Effect of High Dose Ergocalciferol in Chronic Kidney Disease Patients with 25-Hydroxyvitamin D Deficiency

Thananda Trakarnvanich MD*,
Oran Chalapipat MD*, Sinee Disthabanchong MD**,
Sathit Kurathong MD*, Kearkiat Praditpornsilpa MD***,
Wasana Stitchantrakul MS****, La-Or Chailurkit PhD*****

** Division of Nephrology, Department of Medicine, BMA Medical college and Vajira Hospital, Bangkok, Thailand*
*** Division of Nephrology, Department of Medicine, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*
**** Division of Nephrology, Department of Medicine, Chulalongkorn University, Bangkok, Thailand*
***** Research Center, Faculty of Medicine, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*
****** Division of Endocrinology, Department of Medicine, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*

Objective: *To evaluate 25 hydroxyvitamin D (25-OH-D) deficiency in a cohort of predialysis CKD patients and the treatment effect and safety of high dose ergocalciferol supplement in predialysis CKD.*
Material and Method: *Fifty-six predialysis CKD patients who came for a regular visit at a single hospital with calculated glomerular filtration rate $\leq$ 60 mL/min/1.73 m^2 were screened for 25-OH-D levels. Forty-four patients with 25-OH-D deficiency were recruited into this prospective observational study that examined the effect of high dose oral ergocalciferol supplementation. After eight weeks, 37 patients completed the follow-up and biochemical parameters were reevaluated and analyzed.*
Results: *The mean 25-OH-D level of 56 patients was 25.6 $\pm$ 8 ng/mL. Forty-four (78.5%) patients had 25-OH-D levels less than 30 ng/mL and four (7.1%) had severe deficiency with the level less than 15 ng/mL. High dose ergocalciferol supplement successively increased 25-OH-D levels in 35 (95%) patients. 25-OH-D levels increased significantly from 22 $\pm$ 4.8 to 34.5 $\pm$ 10.8 ng/mL after eight weeks ($p < 0.001$). During the study period, there were no changes in serum calcium, phosphate, and PTH. There was no other side effect associated with the treatment.*
Conclusion: *25-OH-D deficiency were found in this cohort of predialysis CKD patients. Ergocalciferol was a safe and effective supplement for the 25-OH-D in predialysis CKD.*

Keywords: *Vitamin D, Hyperparathyroidism, PTH, Ergocalciferol, 25-hydroxyvitamin D*

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One of major consequences of chronic kidney disease (CKD) is alteration of calcium and phosphate metabolism, which is characterized by phosphate retention and calcitriol deficiency resulting in hyperparathyroidism. Calcitriol or 1-25 hydroxycholecalciferol (1, 25-OH-D) is produced in the kidney by 1-alpha hydroxylation of 25-hydroxycholecalciferol (25-OH-D). With the decline of renal function, calcitriol deficiency follows. The function of calcitriol is not only to promote calcium and phosphate absorption in the intestine but it is also to inhibit parathyroid hormone (PTH) secretion. Thus, calcitriol deficiency potentiates hyperparathyroidism in CKD[1]. Recently, high prevalence of low 25-OH-D levels has been reported both in individuals with normal renal function as well as in CKD[2-6]. The deficiency of 25-OH-D, the storage reservoir of vitamin D in the liver, was found to be associated with all-cause and cardiovascular mortality in general population[2,3]. In CKD and hemodialysis, 25-OH-D levels correlated positively

Correspondence to:
Trakarnvanich T, Renal Unit, Department of Medicine, Bangkok Metropolitan Administration Medical College and Vajira Hospital, 681 Samsen Rd, Dusit, Bangkok 10300, Thailand.
Phone: 0-2244-3469, Fax: 0-2244-3469
E-mail: thananda@hotmail.com

with glomerular filtration rate (GFR). Low 25-OH-D levels were able to predict CKD progression as well as mortality[7,8]. To replenish 25-OH-D store, ergocalciferol supplement in high doses is recommended in all stages of CKD patients with low 25-OH-D levels[9]. Data reported from western countries revealed the ability of ergocalciferol in lowering PTH in patients with stage 3 CKD (GFR 30-59 mL/min)[10,11]. Since sun-exposure is less of a concern in Thailand, it is uncertain if 25-OH-D deficiency poses a major problem in Thai CKD patients. Hypercalcemia, the major side effect associated with high dose ergocalciferol should also be addressed[12]. This study examined the presence of 25-OH-D deficiency in a group of CKD patients and the effect of short-term high dose ergocalciferol therapy on 25-OH-D, serum calcium, phosphate, and PTH levels.

