CHAPTER IV

RESEARCH FINDING

Result

Table 1. shows the characteristics of the patients before the study.

Table 1. Characteristics of the patient population.

Characteristics (normal range)	Control	Calcitriol	Unpaired
	Mean ± SD	Mean ± SD	T- test
Number	4	4	
AGE (Year)	44.75 ± 6.75	43 ± 7.07	NS
Body weight (Kg)	59 ± 6.2	58.7 ± 5.3	NS
Duration of CAPD	18 months 18 days	15 months 14 days	NS
BUN (5 - 20 mg/dl)	47.66 ± 6.74	49.45 ± 11.36	NS
Cr (0.5 - 1.2 mg/dl)	12.22 ± 2.8	11.05 ± 2.86	NS
Na (135 - 150 mEq/L)	136.75 ± 2.9	134.5 ± 3.1	NS
K (3.5 - 5.0) mEq/L	3.62 ± 0.7	3.55 ± 0.4	NS
Cl (95 - 105 mEq/L)	91.75 ± 6.8	97.25 ± 7.9	NS
HCO3 (20 - 30 mEq/L)	28.4 ± 3.1	26.7 ± 0.9	NS
Calcium (9 - 11 mg/dl)	9.45 ± 1.5	9.02 ± 0.47	NS
Phosphate (2.5 - 4.8 mg/dl)	4.35 ± 1.1	4.42 ± 1.5	NS
IPTH (13 - 54 pg/ml)	125.2 ± 41	208.6 ± 36	NS
Albumin (3.8 - 5 g/dl)	3.4 ± 0.6	3.25 ± 0.8	NS
Globulin (3 - 4 g/dl)	2.6 ± 0.3	2.4 ± 0.5	NS
SGOT (0 - 38 U/L)	19.75 ± 14	31.3 ± 5	NS
SGPT (0 - 38 U/L)	23.25 ± 17	31.3 ± 86	NS
AP (98 - 279 U/L)	134.5 ± 63	161 ± 56	NS
Aluminium (< 50 ug/L)	18 ± 6.4	17.25 ± 3.4	NS
Magnesium (1.7 - 2.4 mg/dl)	2.4 ± 0.1	2.13 ± 0.4	NS
Hct (35 - 42 %)	24 ± 1	19.75 ± 2.8	NS
Ferritin (10 -200 ng/ml)	966.75 ± 236	1671.5 ± 727	NS
Serum Iron (100 - 170 ug/dl)	93.5 ± 62	110.5 ± 13	NS
Iron binding capacity UIBC (200 - 300 ug/dl)	185.2 ± 27.31	242.6 ± 92	NS

* NS indicates not significant

No significant difference was observed in all parameters . Plasma concentration of Na , K , Cl , HCO3 , calcium , phosphate, alkaline phosphate , SGOT , SGPT and magnesium were normal. Plasma aluminium levels were low in the safety range in both groups. PTH levels were high in both groups with the levels of 125 $\pm$ 42 and 209 $\pm$ 36 pg/ml in control and calcitriol group respectively (normal 13 - 54 pg/ml) . Serum ferritin levels were high with the mean levels were 966.75 and 167.5 ng/ml in control and calcitriol group respectively (normal 10 - 200 ng/ml) .

Complete series of skeletal radiography showed mild calcification of aortic knob , aorta , hip with mild osteoporosis in two cases. One in control group and the other in calcitriol group. No evidence of osteitis fibrosa or hyperparathyroid bone disease was seen in both groups.

After therapy with calcitriol or placebo , it appeared that plasma calcium become higher with calcitriol than control group at the 4th , 5th and 6th months. Plasma alkaline phosphatase seemed to be decreased in both groups. These changes were not statistically significant both within groups or in comparable between groups. Table 2. shows the levels of calcium , phosphate parathyroid hormone levels and alkaline phosphatase at different times of the study.

