Phosphorus Control and Pill Burden among In-Center Hemodialysis and Peritoneal Dialysis Patients Converting to Sucroferric Oxyhydroxide

Kathryn Gray, MS;[1] Linda H. Ficociello, DSc;[2] Claudy Mullon, PhD;[2] and Steven M. Brunelli, MD, MSCE[1]

[1]DaVita Clinical Research, Minneapolis, MN, USA; [2]Fresenius Medical Care, Waltham, MA, USA

Introduction

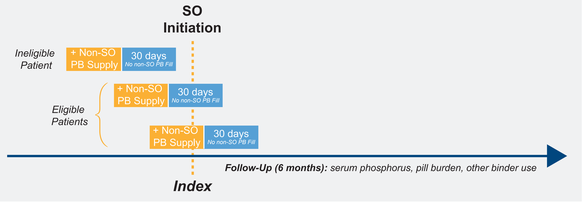
- Sucroferric oxyhydroxide (SO) is an iron-based phosphate binder (PB) indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.
- In clinical trials,[1,2] SO demonstrated:
  - Equivalent control of serum phosphorus relative to sevelamer
  - A lower daily pill burden than sevelamer
- The current analyses examine the real-world effectiveness of SO to lower serum phosphorus in dialysis patients.

Objective

To evaluate serum phosphorus and PB pill burden in patients who converted to SO from another PB as part of routine care.

Methods

Figure 1. Identification of Converters to SO



Data Source and Population

- Data were derived from the electronic health records of a large dialysis organization (LDO) and the prescription records from the LDO's pharmacy program.
- Patients eligible for inclusion in this study were ≥ 18 years old, receiving in-center hemodialysis (ICHD) or peritoneal dialysis (PD) at the LDO, enrolled in the LDO's pharmacy benefits program, and not Veteran's Affairs beneficiaries.

Study Design and Analysis

- This was a retrospective, observational analysis of ICHD and PD patients converting from another PB to SO.
- Converters to SO were defined from prescription fill data as:
  - Having had a supply of a non-SO PB
  - Receiving a first fill of SO
  - Not refilling the non-SO PB such that the supply exhausted for at least 30 days. After this 30-day period, patients were allowed to fill a non-SO PB.
  - As depicted in Figure 1, only patients for whom either the non-SO PB supply or the subsequent 30-day period overlapped the index SO fill were considered eligible for analysis.
- All analyses considered ICHD and PD patients separately.
- Patient demographics and baseline characterstics were described at SO initiation (month 0).
- Longitudinal indices of phosphorus control, PB pill burden, and use of other, non-SO PBs were assessed in each of the 6 months following SO initiation.
  - For each month of follow-up, patients were considered as monotherapy or dual therapy based on whether or not they had supply of a non-SO PB. Given implied carry over non-SO PB supply, these subgroupings were not considered for month 1 of follow-up.