Material and Method

Patients

CKD patients who came for regular follow-up at renal out-patient clinic of Renal Unit at Bangkok Metropolitan Medical College Administration and Vajira Hospital between January 2006 and May 2007 were screened by their GFR calculated using Cockcroft and Gault formula ((140-age) x wt (kg)/(72 x serum creatinine) x 0.85 if female). To be eligible for this prospective, non randomized observational study, patients must be at least 18 years of age, have stable renal function for at least three months with calculated GFR < 60 mL/min/1.73m^2 (body surface area (m^2) = 0.007148 x Weight (kg)$^{0.425}$ x Height (cm)$^{0.725}$) and able to take the pills. Exclusion criteria included history of parathyroid surgery, chronic illnesses and liver disease that might affect vitamin D metabolism. Informed consent was obtained from each patient. This study was approved by Ethical Committee of the Bangkok Metropolitan Medical College Administration.

Clinical protocol

Fifty-six patients were initially screened for 25-OH-D levels. Forty-four patients were found to have 25-OH-D level $\leq$ 30 ng/ml and were included to receive ergocalciferol therapy. Serum calcium, albumin, phosphorus, and intact PTH were measured at baseline prior to receiving ergocalciferol. Serum calcium was corrected using the following formula: serum corrected calcium = 0.8 x (4-albumin) + measured calcium. Intact PTH was analyzed by immunoradiometric assay. 25-OH-D levels were determined by using commercially available ELISA kit (Laison® Diasorin Inc., Syillwater, Minn, USA). For patients with 25-OH-D levels between 15-29.9 ng/mL, ergocalciferol was given orally at 40,000 units (20,000 units per capsule, total of two capsules) per month for two months whereas for 25-OH-D levels < 15 ng/mL, ergocalciferol was given at 40,000 units weekly for four weeks and continued at 40,000 units for another month (modified from K/DOQI clinical practice guidelines for bone metabolism and disease in CKD)[9]. Serum calcium, albumin, and phosphorus were monitored every four weeks. Ergocalciferol dose was adjusted to keep the corrected calcium less than 10.2 mg/dL. Intact-PTH and 25-OH-D levels were re-evaluated after eight weeks of ergocalciferol therapy.

Statistical analysis

Data is presented as mean $\pm$ SD unless specified otherwise. The differences between the mean of two or multiple groups were analyzed by Student's t-test and one-way ANOVA respectively. In abnormal distribution data, Mann-Whitney U and Wilcoxon Signed Ranks test were applied. Relationships between categorical variables were analyzed using Chi-square test. Linear regression analysis was applied to demonstrate the relationship between two continuous variables. Logistic regression analysis was used to assess important factors associated with severe 25-OH-D deficiency. $P < 0.05$ is considered to be statistically significant.

Results

Baseline data

Of the 56 patients screened for 25-OD-D levels, 11 (19.6%) were in CKD stage 3 (GFR 30-59 mL/min/1.73m^2), 29 (51.8%) were in stage 4 (GFR 15-29 mL/min/1.73m^2), and 16 (28.6%) were in stage 5 (GFR < 15 mL/min/1.73m^2). The average age was 64.1 $\pm$ 11.8 years and 38 (68%) patients were male. The mean 25-OH-D level was 25.6 $\pm$ 8 ng/mL. Forty-four (78.5%) patients had 25-OH-D levels less than 30 ng/mL and four (7.1%) had severe deficiency with level less than 15 ng/mL (Fig. 1). Baseline parameters according to 25-OH-D status are shown in Table 1. The mean 25-OH-D levels analyzed according to CKD stage were 26.9 $\pm$ 5.3 for CKD stage 3, 26.5 $\pm$ 8.3 for CKD stage 4 and 23.2 $\pm$ 8.8 ng/mL for CKD stage 5 ($p = 0.36$). As GFR lessened, serum phosphate ($r = -0.43$, $p = 0.001$) and PTH increased ($r = -0.4$, $p = 0.002$) whereas serum calcium declined ($r = 0.33$, $p = 0.01$). PTH had negative correlation with serum calcium ($r = -0.43$, $p = 0.001$) but showed positive correlation with serum phosphate

