A RANDOMIZED STUDY OF CHOLECALCIFEROL SUPPLEMENTATION IN INCIDENT HEMODIALYSIS PATIENTS: PRELIMINARY ASSESSMENT AT THE THIRD YEAR

Cristina Jorge[1,5]; Patrícia Matias[2,5]; Pedro Bravo[3]; Clara Mil-homens[4]; Cecília Silva[4]; Pedro Ponce[4]; Carlos Oliveira[3] ; Célia Gil[2,5]; Aníbal Ferreira[1,5];
(1) - Nephrocare Vila franca de Xira, Portugal; (2) - Dialverca, Forte da Casa, Portugal; (3) - Nephrocare Almada, Miratejo, Portugal; (4) - Nephrocare Lumiar, Lisbon, Portugal; (5) - NIDAN, Vila Franca de Xira, Portugal.

Introduction and Aims

Vitamin D (vitD) deficiency has been associated with significant morbidity and mortality and increased cardiovascular risk in both the general population and in chronic kidney disease (CKD) patients (1-4).

We aimed to prospectively assess the safety and efficacy of nutritional vitD (cholecalciferol) supplementation in incident hemodialysis patients and to compare the clinical results with a control group supplemented with placebo.

Methods

Clinical, biannual laboratory data (Hb, calcium, phosphorus, iPTH, bone alkaline phosphatase, CRP and albumin) and yearly routine exams and vitD levels were analyzed. Therapy, including dose of erythropoiesis stimulating agent and the erythropoietin resistance index (ERI) were also considered.

In the statistical analysis for comparison between groups, T test, Mann Whitney U test or Chi-square test were used; survival analysis was performed by using Kaplan-Meier test or Cox Regression; a p <0,05 was considered significant.

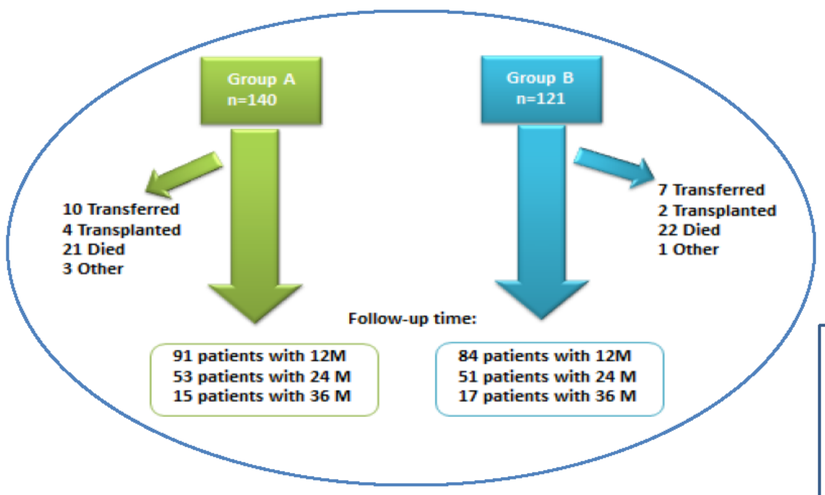
Group A patients received 20 000 U /week of cholecalciferol and Group B patients received placebo – these medications were given thrice per week, after each dialysis session.

Results

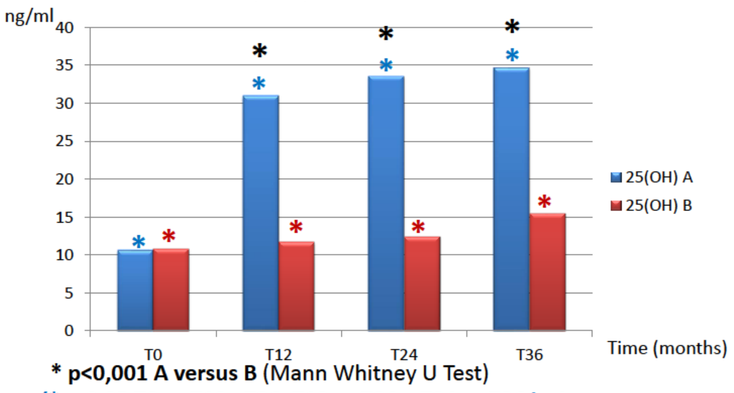
	Group A (n=140)	Group B (n=121)	P
Gender (male/female)	90 / 50 (64,3/35,7%)	82 / 39 (67,8/32,2%)	NS
Age (years)	68 (24-97)	69 (18-89)	NS
BMI (Kg/m2)	24,6 (16,4-39,4)	25,3 (14,5-42,4)	NS
Etiology of CKD			
Hypertension	19 (13,6%)	21 (17,4%)	NS
Diabetes	40 (28,6%)	50 (41,3%)	NS
Glomerular disease	14 (10%)	9 (7,4%)	NS
ADPKD	6 (4,3%)	4 (3,3%)	NS
Kidney graft failure	8 (5,7%)	2 (1,7%)	NS
Unknown	33 (23,6%)	25 (20,7%)	NS
Other	20 (14,3%)	10 (8,3%)	NS