Results

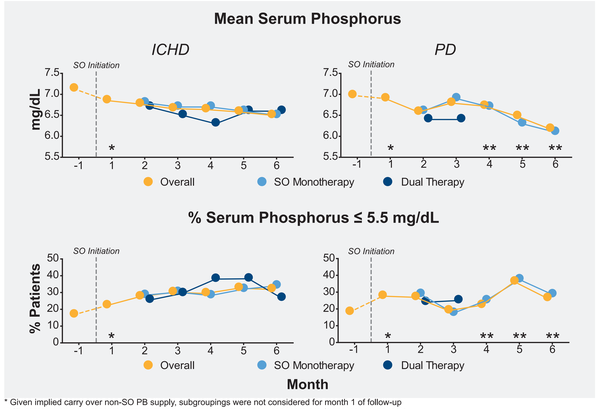
- Characteristics of ICHD and PD patients prior to SO initiation are presented in Table 1.
  - There were 656 ICHD patients and 105 PD patients converting to SO
- Longitudinal trends in serum phophorus are shown in Figure 2.
  - In ICHD patients overall, serum phosphorus was 7.1 mg/dL prior to SO initiation and fell to 6.6 mg/dL during follow-up. The percentage of patients with phosphorus ≤ 5.5 mg/dL rose from 17% to 32%.
    - In ICHD SO monotherapy patients, serum phosphorus fell from 6.8 to 6.5 mg/dL during months 2-6. The percentage of patients with phosphorus ≤ 5.5 mg/dL rose from 28% to 34%.
    - In ICHD dual therapy patients, serum phosphorus was 6.3-6.6 mg/dL during months 2-6. The percentage of patients with phosphorus ≤ 5.5 mg/dL was 27-38%.
  - In PD patients overall, serum phosphorus was 7.0 mg/dL prior to SO initiation and fell to 6.2 mg/dL during follow-up. The percentage of patients with phosphorus ≤ 5.5 mg/dL rose from 18% to 26%.
    - In PD SO monotherapy patients, serum phosphorus fell from 6.6 to 6.1 mg/dL during months 2-6. The percentage of patients with phosphorus ≤ 5.5 mg/dL was 17-38%.
    - In PD dual therapy patients, serum phosphorus was 6.4 mg/dL during months 2 and 3. The percentage of patients with phosphorus ≤ 5.5 mg/dL was 24-25%.
- Longitudinal trends in total binder pill burden and SO pill burden are shown in Figure 3.
  - In ICHD patients, total daily PB pill burden fell from 7.5 prior to SO initiation to 5.5 during follow-up; daily SO pill burden was 3.0-3.9 during follow-up.
    - In ICHD SO monotherapy patients, daily SO pill burden was 3.1-4.1 during months 2-6.
    - In ICHD dual therapy patients, total daily PB pill burden was 9.2-11.0 during follow-up; daily SO pill burden was 2.5-3.2 during months 2-6.
  - In PD patients, total daily PB pill burden fell from 8.7 prior to SO initiation to 5.4 during follow-up; daily SO pill burden was 3.2-4.0 during follow-up.
    - In PD SO monotherapy patients, daily SO pill burden was 3.3-4.4 during months 2-6.
    - In PD dual therapy patients, total daily PB pill burden was 8.3-11.0 during follow-up; daily SO pill burden was 3.1-3.2 during months 2-3.
- Prior to SO initiation, sevelamer was the most commonly used non-SO PB, followed by calcium acetate and lanthanum (Figure 4).
  - During follow-up, adjuvant therapy (on top of SO) was begun with sevelamer, calcium acetate, and lanthanum in 15-21%, 7-9%, and 2-5%, respectively.

Table 1. Baseline Characteristics of ICHD and PD SO Converters

		ICHD Converters N = 656	PD Converters N = 105
Age, years	mean ± SD	50.4 ± 13.4	46.7 ± 12.9
Sex	n (%)		
Male		350 (53.4)	50 (47.6)
Female		306 (46.6)	55 (52.4)
Race	n (%)		
White		188 (28.7)	40 (38.1)
Black		297 (45.3)	30 (28.6)
Hispanic		142 (21.6)	28 (26.7)
Asian		19 (2.9)	5 (4.8)
Other/unknown/missing		10 (1.5)	2 (1.9)
Access	n (%)		
AVF		489 (74.5)	
AVG		107 (16.3)	N/A
CVC		60 (9.1)	
Vintage, mo	median [p25, p75]	43.0 [22.0, 75.0]	33.0 [18.0, 62.0]
Weight, kg	mean ± SD	88.0 ± 26.2	81.2 ± 21.4
BMI, kg/m2	mean ± SD	30.4 ± 8.4	28.6 ± 6.3
Kt/V	mean ± SD	1.54 ± 0.27	2.15 ± 0.43
Calcium, mg/dL	mean ± SD	9.0 ± 0.8	8.9 ± 1.0
Calcium ≤ 10.2 mg/dL	n (%)	633 (96.5)	98 (93.3)
Phosphorus, mg/dL	mean ± SD	7.1 ± 1.7	7.0 ± 1.8
Phosphorus ≤ 5.5 mg/dL	n (%)	116 (17.7)	19 (18.1)
Calcium x Phosphorus product, mg^2/dL^2	mean ± SD	63.5 ± 15.8	61.9 ± 16.8
PTH, pg/mL	median [p25, p75]	517 [334, 847]	412 [274, 613]
PTH in range (150-600 pg/mL)	n (%)	360 (54.9)	70 (66.7)
Composite MBD score	median [p25, p75]	12 [7, 12]	6 [4, 6]
nPCR, g/kg/day	mean ± SD	1.07 ± 0.30	0.89 ± 0.22
Serum albumin, g/dL	mean ± SD	4.0 ± 0.3	3.6 ± 0.5
Hb, g/dL	mean ± SD	10.9 ± 1.3	10.5 ± 1.4
Ferritin, ng/mL	mean ± SD	693 ± 364	624 ± 374
TSAT, %	mean ± SD	29.7 ± 12.1	35.7 ± 17.1