Table 1. Baseline parameters of CKD patients with respect to 25-OH-D status

Parameters	25-OH-D deficiency[a] (n = 44)	Normal (n = 12)	p-value
Male (n/%)	29 (66)	9 (75)	0.55
Age (years)	63.9 ± 11.9	64.8 ± 11.8	0.88
DM (n/%)	22 (50)	6 (50)	1
GFR (mL/min/1.73m^2)	21.5 ± 10.1	22.4 ± 13.1	0.35
Baseline laboratory data			
Albumin (g/L)	4.2 ± 0.4	4.3 ± 0.4	0.78
Ca (mg/dL)	9.5 ± 0.5	9.5 ± 0.5	0.54
PO_4 (mg/dL)	4.3 ± 0.8	4.2 ± 0.8	0.85
$CaxPO_4$ (mg^2/dL^2)	40.9 ± 7.3	39.9 ± 7.9	0.98
Intact PTH[b] (pg/mL)	86.4 (18.3-632.1)	146.8 (40.5-295.1)	0.34
25-OH-D (ng/mL)	22.2 ± 4.6	38 ± 4.6	0.05

[a] 25-OH-D < 30 ng/mL, [b] median (range)

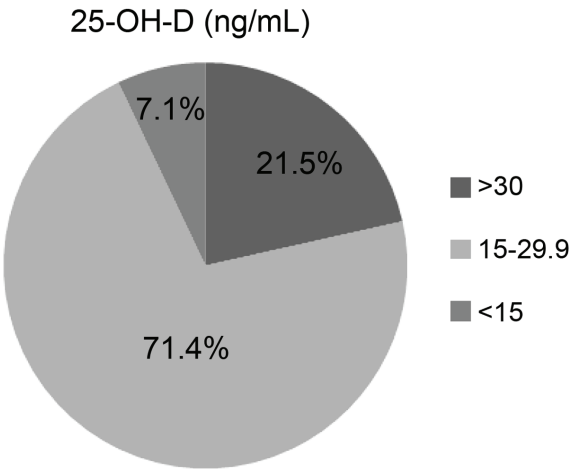

Fig. 1 25-OH-D deficiency (n = 56). Normal > 30 ng/mL, deficiency = 15-29.9 ng/mL and severe deficiency < 15 ng/mL

(r = 0.47, p < 0.001). There was no correlation between 25-OH-D levels with any of the biochemical parameters including age, sex, DM, GFR, calcium, phosphate, PTH, and albumin. However, in univariate logistic regression analysis, serum phosphate and albumin predicted severe 25-OH-D deficiency. Borderline association was also observed with CKD stage 5 (Table 2). Initially, 44 patients were assigned to receive ergocalciferol therapy, however, during the follow-up period, five patients were lost to follow-up and two underwent dialysis, therefore, 37 patients were included in the analysis. Baseline characteristics of these patients are shown in Table 3.

Table 2. Univariate logistic regression analysis on factors associated with severe 25-OH-D deficiency[a] (n = 56)

Parameters	OR[b]	95% CI[c]	p-value
Serum phosphate	3.481	1.14-10.64	0.03*
Serum albumin	0.038	0.002-0.738	0.03*
CKD stage 5	9	0.86-94.24	0.07

[a] 25-OH-D < 15 ng/mL, [b] Odds ratio, [c] Confidence intervals

Table 3. Baseline characteristics of the patients that received ergocalciferol

Parameters	n = 37
Male (n/%)	25 (67.6)
Age (years)	63.6 ± 12.4
DM (n/%)	48 (18.6)
GFR (mL/min/1.73m^2)	21.2 ± 9.9
Baseline laboratory data	
Albumin (g/L)	4.2 ± 0.4
Ca (mg/dL)	9.5 ± 0.5
PO_4 (mg/dL)	4.3 ± 0.8
$CaxPO_4$ (mg^2/dL^2)	41.2 ± 7.3
Intact PTH[a] (pg/mL)	84.9 (18.3-379.7)
25-OH-D (ng/mL)	22.0 ± 4.8

