APPROPRIATENESS OF PRESCRIBING ALFACALCIDOL IN SECONDARY HYPERPARATHYROIDISM IN DIALYSIS PATIENTS: A RETROSPECTIVE STUDY

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Secondary hyperparathyroidism (SHPT) is a common and progressive complication of chronic kidney disease (CKD), often intensifying as patients reach dialysis. Although alfacalcidol and other active vitamin D analogs are often used, improper administration can raise the risk of hypercalcemia and hyperphosphatemia. This study aimed to assess, using clinical criteria indicated by guidelines, whether alfacalcidol should be prescribed to hemodialysis patients with SHPT. Records of 136 adult patients treated in An-Naseria hemodialysis units were reviewed and analyzed using SPSS (version 26). The appropriateness of prescribing alfacalcidol was evaluated in accordance with KDIGO 2017 guidelines, taking into account levels of phosphate, calcium, and parathyroid hormone (PTH). Patients were divided into groups based on whether their prescriptions were appropriate or possibly inappropriate. Patients were 55.1% male and had an average age of 51.42 ± 11.5years. The majority of patients exhibited biochemical values (phosphate: 79.4%, calcium: 74.3%, and PTH: 77.2% normal) within goal ranges. 72 patients (52.9%) were categorized as potentially inappropriate for alfacalcidol medication, whereas 64 patients (47%) were recognized as having appropriate indications based on criteria consistent with guidelines. The mean PTH levels of patients in the appropriate group were substantially higher (923.14 ± 379.59 pg/mL) than those in the inappropriate group (274.71 ± 179.69 pg/mL, $p < 0.001$). Age, sex, calcium, and phosphate levels did not significantly correlate with prescription appropriateness. This cohort may have a significant percentage of alfacalcidol prescriptions that may not follow current guidelines. The sensible use of vitamin D analogs in hemodialysis patients may be improved by better adherence to evidence-based guidelines and routine biochemical monitoring.

Keywords: hyperparathyroidism, dialysis, parathyroid, vitamin D, alfacalcidol

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Compliance with ethical standards: this retrospective study was conducted in accordance with the ethical standards, the research was approved by the Research Ethics Committee of Al-Ayen Iraqi University under approval number AUIQ-REC-2025-003. Due to the retrospective nature of this study using anonymized patient records, the requirement for informed consent was waived by the ethics committee.

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ЦЕЛЕСООБРАЗНОСТЬ НАЗНАЧЕНИЯ АЛЬФАКАЛЬЦИДОЛА ПРИ ВТОРИЧНОМ ГИПЕРПАРАТИРЕОЗЕ У ПАЦИЕНТОВ НА ГЕМОДИАЛИЗЕ: РЕТРОСПЕКТИВНОЕ ИССЛЕДОВАНИЕ

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Вторичный гиперпаратиреоз (ВГПТ) — распространенное прогрессирующее осложнение хронической почечной недостаточности (ХПН), тяжесть которого часто возрастает у пациентов на гемодиализе. Хотя альфакальцидол и другие аналоги активного витамина D используют часто, их неправильное применение может увеличить риск гиперкальциемии и гиперфосфатемии. Целью исследования было оценить целесообразность назначения альфакальцидола пациентам, находящимся на гемодиализе и страдающим ВГПТ, используя указанные в рекомендациях клинические критерии. Данные 136 взрослых пациентов, проходивших лечение в центрах гемодиализа г. Насирия, были рассмотрены и проанализированы с использованием программного обеспечения SPSS (версия 26). Целесообразность назначения альфакальцидола оценивали в соответствии с рекомендациями KDIGO 2017, учитывая уровень фосфора, кальция и паратиреоидного гормона (ПТГ). Пациентов разделили на группы: с целесообразным или потенциально нецелесообразным назначением. Среди пациентов 55,1% были мужчинами 51,42 ± 11,5 лет. У большинства пациентов биохимические показатели (фосфор: 79,4%, кальций: 74,3% и ПТГ: 77,2% от нормы) были в пределах целевых диапазонов. У 72 пациентов (52,9%) назначение альфакальцидола признано нецелесообразным, а у 64 (47%) — целесообразным на основании соответствующих критериев из рекомендаций. Средний уровень ПТГ в группе с целесообразным назначением был значительно выше (923,14 ± 379,59 пг/мл) по сравнению с таковым в группе с нецелесообразным назначением (274,71 ± 179,69 пг/мл, $p < 0.001$). Значимая корреляция между возрастом, полом, уровнем кальция и фосфора и целесообразностью назначения отсутствовала. В этой группе пациентов значительная часть назначений альфакальцидола может не соответствовать действующим рекомендациям. Показатели разумного применения аналогов витамина D у пациентов на гемодиализе можно улучшить за счет более строгого следования научно обоснованным рекомендациям и регулярного мониторинга биохимических показателей.