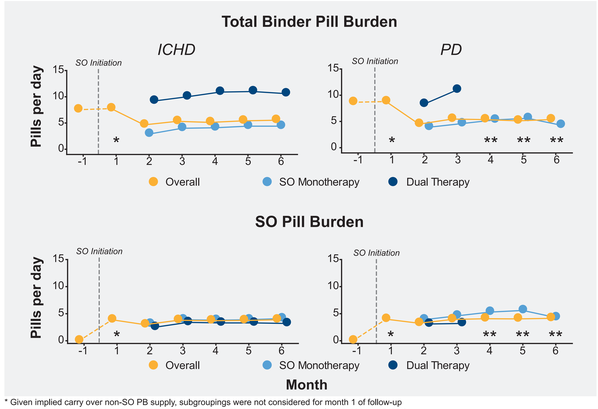
Abbreviations: AVF, arteriovenous fistula; AVG arteriovenous graft; BMI, body mass index; CVC, central venous catheter; Hb, hemoglobin; ICHD, in-center hemodialysis; IV, intravenous; MBD, metabolic bone disease; mo, months; N/A, not applicable; nPCR, normalized protein catabolic rate; PD, peritoneal dialysis; PTH, parathyroid hormone; SD, standard deviation; TSAT, transferrin saturation.

Figure 2. Serum Phosphorus



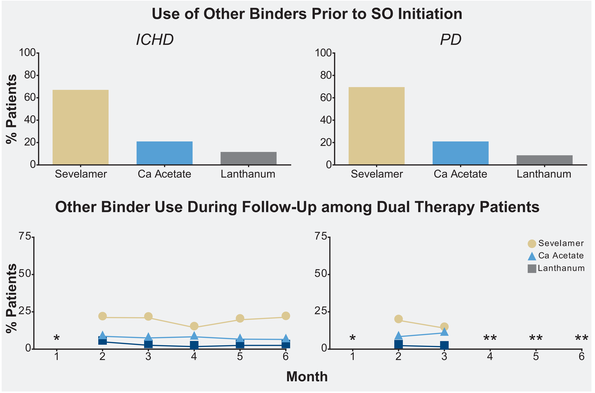
* Given implied carry over non-SO PB supply, subgroupings were not considered for month 1 of follow-up
** To comply with data reporting requirements, data are not reported when there are fewer than 11 patients.

Figure 3. Pill Burden



* Given implied carry over non-SO PB supply, subgroupings were not considered for month 1 of follow-up
** To comply with data reporting requirements, data are not reported when there are fewer than 11 patients.

Figure 4. Other Binder Use



* Given implied carry over non-SO PB supply, other binder use was not considered for month 1 of follow-up.
** To comply with data reporting requirements, data are not reported when there are fewer than 11 patients.

Conclusions

In a real-world population of ICHD and PD patients, conversion to SO was associated with:

- Reductions in serum phosphorus
- Higher percentage of patients with controlled phosphorus
- Lower total PB pill burden

References

1. Floege J., et al. A phase III study of the efficacy and safety of a novel iron-based phosphate binder in dialysis patients. *Kidney Int*. 2014;86(3):638-47
2. Floege J, et al. Long-term effects of the iron-based phosphate binder, sucroferric oxyhydroxide, in dialysis patients. *Nephrol Dial Transplant*. 2015;30(6): 1037-46.

Acknowledgments

We extend our sincere appreciation to the teammates in more than 2,000 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 thank DaVita Clinical Research® (DCR®), and specifically acknowledge Adam G. Walker, PhD, and Abigail Hunt, PhD, of DCR for editorial contributions in preparing this poster.

This study was funded by Frensenius Medical Care.

*Correspondence: kathryn.gray2@davita.com

Poster available at www.davitaclinicalresearch.com

American Society of Nephrology Kidney Week, November 15-20, 2016; Chicago, IL