

Management of Secondary Hyperparathyroidism Among Patients Who Transition From Daily At-Home to 3X Weekly Oral Cinacalcet Given In-Center

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Disclosures

- SK, SS, AGW, GM, SMB, and FT are employees of DaVita Clinical Research
 - SMB's spouse is an employee of AstraZeneca
- GA and DB are employees of DaVita, Inc.

Background

- Results of a small phase 1 clinical trial demonstrated the safety and potential utility of 3X weekly in-center administration of cinacalcet to control secondary hyperparathyroidism (SHPT) in hemodialysis (HD) patients.
- Moreover, a larger observational study demonstrated comparable control of SHPT among HD patients who initiated 3X weekly cinacalcet in-center to those who initiated cinacalcet at home.
- The present study assessed the effectiveness of 3X weekly in-center cinacalcet among HD patients who transitioned from cinacalcet administered daily at home in the management of SHPT.

Patients

- Patients included in these analyses were:
 - ≥ 18 years of age
 - Receiving in-center hemodialysis
 - Not VA beneficiaries
 - Had Medicare as primary insurance
 - Had a physician order to transition from cinacalcet at-home to cinacalcet given in-center between 01 Jul 2018 and 31 December 2019

Data and Analysis

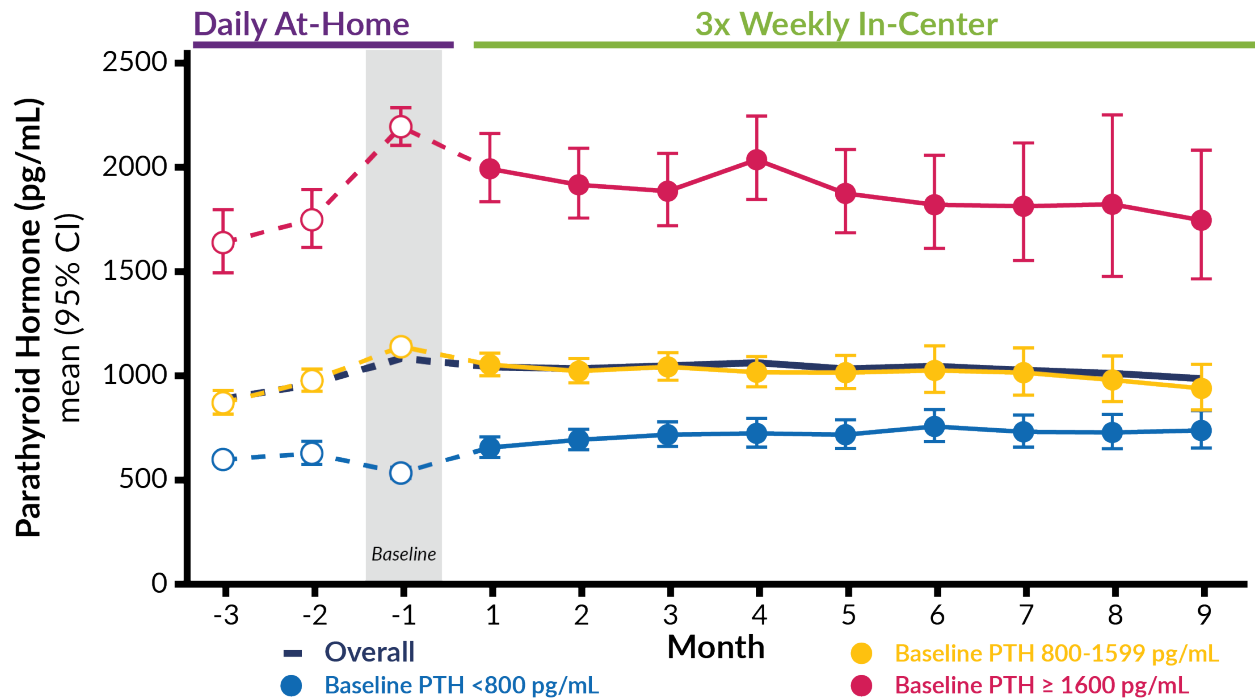
- Data were derived from the electronic medical records of the large dialysis organization
- Baseline was defined as the month prior to transition to in-center cinacalcet was (month -1)
- Patients were followed forward in time up to 9 months after baseline or until loss to follow-up (death, transfer, transplant, withdrawal from dialysis, renal recovery, modality change) or end of study (31 December 2019)
- The following biochemical outcomes were quantified by calculating modeled means and 95% confidence intervals from linear models:
 - Parathyroid hormone levels
 - Calcium levels
 - Phosphorus levels
- Hypocalcemia events were defined as serum calcium levels <8.4 mg/dL

