTD) supplementation is recommended by the last KDIGO guidelines in CKD patients including dialysis patients. However, this recommendation is based on a low level of evidence. We designed a randomized double-blind prospective study comparing the effects of VTD and placebo in dialysis patients on mortality, vascular calcifications and different parameters: 25-OH vitamin D -25(OH)D-, parathormone (PTH), calcium and phosphorus.

METHODS:
Forty-three patients have been included and were followed for one year. Calcium, phosphorus, PTH and 25(OH)D levels were prospectively followed every month. Vascular calcifications were measured at baseline and after one year by the Kauppila method (abdominal aorta calcification by lateral X-ray radiography). Patients were treated either by placebo (n=21) or by 25,000 IU of cholecalciferol every two weeks (n=22). Repeated measured ANOVA test was used to compare the effect of time, treatment group and the interaction of these two parameters.

RESULTS:
Eleven patients died in the first 12 months (6 in the VTD and 5 in the placebo group), one patient drop-out and another one was transplanted, both from the placebo group. Thirty patients completed the study at one year. Phosphorus and calcium concentrations did not change over time in either group. PTH concentrations significantly changed over time (p=0.03 for time effect) due to a slight decrease observed in the VTD compared to the placebo group. However, the difference did not reach statistical significance (p=0.07 for interaction). 25(OH)D concentrations significantly changed over time (p<0.0001 for time effect), rapidly increasing in the VTD group while following the usual seasonal change in the placebo group (p =0.0001 for treatment group effect and p<0.0001 for interaction). The abdominal calcification score significantly increased both in the placebo and the VTD groups without any statistical difference between them.

Table

	Baseline		One year		p
	Placebo	VTD	Placebo	VTD	
Age	73±12	75±9	-	-	NS
Sex Ratio (F/M)	5/9	4/12	-	-	NS
Calcium (mmol/L)	2.08±0.14	2.18±0.12	2.15±0.16	2.20±0.22	NS
Phosphorus (mg/L)	4.7±1.3	3.8±1.1	4.2±1.3	4.6±1.3	NS
PTH (pg/mL)	413±198	335±165	401±263	255±211	Time effect: 0.03 Treatment effect: NS Interaction: 0.07
25-OH vitamin D (ng/mL)	12±5	12±4	17±7	34±8	Time effect: <0.001 Treatment effect: 0.001 Interaction: <0.001
Abdominal calcification score	7.6±7.5	8.2±5.4	10±7.3	10.5±5.9	Time effect: <0.001 Treatment effect: NS

CONCLUSIONS:
VTD supplementation (50,000 IU/month) effectively increased the 25(OH)D concentration in our dialysis patients. Calcium and phosphorus concentrations were not influenced by this therapy. PTH concentration tended to slightly decrease in the VTD group. More importantly, the progression of abdominal calcification score was similar in the two groups. From a "vascular calcification" point of view, VTD may be considered as a safe therapy.

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