A decreasing of iPTH levels was noted in all patients but the statistically significant change was only in the calcitriol group. After oral administration of one capsule (0.25 ug) of calcitriol for 2 months , PTH levels were significantly lower by 50.2 % , from 209 $\pm$ 36 to 104 $\pm$ 90 pg/ml (P = 0.03) , and lower by 91.9 % to the

levels 16.85 ± 6.3 pg/ml (P = 0.04) at six months. the mean of PTH levels was in normal range (13-54 pg /ml) in 4th month of calcitriol group. In control group, even the mean levels were higher than normal value in 6th month, but one case had normal levels of PTH (25.2 pg/ml).

Table 2 . Biochemical parameters at different times of the study.

	Basal	1st month	2nd month	3rd month	4th month	5th month	6th month
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Control							
Calcium (mg/dl)	9.45 ± 2	9.2 ± 1	8.11 ± 2.3	9.37 ± 0.88	9.2 ± 0	9.05 ± 0.9	9.1 ± 0.7
Phosphate (mg/dl)	4.35 ± 1	3.95 ± 1	3.62 ± 0.44	4.55 ± 1	4.93 ± 1	3.5 ± 0.2	5.6 ± 1.4
AP (U / L)	135 ± 63	122 ± 40	154.8 ± 97	123 ± 31	102 ± 29	102.7 ± 25	104 ± 20
PTH (pg/ml)	125 ± 42		86.9 ± 8.6	87.9 ± 21.2	88.4 ± 42	75.48 ± 38.7	68.84 ± 45
Calcitriol							
Calcium (mg/dl)	9.02 ± 0	8.55 ± 0	8.67 ± 0.48	8.75 ± 0.7	10.2 ± 2	10 ± 0.3	10.16 ± 1.1
Phosphate (mg/dl)	4.42 ± 1	4.57 ± 1	4.64 ± 1.1	4.92 ± 0.5	4.76 ± 1	5.46 ± 1.7	6.1 ± 0.9
AP (U / L)	161 ± 56	184.5 ± 85	147.3 ± 28	147 ± 30	158 ± 16	133 ± 15	130 ± 19
PTH (pg/ml)	209 ± 36		104 ± 90.4*	65.7 ± 7.43	26.8 ± 23*	18.39 ± 9.38*	16.85 ± 6.3*

* Paired T-test P < 0.05

Table 3 . Radiographic findings in the patients

	Pre study	3rd month	6th month
Control			
Case 1	Normal	Same	Same
Case 2	Normal	Same	Same
Case 3	Mild osteoporosis, calcify aortic knob and abdominal aorta	Same	Same
Case 4	Calcify aorta and leg vessels	Same	Same
Calcitriol			
Case 1	Osteoporosis of spine	Same	Same
Case 2	Minimally calcify aortic knob	Same	Same
Case 3	Calcify aorta, hip , mild osteoporosis	Same	Same
Case 4	Calcify right acetabulum and abdominal aorta	Same	Mild increase