[a] Median (range)

Therapeutic effect of ergocalciferol

Serum calcium, phosphate, albumin, and PTH after four and eight weeks of ergocalciferol therapy are shown in Table 4. There was no significant difference

Table 4. Blood chemistries at baseline and during ergocalciferol therapy (n = 37)

	Baseline	4 weeks	8 weeks	p-value
Ca (mg/dL)	9.5 ± 0.5	9.6 ± 0.5	9.5 ± 0.6	0.31
PO_4 (mg/dL)	4.3 ± 0.8	4.3 ± 0.8	4.2 ± 1	0.08
Albumin (g/L)	4.2 ± 0.4	4.1 ± 0.4	4.1 ± 0.4	0.06
Intact PTH[a] (pg/mL)	84.9 (18.3-379.7)		74.5 (18.3-751.6)	0.98

[a] Median (range)

Table 5. Blood chemistries at baseline and after 8 weeks of ergocalciferol therapy analyzed by CKD stage

	CKD stage 3 (n = 6)		p-value	CKD stage 4 (n = 19)		p-value	CKD stage 5 (n = 12)		p-value
	Baseline	8 weeks		Baseline	8 weeks		Baseline	8 weeks	
Ca (mg/dL)	9.7 ± 0.3	9.5 ± 0.3	0.09	9.5 ± 0.5	9.6 ± 0.6	0.47	9.4 ± 0.6	9.4 ± 0.6	0.76
PO_4 (mg/dL)	3.8 ± 0.3	3.8 ± 0.5	0.93	4.3 ± 0.8	3.8 ± 0.8	0.05*	4.6 ± 0.8	5.0 ± 1.1	0.15
Albumin (g/L)	4.4 ± 0.3	4.3 ± 0.3	0.65	4.1 ± 0.3	4.0 ± 0.4	0.24	4.3 ± 0.6	4.1 ± 0.4	0.07
Intact PTH[a] (pg/mL)	76.5 (23-121)	64.9 (53-106)	0.92	83.9 (31-281)	67 (20-359)	0.12	104.7 (18-380)	109.1 (18-752)	0.06
25-OH-D (ng/mL)	23.9 ± 3.4	39.1 ± 4.4	0.002*	22.5 ± 4.5	34.0 ± 11.4	<0.001*	20.3 ± 5.5	33.0 ± 12.0	0.001*

[a] Median (range)

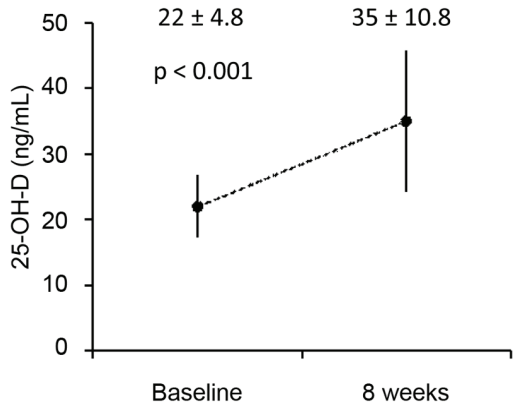

Fig. 2 25-OH-D levels at baseline and after 8 weeks of ergocalciferol supplement

in any of the parameters during ergocalciferol therapy. Twenty-five OH-D levels before and after 8-week course of ergocalciferol, which are shown in Fig. 2. 25-OH-D levels increased significantly from 22 ± 4.8 to 34.5 ± 10.8 ng/mL ($p < 0.001$). All but two patients had increased 25-OH-D levels. Twenty-two (60%) patients had 25-OH-D levels at least 30 ng/mL after eight weeks of ergocalciferol. When analyzed by CKD stages, a significant trend toward the increase in serum phosphate with advanced CKD was observed ($p = 0.04$) (Table 5). There was no significant change in serum calcium, albumin and PTH between baseline and after eight weeks of ergocalciferol in any of the CKD stages. Serum phosphate decreased significantly in CKD stage 4 patients but was unchanged in CKD stage 3 and 5. 25-OH-D levels increased significantly in all CKD stages.