Baseline comorbidities

DM	60 (42,9 %)	68 (56,2%)	**<0,05**
HTN	129 (92,1%)	108 (89,3%)	NS
CAD	26 (18,6%)	37 (30,6%)	**<0,05**
CVD	24 (17,1%)	31 (25,6%)	NS
PAD	25 (17,9%)	23 (19%)	NS
Dysrhythmia	26 (18,6%)	28 (23,1%)	NS
Chronic heart failure	22 (15,7%)	25 (20,7%)	NS
Neoplasia	23 (16,4%)	18 (14,9%)	NS
Chronic liver disease	4 (2,9%)	8 (6,6%)	NS
COPD	19 (13,6%)	16 (13,2%)	NS
Past Fracture	10 (7,1%)	8 (6,6%)	NS



Evolution of 25 (OH) vitamin D3 serum levels

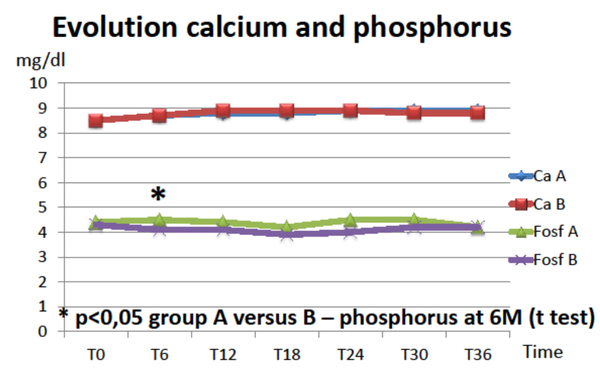


*** p<0,001 A versus B** (Mann Whitney U Test)
(*p<0,05 T0 vs T12 –T36, T12 vs T24 e T24 vs T36 in A;
*p<0,05 T0 vs T12-T36 in B) (related samples Wilcoxon)

As expected, baseline levels of 25 (OH) vit D were similar between the 2 groups and after 12M significantly higher in group A

Medication with active vitamin D, cinacalcet, phosphate binders and anti-hypertensives was similar between the 2 groups at all time points

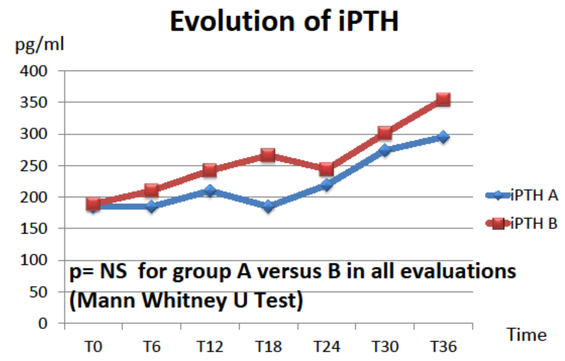
Evolution calcium and phosphorus



* p<0,05 group A versus B – phosphorus at 6M (t test)

Serum calcium and serum phosphate were similar in the 2 groups except at 6M, in which phosphate was higher in group A

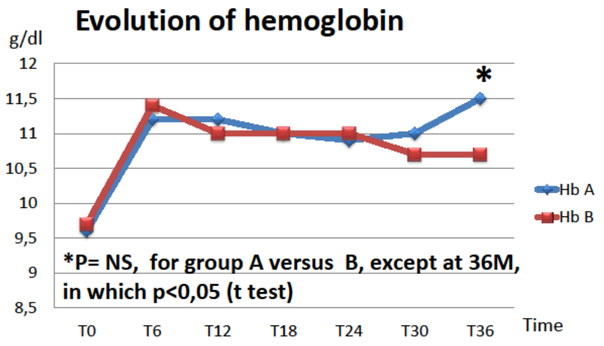
Evolution of iPTH



p= NS for group A versus B in all evaluations (Mann Whitney U Test)

The evolution of iPTH was similar in the 2 groups

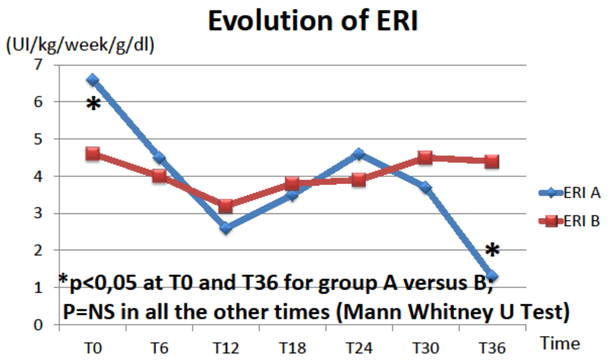
Evolution of hemoglobin



*P= NS, for group A versus B, except at 36M, in which p<0,05 (t test)