Ключевые слова: гиперпаратиреоз, диализ, паращитовидная железа, витамин D, альфакальцидол

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Secondary hyperparathyroidism is one of the commonly reported complications in patients diagnosed with chronic renal failure where dialysis is performed routinely [1]. This known disorder is typified by elevated secretion of PTH accompanied by hyperplasia of parathyroid gland, is primarily attributed to phosphate retention and the reduced capability to generate 1, 25 dihydroxy vitamin D3, calcitriol. These factors directly and indirectly affect the function of parathyroid gland [2].

Depleted serum concentration of 1, 25-dihydroxy vitamin D3 decreases both the intestinal transport and bone mobilization calcium, then the increased serum phosphate cause diminution to free serum calcium which contributes to the development of hypocalcemia. Furthermore, the parathyroid glands initially respond to the depleted calcium levels via elevating the synthesis & the secretion of PTH, but, on the other hand prolonged hypocalcemia subsequently leads to hyperplasia of parathyroid gland [3]. Additionally, hyperphosphatasemia can directly promote the synthesis of PTH, elevate the hyperplasia of parathyroid, and reduce the number of calcium receptors. The reduction of serum 1,25-dihydroxy vitamin D3 concentration decrease its direct suppressive influences on the gene transcription of PTH and the hyperplasia of parathyroid cell also, may play role in reducing the levels of receptors for calcium and vitamin D [4].

Prevention and treatment of secondary hyperparathyroidism require both the control of serum phosphate and the restoration of 1, 25-Dihydroxy 2D3 levels. It is crucial to recall that parallel managing of concomitant hypocalcemia and hyperphosphatemia along with avoiding hypercalcemia are essential, as advocated by different sources, especially by the updated 2017 kidney disease: (KDIGO) CKD-Mineral and Bone Disorder guidelines [5].

According to resources, 1, 25-dihydroxy vitamin D have an inhibitory influence on the gene of PTH, an upregulatory influence on the calcium sensing receptors expression, along with autologous, upregulation of the receptors of vitamin D, all affect biosynthesis and secretion of PTH. Moreover, these known direct influences on the parathyroid glands, the hormone which has both phosphataemic & calcaemic effects, furthermore its important for the suppression and the regulation of PTH concentrations, also it affects the skeleton and several cell functions especially, these depending on calcium regarding their homeostatic regulations [4].

In patients diagnosed with chronic uremia, depleted kidney functions, diminished kidney mass, and, obviously reduced renal 1-α-hydroxylase activities, as confirmed by the diminished plasma levels of 1,25-dihydroxy vitamin D which was observed in several studies performed on patients with CKD [6]. Consequently, vitamin D (active form) is considered as one of the most essential elements of the therapy of renal osteodystrophy regarding its crucial pharmacological and physiological activity on parathyroid cell function and proliferation [7].

On many occasions, vitamin D has been successfully used but unfortunately, it is usually precluded by the reported narrow therapeutic index for PTH suppression without causing hypercalcemia, particularly when used with calcium [8]. The PTH suppression is usually associated with higher adynamic bone disease prevalence. For these reasons, upon treating hyperphosphatemia, the values of PTH which are continually more than 2 to 9 folds of the PTH assay upper limit were treated [9].