Side effects associated with high dose ergocalciferol therapy

During the treatment period, there was no incidence of hypercalcemia or hyperphosphatemia that necessitated discontinuation of the medication. Patient tolerated the drug well and without specific complaints of medication.

Discussion

The present study is firstly aimed to examine the effect of high dose ergocalciferol supplementation in Thai predialysis CKD patients with low 25-OH-D levels. In the present cohort, almost 80% prevalence of 25-OH-D deficiency was observed, which was similar to those reports from western countries[5,6]. However,

the mean 25-OH-D levels measured in patients across latitudes in the United States were 19.4 ng/mL, slightly lower than that found in the present study, suggesting geographical influence such as sunlight exposure on the abundance of 25-OH-D store. This is supported by the observed increase in 25-OH-D levels during the summer period in western countries[6]. Malnutrition, suggested by the relationship of severe deficiency with low serum albumin, may also contribute to low 25-OH-D levels. The association of serum albumin and 25-OH-D levels has also been reported by others[5]. The relationship of 25-OH-D deficiency with high serum phosphate may be related to the more advance CKD stage.

Ergocalciferol is a synthetic derivative of 25-OH-D recommended for the treatment of vitamin D deficiency, hypoparathyroidism, vitamin D resistant rickets, and hypophosphatemia. K/DOQI clinical practice guidelines for bone metabolism and disease in CKD recommended supplementation with ergocalciferol in patients whose 25-OH-D level less than 30 ng/mL at a dosage of 50,000 units weekly to monthly depending on the severity[9]. The reported side effects associated with high dose ergocalciferol in patients with normal renal function included hypercalcemia[12]. In the present study, ergocalciferol 40,000 units were used due to the availability of only 20,000 unit capsule in Thailand. High dose ergocalciferol supplementation was able to increase 25-OH-D levels after eight weeks of therapy in 95% of the patients. In 60% of the patients, 25-OH-D levels reached the normal limit of 30 ng/mL, which was similar to previous reports. Zisman et al observed normalization of 25-OH-D levels in 68.3% in CKD stage 3 and 67.9% in CKD stage 4 after at least six months of supplement[11].

In contrast to other reports that showed PTH lowering effect of ergocalciferol supplementation in CKD stage 3 patients[10,11], the authors did not find such effect in any of the CKD stages. It was believed that 25-0H-D restoration resulted in an increase in 1, 25-OH-D production, and thus the suppression of PTH especially in CKD stage 3 when there was sufficient kidney function for 1-alpha hydroxylation of 25-OH-D[11]. In a retrospective study by Al-Aly et al, the average 25-OH-D levels were 17.5 and 14.7 ng/mL in CKD stage 3 and 4 respectively, whereas in the present study the levels were 23.9 and 22.5 ng/mL[10]. It is possible that ergocalciferol supplementation in the presence of mild 25-OH-D deficiency might not significantly alter 1, 25-OH-D levels and thus resulting in no significant change in PTH or the dose of ergocalciferol was not high enough to bring about the rise in 1,25-OH-D levels. In addition, the duration of follow-up of eight weeks may be too short for the changes of PTH to occur. Another possibility is the tendency toward lower PTH levels in the present study comparing to others. PTH levels for CKD stage 3 and 4 in Al-Aly et al and Zisman et al were in the range of 150-175 and 160-350 pg/mL, respectively, whereas in the present study, the level was 84 and 105 pg/mL indicating milder hyperparathyroidism. Less 25-OH-D deficiency and relatively mild hyperparathyroidism might disguise the PTH lowering effect of ergocalciferol. Nevertheless, in a recent double-blind randomized controlled study by Chandra et al using cholecalciferol which is a more potent 25-OH-D supplement, the decrease in PTH in CKD stage 3 and 4 was present after 12 weeks of therapy when compared to the placebo group but the difference did not reach statistical significance[13]. Thus, the lowering effect of 25-OH-D supplement on PTH is variable and a larger randomized control study that monitors the changes in 1,25-OH-D levels as well as bone histology will be required.