Hb was similar in the 2 groups, except at 36M, when it was significantly higher in group A

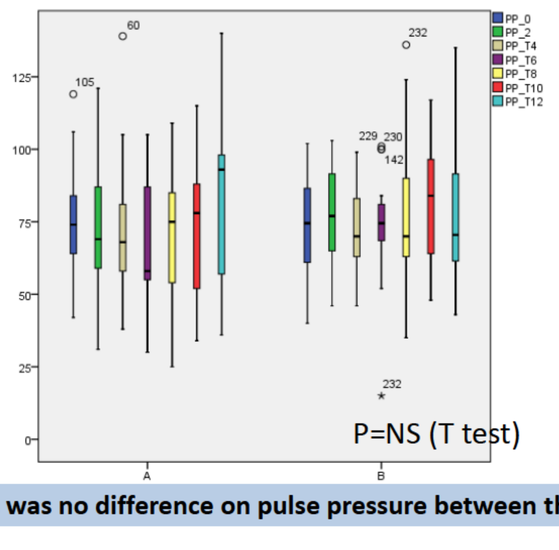
Evolution of ERI



*p<0,05 at T0 and T36 for group A versus B; P=NS in all the other times (Mann Whitney U Test)

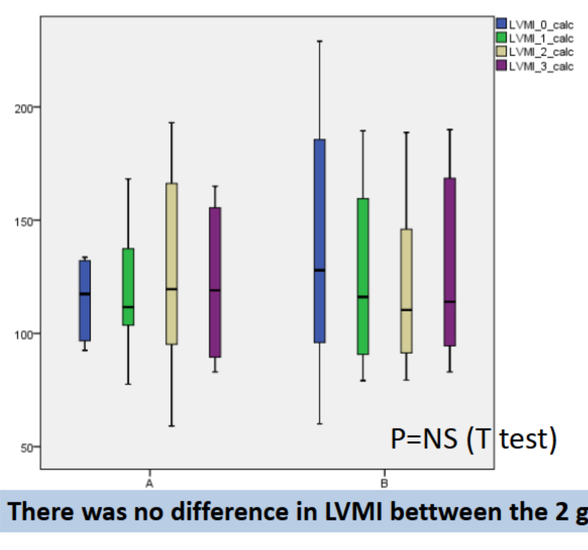
Basal ERI was significantly higher in group A, being significantly lower also in group A at 36M without differences in the other times

Pulse pressure evolution (T0 – T36)



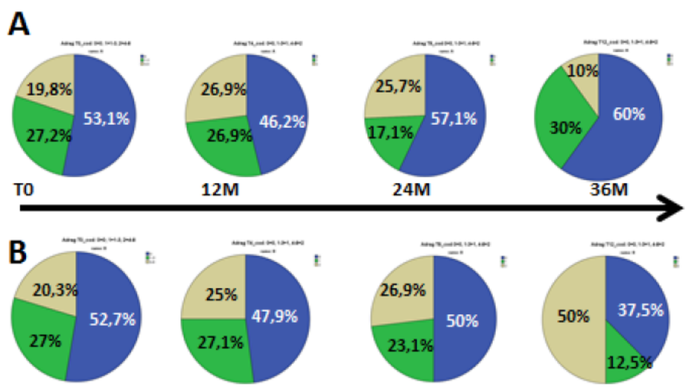
There was no difference on pulse pressure between the 2 groups

Left ventricular mass index evolution (T0 – T36)



There was no difference in LVMI bettween the 2 groups

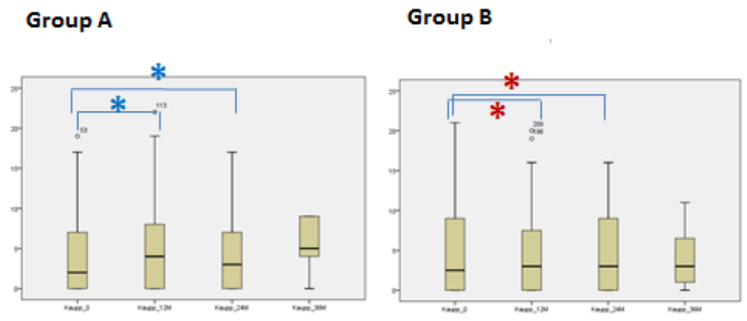
Adragão score of vascular calcification: T0-T12-T24 -T36 M



P=NS for group A versus group B (χ^2)

