

## Introduction

In comparison to other individuals, patients with chronic kidney disease (CKD) are more likely to have vitamin D deficiency.<sup>1</sup> Vitamin D deficiency is associated with increased serum parathyroid hormone (PTH), low bone mineral density,<sup>2, 3</sup> and increased serum phosphorus (P) and calcium (Ca).<sup>4</sup> Paricalcitol and doxercalciferol are active vitamin D sterols indicated for prevention/treatment of secondary hyperparathyroidism associated with CKD.<sup>5, 6</sup> The relative effectiveness of various forms of intravenous vitamin D is unknown because few comparative effectiveness studies have been conducted within this therapeutic area.

## Methods

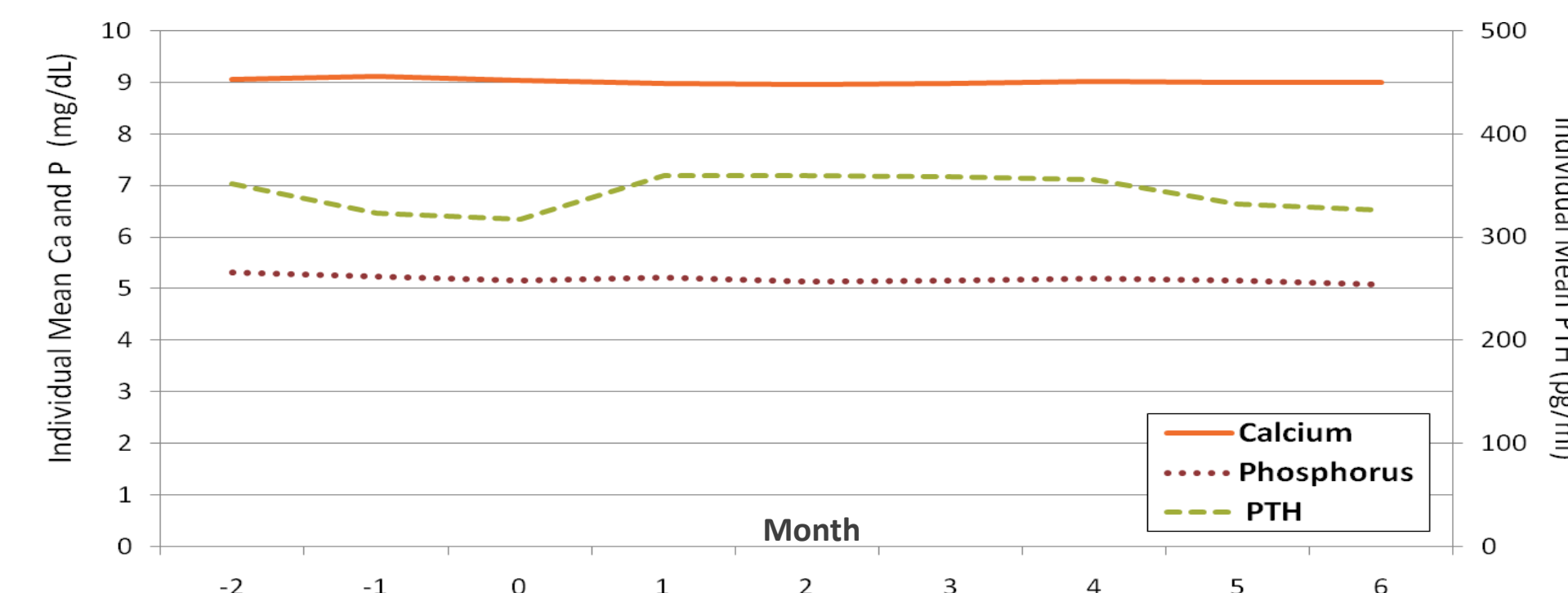
- The aim of this single-arm, prospective study was to measure pre/post levels of P, Ca and PTH to assess non-inferiority of clinical outcomes in dialysis facilities that switched all patients from intravenous paricalcitol to intravenous doxercalciferol.
- Patients' monthly lab values for 2 months before switch were compared to 6 months following switch.
- Facility-level comparisons were made 6 months before to 6 months after switch.
- **Endpoints**
  - *Primary:* Patients' mean serum levels for PTH, Ca and P.
  - *Secondary:* Percent patient-time within KDIGO targets for PTH (150-600 pg/mL); percent patient-time within KDOQI target range for Ca (8.4-9.5 mg/dL) and P (3.5-5.5 mg/dL); patient hospitalizations (admissions per patient-year).
- **Analysis**
  - Both analyses used mixed models; patient-level models included a random effect for dialysis center.
  - Pre-set criteria for inferiority: Rise in P or Ca  $\geq$  0.5 mg/dL, or rise in PTH  $\geq$  100 pg/mL.