Baseline Characteristics - 1

	Overall N = 874	PTH <800 pg/mL N = 388	PTH 800-1599 pg/mL N = 330	PTH ≥ 1600 pg/mL N = 156
Age , years, mean ± SD	59.1 ± 14.1	62.0 ± 13.2	58.3 ± 14.1	53.5 ± 14.3
Female , n (%)	376 (43.0)	167 (43.0)	142 (43.0)	67 (42.9)
Race , n (%)				
White	228 (26.1)	107 (27.6)	76 (23.0)	45 (28.8)
Black	479 (54.8)	189 (48.7)	195 (59.1)	95 (60.9)
Other/unknown/missing	167 (19.1)	19 (92.0)	92 (23.6)	24 (59.0)
Vascular access type , n (%)				
AVF	631 (72.2)	285 (73.5)	245 (74.2)	101 (64.7)
AVG	160 (18.3)	78 (20.1)	58 (17.6)	24 (15.4)
CVC	83 (9.5)	25 (6.4)	27 (8.2)	31 (19.9)
Diabetes , n (%)	615 (70.4)	283 (72.9)	239 (72.4)	93 (59.6)
CCI , mean ± SD	5.1 ± 1.8	5.5 ± 1.8	5.0 ± 1.7	4.5 ± 1.8
1,25-hydroxyvitamin D use , n (%)	792 (90.6)	357 (92.0)	305 (92.4)	130 (83.3)
PTH , pg/mL				
mean ± SD	1105 ± 684	513 ± 194	1140 ± 213	2194 ± 577
median [p25, p75]	979 [621, 1437]	544 [376, 676]	1121 [968, 1308]	2008 [1785, 2369]
Calcium , mg/dL, mean ± SD	9.1 ± 0.7	9.1 ± 0.8	9.0 ± 0.7	9.1 ± 0.7
Phosphorus , mg/dL, mean ± SD	6.6 ± 1.9	6.1 ± 1.7	6.8 ± 1.9	7.6 ± 2.0
Albumin , g/dL, mean ± SD	3.9 ± 0.3	3.9 ± 0.4	3.9 ± 0.4	3.9 ± 0.3

Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; CCI, Charlson comorbidity index; CVC, central venous catheter; PTH, parathyroid hormone; SD, standard deviation.