This study sought to assess the appropriateness of alfacalcidol prescribing for SHPT in a cohort of hemodialysis patients by comparing actual prescription patterns against established, guideline-based clinical criteria. Although the 2017 KDIGO guidelines offer clear recommendations, the translation of these guidelines into clinical practice can vary.

METHODS

In this retrospective study, we collected 150 patient profiles from March 2025 to January 2026, of whom 136 adult patients diagnosed with secondary hyperparathyroidism and receiving vitamin D supplement (alfacalcidol) in hemodialysis units in An-Naseria Hospital were included.

Inclusion criteria

The patients treated by at least one course of vitamin D supplement were considered.

Also, before deciding to treat secondary hyperparathyroidism in dialysis patients using vitamin D, it's important that the patient has met the following criteria:

1) > 18 years old;
2) diagnosed with SHPT;
3) received at least 1 course of alfacalcidol.

Exclusion criteria

Medication records with incomplete information about our main variables were excluded.

Patients were categorized for the primary analysis based on whether alfacalcidol use was "indicated" or "not indicated" using standards that were in line with the 2017 KDIGO guidelines [5]. A patient had to have a specific, documented reason for therapy in order to be classified as "indicated," which was defined as:

PTH Level: Either a steadily increasing trend on serial readings above the target range (2–9 times the ULN) or intact PTH (iPTH) levels were > 585 pg/mL (indicating 9 times the upper limit of normal for the local assay [upper limit of normal: 65 pg/mL]).

Controlled Phosphorus and Calcium: According to KDIGO criteria, the patient did not develop uncontrolled hyperphosphatemia (Phosphorus > 5.5 mg/dL) or hypercalcemia (Corrected Calcium > 2.63 mmol/L) when alfacalcidol was started.

The "not indicated" group included patients who received alfacalcidol but did not fit these criteria (e.g., PTH levels < 585 pg/mL without a rising trend or uncontrolled hyperphosphatemia/hypercalcemia).

The research was approved by Ethical approval number: AUIQ-REC-2025-003 from research Ethics Committee Alayen Iraqi University.

The data were collected from the archived files in the hemodialysis units in nephrology department of An-naseria Hospitals.

Statistical analysis

The data was statistically analyzed by considering 0.05 as alpha error and 95% as confidence interval. The data were presented as (mean ± SD). Percentage and frequency described the baseline and demographic factors. Fisher's exact test was chosen for the categorical comparisons, otherwise *t*-test was applied.

RESULTS

We performed our study on 136 patients. Those patients were separated according to KDIGO-aligned criteria into 2 groups,

Table 1. Demographic data & biochemical factors of secondary hyperparathyroidism patients

Variables	Number (*n* = 136) %
Sex Male Female	 75 55.1 61 44.9
Age (mean ± SD)	51.42 ± 11.5
ПТГ (пг/мл) Normal Abnormal	 105 77.2 31 22.8
Corrected calcium level (mmol/l) Normal Abnormal	 101 74.3 35 25.7
Phosphorus level (mg/dl) Normal Abnormal	 108 79.4 28 20.6

firstly, group 1 (vitamin D indicated) included patients who met all our three including criteria. Secondly, group 2 (vitamin D not indicated) met one or more of the previously mention criteria. Regarding the demographic data of the study population, we found that the mean age of our patients was 51.42 ± 11.5. The percent of males and females in our study were 55.1 and 44.9%, respectively.

The biochemical data is also shown in Table 1. We observed that 77.2% PTH level within the normal level of dialyzed patients, the abnormal level was found in 22.8%. We found that corrected calcium level was normal in 74.3% of the patients and abnormal in 25.7%. Regarding phosphorus level, 79.4% of the patients were normal while 20.6 were abnormal.

Biochemical and dialysis variables in vitamin D indicated and non-indicated patients by mean and standard were investigated and shown in Table 2. It was found that mean of PTH was high in indicated patients (923.14 ± 379.59), this mean decreased sharply in not indicated patients (274.71 ± 179.69). Conversely, the mean of corrected calcium level was higher in Not Indicated group than indicated one, where it was 2.87 ± 0.41 and 1.65 ± 0.49, respectively. Regarding Phosphorus level, almost no difference was observed between indicated & non-indicated patients, where the mean was 3.61 ± 0.59 and 4.97 ± 1.3, respectively.

