Serum Phosphorus and Phosphate Binder Pill Burden in Diabetic Hemodialysis Patients Switched to Sucroferric Oxyhydroxide as Part of Routine Care

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Background

- Diabetes is a leading cause of end-stage renal disease (ESRD) treated with chronic dialysis.[1,2,3]
- According to the *2015 USRDS Annual Report*, 37% of hemodialysis (HD) patients in the US have serum phosphorus (sP) levels exceeding recommended 5.5 mg/dl.[2,4]
- Elevated sP levels increase the risk of mortality and morbidity in dialysis patients, with higher risks observed among patients with diabetes.[5,6]
- The majority of dialysis patients are prescribed phosphate binders (PB) to control sP levels.[7]
- However, poor adherence to PB therapy and less phosphorus control is common and associated with a high pill burden.[8,9]
- Sucroferric oxyhydroxide (SO) is a chewable, iron-based PB with a starting dose of 3 pills/day.[10]
- The aim of this retrospective database analysis was to assess the effectiveness of SO in controlling sP and reducing the pill burden in a cohort of patients with diabetes prescribed SO as a part of routine care.

Methods

- Eligible patients for analysis were adult, in-center HD patients who had diabetes documented in their electronic records, and received their first SO prescription fill through a renal pharmacy service between 4/1/2014 and 4/1/2015.
- Patients were on PB before switching to SO: 61% sevelamer, 23% calcium acetate, 6% lanthanum, and 10% switched between these binders.
- All available sP were averaged over baseline (BL; 3 months prior to switching to SO), F1 (1-3 months of SO prescription), and F2 (4-6 months of SO prescription).
- The following measures were compared between BL and F1:
  i. Prescribed PB pill burden
  ii. Serum phosphorus, serum calcium and intact parathyroid hormone (iPTH)
  iii. Percent of patients achieving KDOQI recommended serum phosphorus levels (3.5 – 5.5 mg/dl)
  iv. Ferritin, transferrin saturation (TSAT), and hemoglobin
- A sub-group analysis was conducted for patients with 4-6 months of SO prescription.

Results

- Patients (N=605) were on average 55 years old with a mean dialysis vintage of 4.0 years and BMI of 33.2 kg/m^2.
- At BL, the majority of patients had hyperphosphatemia (mean sP of 6.8 mg/dl) and were prescribed on average 9.5 PB pills/day.
- Mean HbA1c was 7.2% at BL (n=332), 7.2% at F1 (n=220), and 7.4% at F2 (n=95) - all comparisons, p=n.s.

Table 1: Comparison of Clinical Markers Between BL and F1 (N=605)

Measure	BL	F1	P-value[a]
Prescribed PB Pill Burden (pills/day)	9.5 ± 4.2	3.7 ± 1.3	<0.0001
Mineral Bone Disease Markers			
Serum Phosphorus (mg/dl)	6.8 ± 1.3	6.5 ± 1.6	<0.0001
% of patients with in-range sP[b]	13.2	27.9	<0.0001
Serum Calcium (mg/dl)	9.2 ± 0.7	9.1 ± 0.7	0.2
iPTH (pg/ml)	528.9 ± 400.2	546.6 ± 443.5	0.2
Anemia and Iron Indices in Patients on IV Iron (N= 518)[c]			
Ferritin (ng/ml)	1000.3 ± 467.7	1045.8 ± 509.5	0.08
TSAT (%)	34.0 ± 10.0	35.5 ± 12.1	0.004
Hemoglobin (g/dl)	10.9 ± 0.9	10.9 ± 1.0	0.7
Anemia and Iron Indices in Patients Not on IV Iron (N= 87)[c]			
Ferritin (ng/ml)	1216.8 ± 473.6	1225.2 ± 951.3	0.9
TSAT (%)	38.5 ± 16.3	35.8 ± 16.8	0.04
Hemoglobin (g/dl)	11.0 ± 1.3	11.1 ± 1.5	0.5

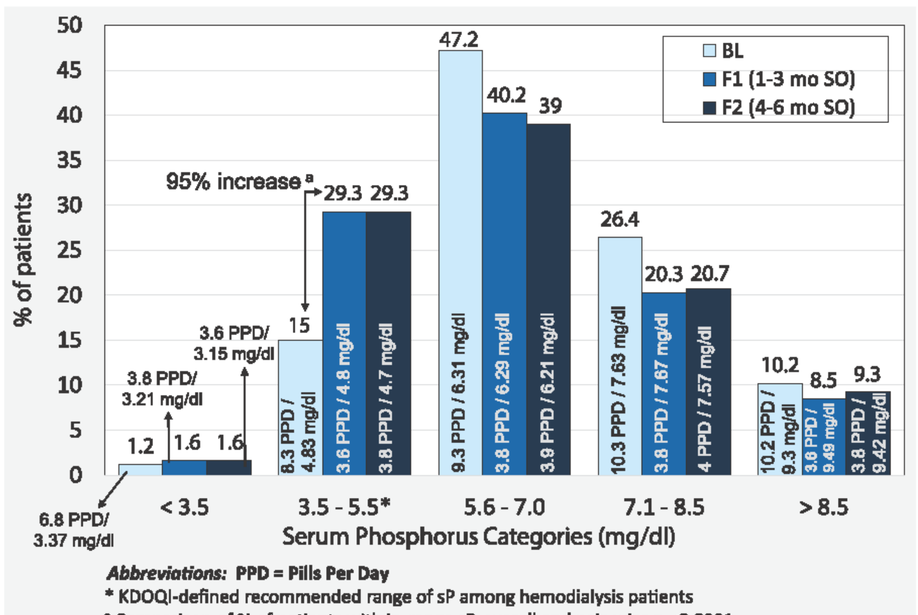
Values are expressed as Mean ± SD or % of patients
[a] Comparisons were carried out using paired t-test (for continuous data) and McNemar test (for categorical data)
[b] KDOQI defined in-range sP (3.5-5.5 mg/dl)
[c] IV iron treatment included iron sucrose, ferumoxytol, and sodium ferric gluconate

Sub-Group Analysis of Patients Prescribed SO for 4-6 Months (N=246)

Comparing BL with F1 and F2, the following observations were made:

- Mean prescribed PB pill burden decreased (p <0.0001, overall and pair-wise) from 9.5 (± 4.3) at BL to 3.7 (±1.2) pills/day at F1and 3.8 (±1.3) pills/day at F2.
- Percent of patients within KDOQI recommended sP increased by 95% from BL to F1 and this increase was sustained between F1 and F2.
- There was a minimal decrease in serum calcium (p=0.04) between BL (9.15 ±0.7 mg/dl), F1 (9.10 ±0.6 mg/dl) and F2 (9.05 ±0.6 mg/dl)
- There was no significant change in iPTH (p=0.2) between BL, F1 and F2.

Figure1: Distribution of sP Among HD Patients with Diabetes (N=246)



Conclusions

- A cohort of HD patients with diabetes prescribed SO as part of routine care was followed for up to 6 months.
- Patients were prescribed 61% fewer PB pills when switched to SO (9.5 pills/day during BL to 3.7 pills/day during F1, p<0.0001).
- There was a 111% increase (p< 0.0001) in the number of patients achieving KDOQI recommended sP (3.5-5.5 mg/dl) from BL to F1 (13.2% to 27.9%, p<0.0001).
- In sub-group analysis of patients prescribed SO for 4-6 months, the following were observed:
  – Significant decrease in mean PB pill burden from BL to F2 (9.5 to 3.8 pills/day, p<0.0001)
  – A 95% increase (p<0.0001) in patients achieving in-range sP from BL to F2

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