Fig 2. Total plasma calcium levels in the patients

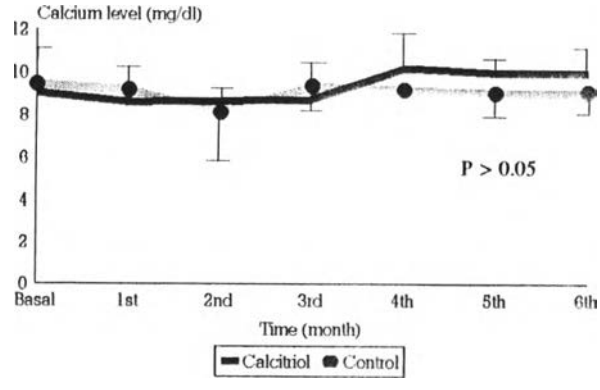


Fig 3. Phosphate levels in the patients

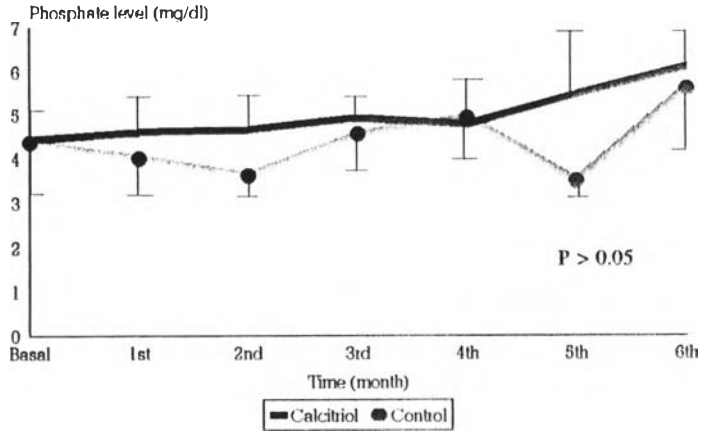


Fig 4. AP levels in the patients

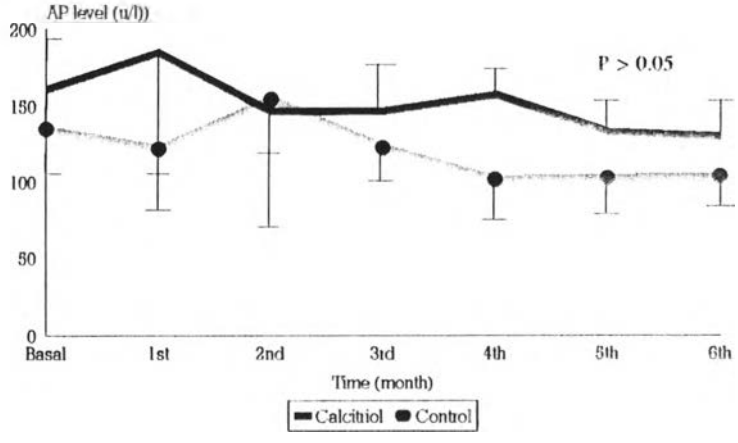
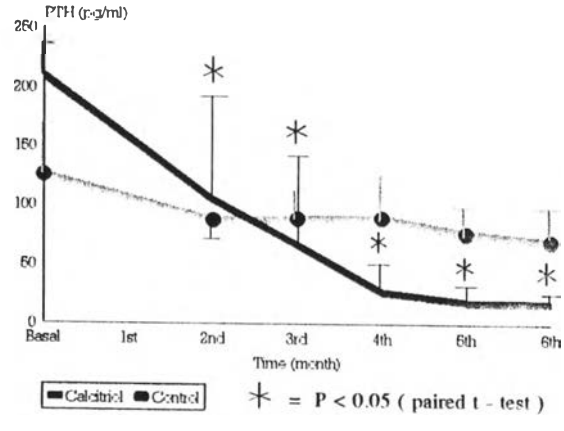


Fig 5. iPTH levels in calcitriol and control group



In the comparison between group , the different of PTH levels at the beginning and at the end of the study in calcitriol group was statistically higher than in control group since the 3rd month ($P < 0.05$) PTH levels were in normal at the 2nd and the 3rd month in two patients of calcitriol group with the dosage of 1 capsule (0.25 ug) per day . In the other two patients,PTH levels were normal at the 4th month with the dosage of 2 capsules per day.

One case in calcitriol group developed hypercalcemia (Ca >11 mg/dl) and hyperphosphatemia (P > 4.8 mg/dl) in the last month of the study and in this case , skeletal radiography showed mild increasing of soft tissue calcification at the acetabulum of femur (table 4).

All patients except one in calcitriol group showed the same radiographic finding. The other laboratory data was stable and had no statistically significant change from the beginning of the study . No one complained about clinical symptoms of osteodystrophy such as bone pain or muscle weakness etc.