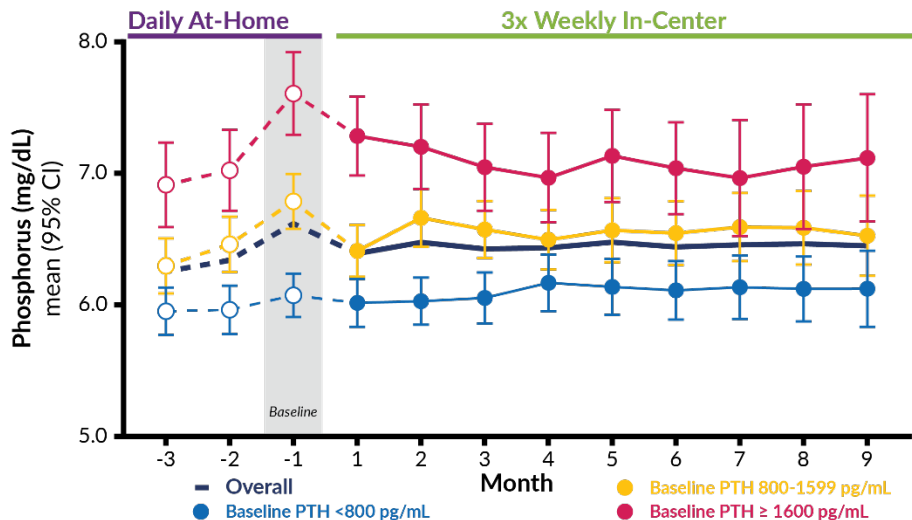
Parathyroid Hormone



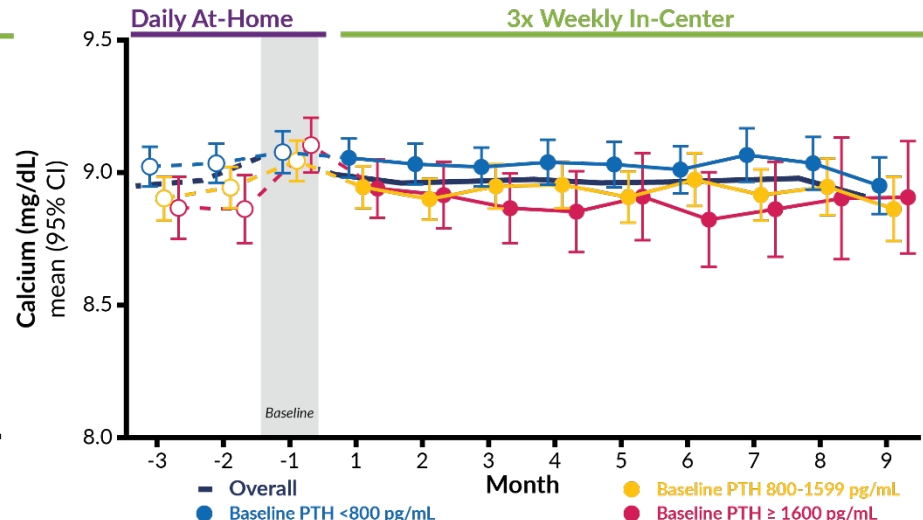
- Overall, PTH levels were stable after transition, irrespective of baseline PTH
 - Among patients with baseline PTH <800 pg/mL, PTH levels initially increased but stabilized after transition
 - Among patients with baseline PTH 800 to 1599 pg/mL and PTH ≥ 1600 pg/mL, PTH levels initially decreased but then stabilized following transition

Phosphorus and Calcium

Phosphorus

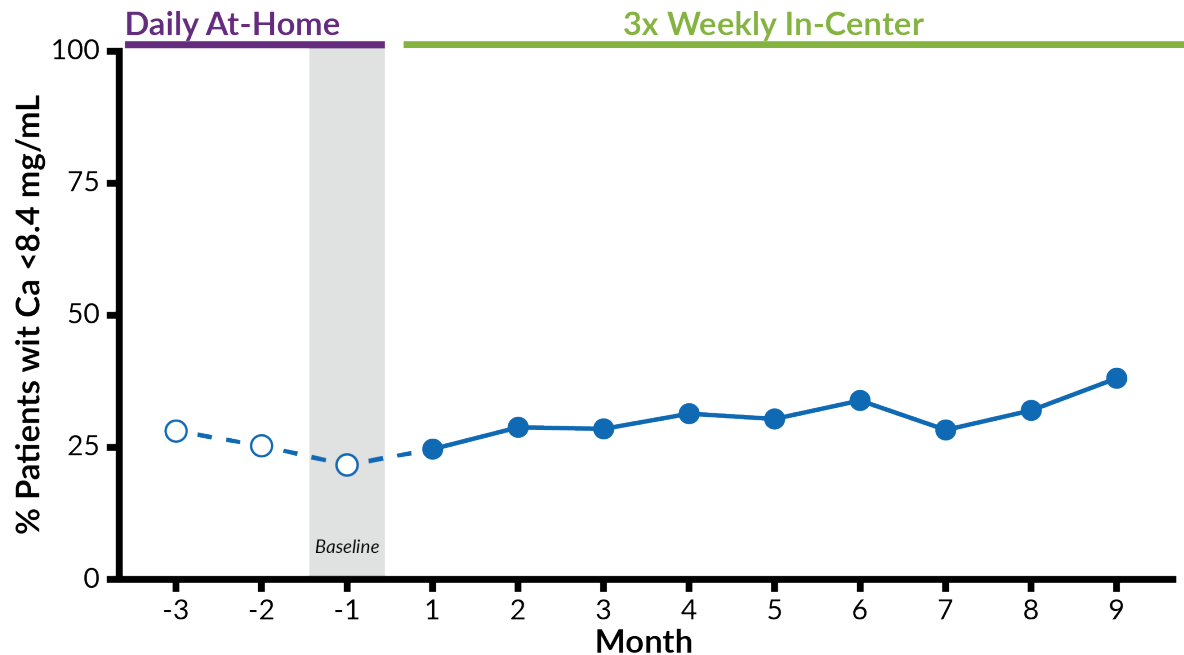


Calcium



- Phosphorus and calcium levels were generally stable for all patients following transition

Hypocalcemia Events



- Hypocalcemia (calcium < 8.4 mg/mL) was observed in approximately 25% to 38% of patients during follow-up.

Conclusion and Limitations

- Conclusions
 - These results suggest that SHPT can be stably maintained by transitioning patients from daily at-home cinacalcet to cinacalcet given in-center 3X per week
 - We postulate that increased prescription adherence is the likely factor mediating this effect
- Limitations
 - Analyses were not adjusted for patient baseline characteristics
 - The study sample size was relatively small and follow-up was limited to 9 months