## Results

### Characteristics of Patients at Participating Facilities at Date of Facility Switch

Continuous Variables	n	Mean (SD)
Age (yr)	828	59.4 (14.9)
Vintage (yr)	828	3.2 (3.7)
Body Mass Index	790	26.8 (6.6)
Categorical Variables	n	%
Male	490	59.2
Race		
African-American	221	26.7
Asian/Pacific Islander	116	14.0
Caucasian	310	37.4
Hispanic	150	18.1
Native American/Alaskan	5	0.6
Other	26	3.1
Primary Cause of ESRD		
Diabetic kidney disease	379	45.8
Hypertensive kidney disease	292	35.3
Polycystic kidney disease	11	1.3
Other cause	146	17.6
Access Type		
Fistula	411	50.0
Graft	141	17.1
Catheter	270	32.9

### Monthly Patient-Level Means Before and After Switch



- To confirm patient-level findings, facility-level patient mean time within range was calculated.

### Facility-Level Proportion of Patient-Time Within Range for Phosphorus, Calcium and PTH

Parameter	Range	Mean% of Patient-Time in Range		
		Months -2 and -1	Month 0	Months 1-6
Phosphorus	< 3.5 mg/dL	7.6	9.5	9.1
	3.5-5.5 mg/dL	<b>56.3</b>	<b>57.4</b>	<b>58.2</b>
	> 5.5 mg/dL	35.8	32.8	32.3
Calcium	< 8.4 mg/dL	9.1	12.7	11.9
	8.4-9.5 mg/dL	<b>74.4</b>	<b>73.0</b>	<b>75.7</b>
	> 9.5 mg/dL	16.3	14.0	11.8
PTH	< 150 pg/mL	16.9	20.1	13.4
	150-600 pg/mL	<b>58.6</b>	<b>60.4</b>	<b>60.6</b>
	> 600 pg/mL	7.5	6.1	6.5

Abbreviation: PTH = parathyroid hormone; NOTE: In-range values are in bold type.

- Facility-level analyses showed results similar to individual-level analysis. (Figure 1 and Table 2)
- There were no meaningful differences seen in facility-level mean values for P, Ca or PTH.
- Facility-level means for patient-time within target range for P, Ca and PTH were constant or higher across time frame of study.

### Rates of Hospitalization

- Patient hospitalization rates were similar pre- and post-switch:
  - Pre: 1.77 (95% CI: 1.50, 2.04) admissions/patient-year
  - Post: 1.64 (95% CI: 1.49, 1.79) admissions/patient-year
- Mean hospitalized days/patient-year were similar between periods:
  - Pre: 14.54 (95% CI: 12.43, 16.66) days/patient-year
  - Post: 13.52 (95% CI: 12.32, 14.71) days/patient-year

## Conclusions

- No increase in patient-level mean P, corrected Ca or intact PTH, and no decrease of time within range for these measures, was seen following switch to doxercalciferol.
- Patient-level findings were consistent with the facility-level analysis.
- No change in hospitalizations or hospitalized days/patient-year were found.
- Outcomes with doxercalciferol were not inferior to outcomes with paricalcitol.

## References

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