Table 3 illustrates the distribution and the association between PTH level (pg/ml) and vitamin D indicated and not-indicated patients. As shown, PTH was normal in the majority of the not indicated group while 34.4% of the patients in the indicated group showed abnormal values. We found highly statistically significant different between vitamin D indicated & not-indicated in association with PTH, where *p*-value was < 0.001*.

As shown in Table 4, we found that there was slight difference between normal corrected calcium level in indicated and not-indicated groups, where it was 81.9% in not indicated group and 64.1% in Indicated group. The same observation was noticed regarding the abnormal level it was 35.9% and 18.1% of patients in indicated and not-indicated groups, respectively. No significant different was detected between indicated & not indicated groups regarding corrected calcium level where *p*-value = 0.919.

Table 5 showed the distribution of normal and abnormal phosphorus level (mg/dl) between indicated and not indicated groups. We found that the normal Phosphorus level was detected in 96.4% in not indicated group and 79.7% in the indicated group. Only 30.6% and 20.3%was abnormal in the not indicated & indicated group, respectively. No significant different was detected between vitamin D indicated & not-indicated in association with phosphorus level, where *p*-value = 0.468.

DISCUSSION

Vitamin D therapy for secondary hyperparathyroidism was applied for several decades, and there is different clinical practices and guidelines to support this. But, uncertainty regarding the clinical significance was raised [10]. Questions

Table 2. Biochemical and dialysis variables in vitamin D indicated and non-indicated patients

Variable	Indicated (Group 1) (Mean ± SD)	Not Indicated (Group 2) (Mean ± SD)
PTH (pg/ml)	923.14 ± 379.59	274.71 ± 179.69
Corrected calcium level (mmol/l)	1.65 ± 0.49	2.87 ± 0.41
Phosphorus level (mg/dl)	3.61 ± 0.59	4.97 ± 1.3

Table 3. PTH level (pg/ml) in association with vitamin D indicated and not-indicated patients

PTH (pg/ml)	Intervention					
	Not indicated (Group2)		Indicated (Group1)		Total	
	N	%	N	%	N	%
Normal	65	90.3	22	34.4	87	64
Abnormal	7	9.7	42	65.6	49	36
Total	72	100	64	100	136	100
P-value	< 0.001*					

Note: Chi-square test was utilized; * — P-value is significant.

Table 4. Corrected calcium level (mmol/l) in association with vitamin D indicated and not-indicated patients

Corrected calcium level (mmol/l)	Intervention					
	Not indicated (Group2)		Indicated (Group1)		Total	
	N	%	N	%	N	%
Normal	59	81.9	41	64.1	100	73.5
Abnormal	13	18.1	23	35.9	36	26.5
Total	72	100	64	100	136	100
P-value	0.919					

Note: Chi-square test was utilized.

Table 5. Phosphorus level (mg/dl) in association with vitamin D indicated and not-indicated patients

Phosphorus level (mg/dl)	Not indicated (Group2)		Indicated (Group1)		Total	
	N	%	N	%	N	%
Normal	50	96.4	51	79.7	101	84.3
Abnormal	22	30.6	13	20.3	35	25.7
Total	72	100	64	100	136	100
P-value	0.468					

Note: Chi-square test was utilized.

such as; which kind of vitamin D should be used, in what patient, and, when to be used was importatnt to answer.

In our study, Regarding Demographic data of secondary hyperparathyroidism patients, the mean age of patients was 51.42. It was observed that the percent of the males was higher than females, where, 55.1% was males and 44.9% was females. Almost the same result was detected by Gupta et al., who found that males 55% and 45% of patients were males and females, respectively. And the age mean was higher than ours (60.4%) [11]. Xu et al., reported a higher percent of males than females where 62% of patients were males and 38% was females, the mean age of their patients was 66 years old [12] .