In the present study, there was no side effect associated with the treatment. Serum calcium and phosphate remained unchanged in all CKD stages. There was no incidence of hypercalcemia or hyperphosphatemia. This finding is similar to other studies in CKD, hemodialysis and peritoneal dialysis patients that observed no adverse consequences associated with high dose 25-OH-D supplements[4,11,13-15]. The present study is limited by the observational nature as well as the small number of patients and the short duration of follow-up. 1,25,OH-D levels were not measured, therefore, reason for the absence of changes in PTH could not be ascertained. A larger randomized control trial designed to follow-up long term outcome such as CKD progression and mortality will provide insight into the benefits of 25-OH-D supplement. In conclusion, 25-OH-D deficiency is prevalent in this cohort of predialysis CKD patients. Ergocalciferol is safe and effective supplement of 25-OH-D in predialysis CKD.

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การให้ยา ergocalciferol ขนาดสูงในผู้ป่วยโรคไตวายเรื้อรังระยะก่อนการบำบัดทดแทนไต

ธนันดา ตระการวนิช, โอฬาร ชาลาภิภัท, สินี ดิษฐบรรจง, สาธิต คูระทอง, เกื้อเกียรติ ประดิษฐ์พรศิลป์, วาสนา สถิตย์จันทรากุล, ละออ ชัยลือกิจ

วัตถุประสงค์: *เพื่อศึกษาการขาด 25-hydroxyvitamin D (25-OH-D) ในผู้ป่วยโรคไตวายเรื้อรังระยะก่อนการบำบัดทดแทนไต และความสามารถของยา ergocalciferol ทางปากขนาดสูงในการเพิ่มระดับ 25-OH-D รวมไปถึงความปลอดภัยของการใช้ยาในผู้ป่วยกลุ่มนี้*

วัสดุและวิธีการ: *ผู้ป่วยโรคไตวายเรื้อรังจำนวน 56 คน ที่มาตรวจอย่างสม่ำเสมอที่แผนกผู้ป่วยนอกและมี glomerular filtration rate น้อยกว่า 60 mL/min/1.73m^2 ได้รับการตรวจระดับ 25-OH-D จากการวิเคราะห์เบื้องต้นพบว่าผู้ป่วย 44 คน มีภาวะขาด 25-OH-D ผู้ป่วยทั้ง 44 คนนี้ได้เข้าสู่การศึกษาแบบ prospective observational เพื่อประเมินความสามารถของ ergocalciferol ในการรักษาภาวะขาด 25-OH-D หลังจากติดตามผู้ป่วยไป 8 สัปดาห์ มีผู้ป่วย 37 คน ที่มา follow-up ครบ จึงได้ทำการวิเคราะห์ข้อมูลต่าง ๆ ของผู้ป่วย 37 คน ดังกล่าว*

ผลการศึกษา: *ระดับ 25-OH-D เฉลี่ยสำหรับผู้ป่วย 56 คน คือ 25.6 $\pm$ 8 ng/mL มีผู้ป่วย 44 คน (78.5%) ที่มีการขาด 25-OH-D และมีผู้ป่วย 4 คน (7.1%) ที่มีภาวะขาดอย่างรุนแรงกล่าวคือมีระดับ 25-OH-D น้อยกว่า 15 ng/mL ยา ergocalciferol สามารถเพิ่มระดับ 25-OH-D ได้ในผู้ป่วย 35 คน (95%) โดยมีระดับเพิ่มขึ้นจาก 22 $\pm$ 4.8 เป็น 34.5 $\pm$ 10.8 ng/mL ($p < 0.001$) จากการศึกษาไม่พบการเปลี่ยนแปลงของระดับแคลเซียมฟอสเฟต และ PTH ระหว่างและหลังจากการให้ยาไป 8 สัปดาห์ และไม่พบผลข้างเคียงอื่น ๆ*

สรุป: *ความชุกของการขาด 25-OH-D ในผู้ป่วยโรคไตวายเรื้อรังระยะก่อนการบำบัดทดแทนไตกลุ่มนี้มีระดับค่อนข้างสูง และการให้ยา ergocalciferol ขนาดสูงนั้นได้ผลดีในการเพิ่มระดับ 25-OH-D และมีความปลอดภัย*