Comparative Effectiveness of Cinacalcet Delivered Daily at-Home Versus Three Times Weekly In-Center

Steph Karpinski, MS, MA[1,2]; Gilbert Marlowe, BS[1,2]; Carey Colson, MBA[1,2]; Kathryn Husarek, PhD[1,2]; Scott Sibbel, PhD, MPH[1,2]; Vishal Ratkalkar, MD[2,3]; Francesca Tentori, MD, MS[1,2]; Steven M. Brunelli, MD, MSCE[1,2]

[1]DaVita Clinical Research, Minneapolis, MN; [2]DaVita Patient Safety Organization, Denver, CO; [3]Georgia Renal and Hypertension Care, Newnan, Georgia, USA

Introduction

- Chronic kidney disease-mineral and bone disorder (CKD-MBD) is a common syndrome in end-stage kidney disease (ESKD) and marked by dysregulation of calcium (Ca), phosphorus (P), and parathyroid hormone (PTH).
- A recent review of the evidence suggests that the treatment of CKD-MBD should be based on better control of all 3 elements and leverage existing pharmacological therapies, including phosphate binders, active vitamin D receptor activators (VDRAs) and calcimimetics.[1]
- Cinacalcet is an oral calcimemetic that is typically prescribed as a daily therapy taken at home.
- Concerns about drug adherence have been raised in the context of high pill burden faced by ESKD patients.
- Recent clinical trials have provided evidence that administration of cinacalcet at the dialysis center three times a week might be a safe and effective treatment option.

Objective

In this study we sought to evaluate the comparative effectiveness of cinacalcet delivered daily at home versus three times weekly in-center in a contemporary, "real-world" cohort of hemodialysis patients.

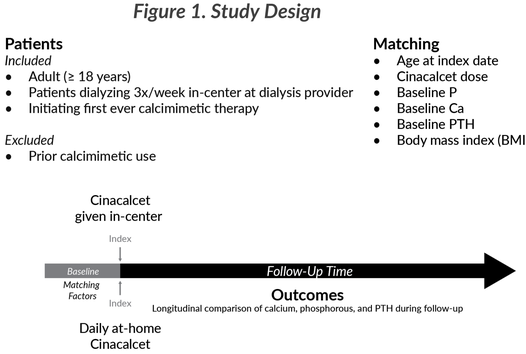
Methods

- Dialysis provider data: Jan 01, 2008 - Sept 30, 2022.
- Study Design: retrospective, 1:1 matched cohort study:
  - Matched on relevant clinical and pharmacologic characteristics (Figure 1).
  - Exposed group: cinacalcet given in–center three times weekly.
  - Nonexposed group: prescribed cinacalcet at home.
- Primary outcome of interest was the proportion of patients achieving triple control of Ca, P, and PTH.
  - Control is defined as: Ca value within 8.4-10.2 mg/dL, P value within 3.5-5.3 mg/dL, PTH value within 150-600 pg/mL.
- Secondary outcomes are the proportion of patients achieving single control of Ca, P, or PTH.
- All outcomes were estimated using generalized linear mixed models with a random slope for month of follow-up to account for repeated measures within subjects.

Methods, continued

- Patients were followed until a censoring event or administratively censored 12 months after baseline.

Figure 1. Study Design



Results

Table 1. Baseline Patient Characteristics

	Overall		In-center		At-home	
	N	(%)	N	(%)	N	(%)
Patients	2,894	100	1,447	100	1,447	100
Race / Ethnicity						
Asian	132	4.6	55	3.8	77	5.3
Black	1,204	41.6	631	43.6	573	39.6
Hispanic	516	17.8	248	17.1	268	18.5
White	799	27.6	397	27.4	402	27.8
Other/ unknown	243	8.4	116	8.0	127	8.8
Female	1,258	43.5	628	43.4	630	43.5
History of Diabetes	2,040	70.5	1,043	72.1	997	68.9
Etiology of ESKD						
Diabetes	1,133	39.1	591	40.8	542	37.5
Hypertension/large vessel disorder	704	24.3	351	24.3	353	24.4
Other	1,057	36.6	505	34.9	552	38.1

