ORAL PARICALCITOL IN CHRONIC KIDNEY DISEASE (CKD) PATIENTS STAGES 3-5 AND SECONDARY HYPERPARATHYROIDISM (SHPT): A ONE-YEAR PROSPECTIVE STUDY

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INTRODUCTION: Active vitamin D is an effective treatment for SHPT often complicated by hypercalcemia and hyperphosphatemia. Paricalcitol, a selective vitamin D receptor activator, causes less Calcium (Ca) and Phosphorus (P) rise. There is not enough experience on long-term treatment with oral paricalcitol for stage 3-5 CKD non-dialysis patients with SHPT in daily clinical practice.

AIM OF THE STUDY: The purpose of this observational prospective single center study is to present data on the use of oral paricalcitol in real-life clinical practice in patients with CKD 3-5 and SHPT.

PATIENTS AND METHODS:

- We studied 55 patients, M/F: 38/17, median age 72 years (18-87), 17 diabetics, 9 on ACE inhibitors or angiotensin receptor blockers (ACEi/ARBs), CKD stage 3/4/5: 27/23/5, with SHPT, who received oral paricalcitol in individualized doses, based on serum intact parathyroid hormone (iPTH), Ca and P levels, for a follow-up period of 12 months.
- Patients having received vitamin D or bisphosphonates within 3 months prior to treatment initiation, as well as those with malignancy were excluded.
- Three months before and 12 after treatment initiation we measured, monthly, serum levels of iPTH, Ca, P, alkaline phosphatase (ALP), albumin (ALB), total cholesterol (TCH), triglycerides (TG), HDL, LDL-cholesterol (LDL), hemoglobin (Hb), and 24-hour urinary protein (UPROT). CaxP product and creatinine clearance with 24-hour urine collection (CrCl) were calculated. Changes in mean values before and after treatment initiation were compared.

Table 1: Patients characteristics

Number of patients	**55**
Male/female	**38/17**
Age (median, range) years	**72 (18-87)**
Cause of CKD:	
Diabetic nephropathy	**16**
Chronic glomerulonephritis	**2**
Nephrosclerosis	**5**
Polycystic kidney disease	**1**
Scleroderma	**1**
Unknown nephropathy	**30**
Diabetics	**17**
CKD stage 3/4/5	**27/23/5**
On ACEi or ARBs	**9**

RESULTS:

- Mean weekly paricalcitol dose was 4.89±1.81 μg (range 2-7) and there was a significant decrease in serum iPTH and ALP levels with an increase in serum Ca, P and CaxP (Table 2).
- Mean weekly paricalcitol dose was higher in CKD3 vs CKD4: 6.2 μg (2-7) vs 3.8 μg (2-7), *P*=0.04.
- P, CaxP, ALP and iPTH levels were higher in CKD4 than in CKD3 throughout the study.
- P levels were found higher in female than male patients (4.6±0.9 vs 3.9±0.8 mg/dl, P=0.005).
- Males under paricalcitol treatment did not change their serum Ca and P levels significantly but dropped their LDL (102.1±28.2 to 95.8±25.9 mg/dl, P=0.03).
- Diabetics had significantly higher serum P than non-diabetics during the study.
- There was a positive effect on ALB levels in ACEi/ARB group (3.7±0.4 to 3.8±0.3 g/dl, P=0.02), while their serum Ca remained stable. P in CKD3 and Ca in CKD4 also remained stable.
- In multi-variable analysis a significant positive correlation between mean weekly paricalcitol dose and end of study iPTH levels and a negative to the CKD stage, as well as a significant negative correlation between terminal CrCl and P, CaxP, iPTH, anaemia and UPROT were observed.

Table 2: Changes in mean values before and after treatment initiation

	Before	After	P
iPTH (pg/ml)	252.8±138.05	176.4±75.8	<0.0001
ALP (U/l)	239.5±89.05	210.3±85.9	<0.0001
Ca (mg/dl)	9.1±0.5	9.3±0.6	0.02
P (mg/dl)	3.8±0.6	4.1±0.9	0.002
CaxP (mg^2/dl^2)	34.9±5.8	38.2±7.5	<0.001
Hb (g/dl)	11.9±1.4	11.6±1.9	NS
ALB (g/dl)	3.8±0.4	3.8±0.4	NS
TCH (mg/dl)	186.1±35.8	182.7±34.3	NS
TG (mg/dl)	148.8±88.8	149.4±73.9	NS
LDL (mg/dl)	103.3±25.9	99.6±23.9	NS
HDL (mg/dl)	45.4±14.1	47.4±14.9	NS
UPROT (g/24h)	1.3±1.97	1.3±1.94	NS
CrCl (ml/min)	27.7±9.6	26.5±10.5	NS

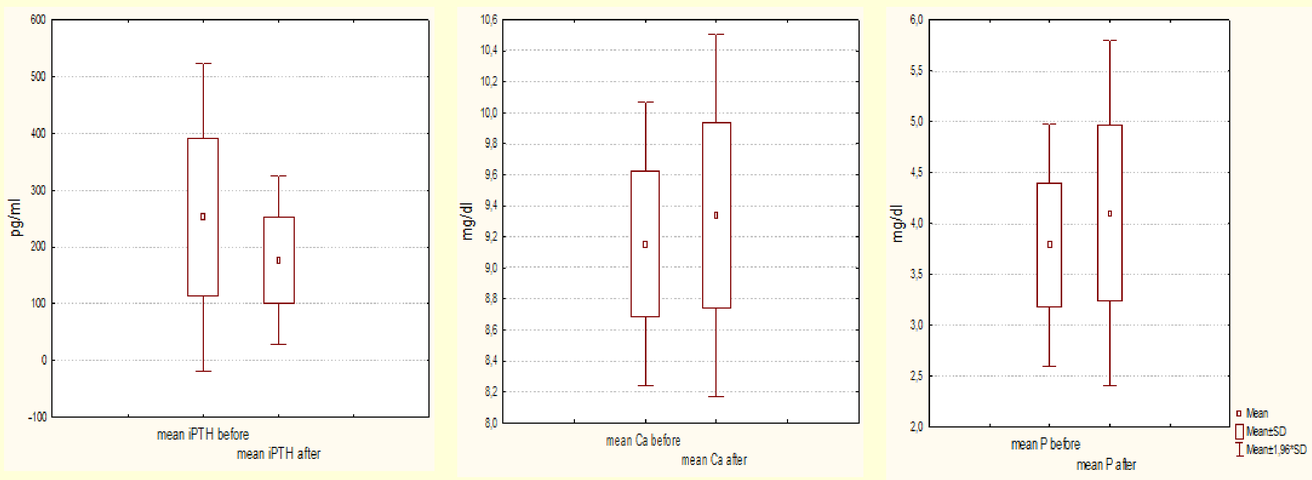

Fig 1: Changes in mean iPTH, Ca and P values before and after treatment initiation

CONCLUSIONS:

Long-term oral paricalcitol dose is an efficient, well-tolerated and safe treatment of SHPT in patients with CKD stage 3-5 in everyday clinical practice. Renal function remained stable during follow-up. Despite higher paricalcitol dose in CKD3 patients serum phosphorus remained stable, whereas lower dose in CKD4 appeared to protect against serum calcium rise. However, calcium and/or phosphorus elevations, especially in females CKD4 patients and diabetics, although within normal range, emphasize the need for close follow-up, additional dietary counseling and/or early phosphate-binders administration.

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