In our result patients we found that PTH was higher in patients who need vitamin D supplementation (923.14) and it was much lower (274.71) in none indicated patients. It was observed that the corrected calcium level was lesser in vitamin D indicated group (1.65) compared to vitamin D not indicated group (2.87). On the other hand, the phosphorus level was higher in the not indicated group (4.97) than the indicated group (3.61) almost the same in our study. De Vincentis reported that while vitamin D levels were above normal for the whole period of high-dose treatment, serum PTH showed a declining trend, and readings that are close to the lower end of the typical range may be warning signs of intoxication. This parameter gradually declined throughout the first phase of cholecalciferol supplementation in agreement with the declining serum PTH trend, taking into account the trend of serum calcium [13].

In our study, we didn't detect significant relationship between age, with regard to indicated & not indicated vitamin D. This result was in accordance with El-Arbagy et al., who showed no significant association between age and vitamin D [14].

In our study we found there is no significant correlation between calcium, phosphorus level, with regard to indicated and not indicated vitamin D. Our findings were in agreement with El-Arbagy et al., reported that there is no significant association between the vitamin D supplementation and the level calcium and phosphorus [14]. Additionally, Bellavia et al., found that the effect of plasma phosphorus concentration is independent of the level of plasma calcium levels concentration or vitamin D activation [15] It was reported by different studies that there wasn't any relationship between Ca and vitamin D supplementation [16, 17]. On the other hand, other documented cases lack information regarding baseline renal function. Consequently, it makes sense to believe that having adequate renal function at baseline plays a significant role in postponing the occurrence of toxicity due to high dose dosing with vitamin D. This is at odds with residual chronic kidney failure was recorded in several cases [13, 18].

In our research, we detected significant correlation regarding PTH levels in indicated and not indicated vitamin D. These results were in line with some other studies who reported that PTH correlated significantly with vitamin D [19]. Also, Wolf et al., claimed that vitamin D state is weakly correlated with serum levels of PTH[20]. In contrast to our study, El-Arbagy et al., and Coen et al. who reported that no significant association between the vitamin groups for what concerns PTH [14]. The intricacy of the therapeutic decision-making process may not be fully captured by the levels of these indicators at a single time point, as they are frequently controlled concurrently with other therapies (such as phosphate binders and calcimimetics).

Based on KDIGO 2017, our updated analysis indicates that many patients in this group were given alfacalcidol without fulfilling the required criteria. There are various reasons why this pattern of possible usage is concerning. First, using active vitamin D analogs can depress PTH to suboptimal levels, raising the risk of adynamic bone disease in patients with well-controlled PTH, especially those who are adynamic or have limited bone turnover [8]. Second, these drugs may worsen hyperphosphatemia and hypercalcemia, which are separate risk factors for dialysis patients' mortality and cardiovascular calcification [21, 22] .

Study limitations

There are a number of limitations to this study. First, generalizability is restricted and causal inference is not possible due to the retrospective, single-center design. Second, statistical power was diminished by the indicated group's small sample size. Third, as advised by KDIGO 2017 guidelines, native vitamin D status was not assessed before alfacalcidol commencement since serum 25-hydroxyvitamin D levels were not measured. Lastly, specific information regarding the duration, dosage, and concurrent medicines of alfacalcidol was lacking.

CONCLUSIONS

In our study, 79.4% of patients had normal PTH (77.2%), corrected calcium (74.3%), and normal phosphorus levels (79.4%) patients — yet vitamin D was still prescribed in the majority of cases, despite not being clinically indicated. This finding strongly suggests that vitamin D supplementation was unnecessary for most patients and was being used outside evidence-based treatment protocols. Collectively, the results indicate a clear pattern of vitamin D misuse among hemodialysis patients with secondary hyperparathyroidism. Recommendation: routine monitoring of vitamin D, calcium, PTH, and phosphorus levels is essential to prevent unnecessary vitamin D supplementation. These parameters may need to be assessed more frequently such as monthly when therapeutic adjustments are made that could influence their values. Decisions to initiate or modify vitamin D therapy should always be guided by these laboratory results, ensuring appropriate use and reducing the risk of misuse.

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