Evolution of distribution in each group: not significant in A or B (Friedman test)

Kauppila score at baseline, at 12M, at 24M and at 36M



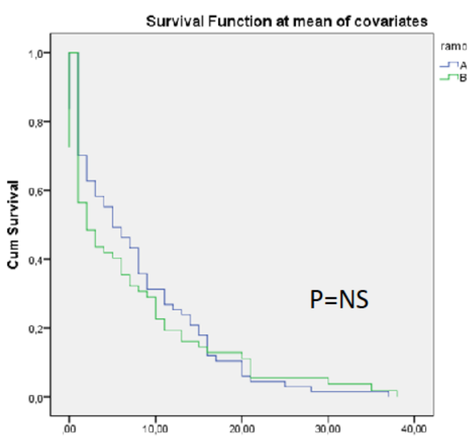
P=NS for group A versus group B (Mann Whitney U Test)

	T0	12M	24M	36M
A	2 (0; 19)	4 (0;22)	3 (0; 17)	5 (0; 9)
B	2,5 (0;21)	3 (0; 20)	3 (0;16)	3 (0; 11)

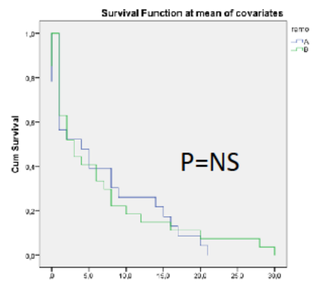
** p<0,05 Wilcoxon

There were no differences in vascular calcifications between the 2 groups

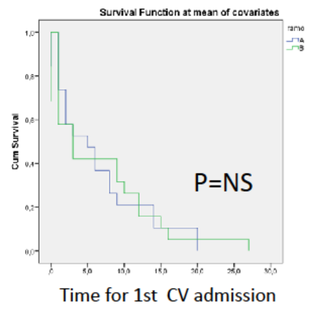
Global admissions



Admissions for infection



Cardiovascular hospitalizations

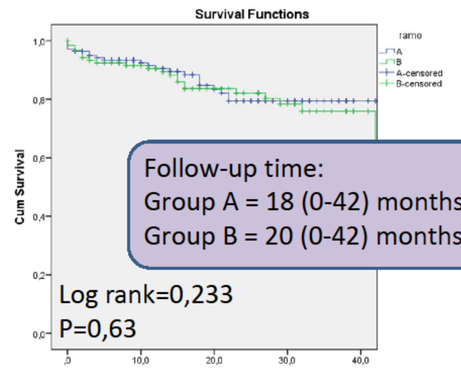


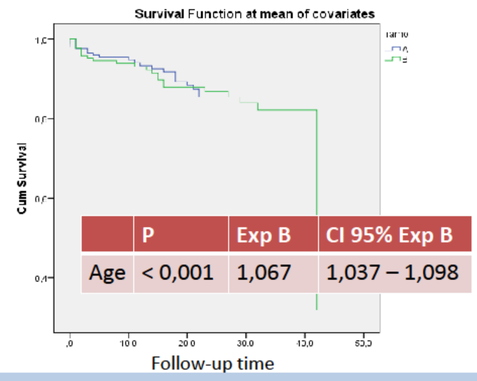
	Infection	Cardiovasc	Neo	Fracture	Other	Total
Group A	35	37	4	1	60	137
Group B	51	25	4	1	64	145

P=NS (χ^2 or *Fisher test)*

There were no differences in hospitalizations between the 2 groups

No difference in survival between the 2 groups: Kaplan-Meier





	P	Exp B	CI 95% Exp B
Age	< 0,001	1,067	1,037 – 1,098

and in Cox regression – adjusted to age, DM and CAD

Conclusions

Cholecalciferol administration at a dose of 20 000 U / week proved to be safe and effective in raising the vitamin D levels and in correcting vitamin D deficiency. This supplementation was accompanied by a significant decrease in ERI, particularly relevant because was associated with higher values of Hb, at 36M. In this interim analysis of the study, no other significant differences between the 2 groups were observed.

References: *1) N Engl J Med*. 2007; 357(3):266-81; 2) *Nephrol Dial Transplant*. 2009 Feb;24(2):611-8; 3) *Arch Intern Med 2008;* 168 (15): 1629-37; 4) *Am J Kidney Dis* 2011 Sep;58(3):374-82

Contact of first author: cristinamjorge@gmail.com

53 ERA
756--SP
Late Breaking Clinical Trials.
C Jorge
DOI: 10.3252/pso.eu.53era.2016
ePosters supported by F. Hoffmann- La Roche Ltd.
53rd CONGRESS ERA-EDTA VIENNA AUSTRIA MAY 21-24 2016
PosterSessionOnline.com