Results, continued

Table 2. Baseline Clinical/Demographic Patient Characteristics

	Overall		In-center		At-home	
	N	Median (IQR)	N	Median (IQR)	N	Median (IQR)
Parathyroid hormone (pg/mL)	2,894	791 (673, 946)	1,447	791 (673, 946)	1,447	791 (673, 946)
Phosphorous (mg/dL)	2,894	5.9 (5.1, 7.0)	1,447	5.9 (5.1, 7.0)	1,447	5.9 (5.1, 7.0)
Calcium (mg/dL)	2,894	9.1 (8.8, 9.5)	1,447	9.1 (8.9, 9.5)	1,447	9.1 (8.8, 9.5)
Age (years)	2,894	63 (55, 71)	1,447	64 (56, 71)	1,447	63 (55, 71)
Body mass index (kg/m^2)	2,892	28.7 (25.1, 33.0)	1,446	28.6 (25, 32.8)	1,446	28.8 (25.2, 33.3)
Vintage (years)	2,894	2.1 (0.8, 4.2)	1,447	2.3 (0.9, 4.2)	1,447	2.0 (0.7, 4.4)

Table 3. Baseline Pharmacologic Characteristics

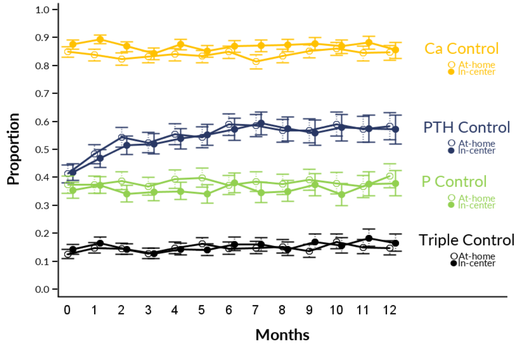
	Overall		In-center		At-home	
	N	(%)	N	(%)	N	(%)
VDRA use						
No	1,029	35.6	380	26.3	649	44.9
Yes	1,865	64.4	1,067	73.7	798	55.1
Phosphate binder [Ca, non-Ca][1]						
No, No	1,064	36.8	456	31.5	608	42.0
No, Yes	1,266	43.7	666	46.0	600	41.5
Yes, No	405	14.0	244	16.9	161	11.1
Yes, Yes	159	5.5	81	5.6	78	5.4
Triple control [PTH, P, Ca][2]						
No, No, No	127	4.4	65	4.5	62	4.3
No, No, Yes	1,734	59.9	866	59.8	868	60.0
No, Yes, No	26	0.9	13	0.9	13	0.9
No, Yes, Yes	704	24.3	353	24.4	351	24.3
Yes, No, No	18	0.6	9	0.6	9	0.6
Yes, No, Yes	168	5.8	83	5.7	85	5.9
Yes, Yes, No	4	0.1	2	0.1	2	0.1
Yes, Yes, Yes	113	3.9	56	3.9	57	3.9

VDRA, Vitamin D Receptor Activator
[1] Phosphate binder: a Ca value of "Yes" is defined as the presence of a calcium-containing binder during the baseline period, and a non-Ca value of "Yes" is defined as the presence of a non-calcium-containing binder during the baseline period.
[2] Triple control: a PTH value of "Yes" is defined as within 150-600 pg/mL, a P value of "Yes" is defined as within 3.5-5.3 mg/dL, and a Ca value of "Yes" is defined as within 8.4-10.2 mg/dL at baseline.

- Patients who received cinacalcet at-home were less likely to use a VDRA and a calcium-based phosphate binder.

Results, continued

Figure 2. Fitted Proportion of Controlled PTH, Ca, P, and Triple Control during Follow-up



- There was no difference in triple control, PTH, and P levels between in-center or at-home cinacalcet groups during follow-up.
- Calcium was better controlled during months 2, 3, and 8 in the in-center cinacalcet group.

Conclusions

- In a well-matched cohort with similar backgrounds of CKD-MBD control, administering cinacalcet in-center is at least as effective as prescribed for daily home use.

Limitations

- Longitudinal estimates may be affected by differential losses to follow up and differential outcome measurement.
- Data are limited to a single year time horizon, a longer term outlook cannot be observed in available data.

Acknowledgments

1. Sibbel, S, et. al., Chronic Kidney Disease Mineral and Bone Disorder: What is the Appropriate Role for Calcimimetics?, 2022

We extend our sincere appreciation to the teammates in DaVita clinics who work every day to take care of patients and also to ensure the extensive data collection on which our work is based. We acknowledge Kathryn Husarek of DaVita Clinical Research® (DCR®) for editorial contributions in preparing this poster.

This publication is the result of a research project conducted by the DaVita Institute for Patient Safety, Inc., a federally listed Patient Safety Organization, and is published with its permission. The data discussed herein has been certified as non-identifiable pursuant to 42 C.F.R. 3.212(a)(1). DaVita Clinical Research is a contractor to the DaVita Institute for Patient Safety, Inc.

*Correspondence: Physiciansupport@davita.com

Poster available at www.davitaclinicalresearch.com

American Society of Nephrology Kidney Week, November 1-5, 2023, Philadelphia, PA