Effect of Velphoro on Serum Phosphate & Albumin in Peritoneal Dialysis Patients

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Background

- Hyperphosphatemia is common in patients on peritoneal dialysis (PD).
- Dietary phosphorus restriction often leads to ↓ protein intake, which may result in hypoalbuminemia.
- Hypoalbuminemia is associated w/ an ↑ risk of morbidity & mortality in PD.
- In observational studies, sucroferric oxyhydroxide (SO)/Velphoro®, was associated w/ ↑ phosphate control & ↑ serum albumin in hemodialysis patients.

Whether SO improves phosphate control & nutritional status in PD patients is unknown.

Methods

- We performed a prospective, open-label, 6-month, pilot study of 17 adult PD patients from the Denver Metro area. Inclusion criteria:
  - automated peritoneal dialysis for at least 3 months,
  - serum albumin ≤ 3.8 g/dL,
  - serum phosphate ≥ 5.5 mg/dL or ≤5.5 mg/dL on a binder other than SO.
- Patients currently on phosphate binders underwent a 2-week washout period.
- Participants were started on SO at a dose of 1 tablet daily with meals.
- Serum phosphate was checked monthly and the dose of SO was titrated to a goal serum phosphate of < 5.5 mg/dL.

The primary outcome was change in serum phosphate and serum albumin over 6 months.

Results

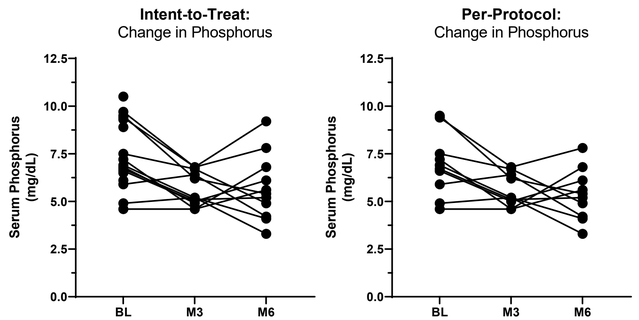
Table 1

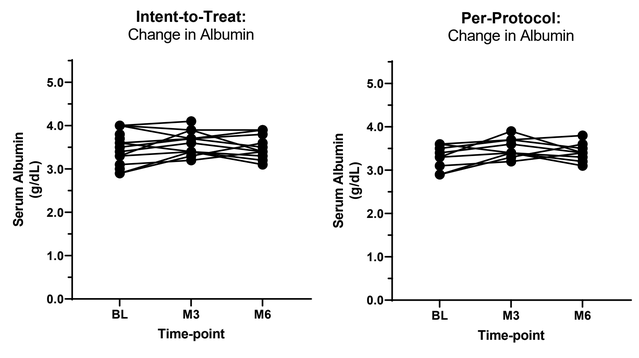
Variable	Time-point: Baseline Value	3 Month	6 Month	P Value
All Randomized Participants				
Phosphorus, mg/dL	7.5 ± 1.8	5.6 ± 1.1	5.7 ± 1.7	<0.001
Albumin, g/dL	3.5 ± 0.37	3.6 ± 0.27	3.5 ± 0.27	0.42
Intact PTH, pg/mL	481 ± 344	459 ± 504	471 ±448	0.30
Appetite level	2.2 ± 0.9	2.4 ± 0.9	2.6 ± 0.7	0.44
Appetite change	0.2 ± 0.4	0.2 ± 0.4	0.2 ± 0.4	0.95
Desire to change diet	0.5 ± 0.5	0.2 ± 0.4	0.5 ± 0.5	n/a
Participants with 3 Time-points & BL Albumin <3.8 (n=7)				
Phosphorus, mg/dL	6.9 ± 1.4	5.6 ± 0.8	5.4 ± 1.4	<0.05
Albumin, g/dL	3.3 ± 0.3	3.4 ± 0.2	3.4 ± 0.2	0.08
Intact PTH, pg/mL	503 ± 476	464 ± 581	495 ± 512	0.38
Appetite level	2.8 ± 0.7	2.4 ± 1.0	2.6 ± 0.7	0.43
Appetite change	0.2 ± 0.4	0.1 ± 0.3	0.2 ± 0.4	0.37
Desire to change diet	0.7 ± 0.5	0.2 ± 0.4	0.6 ± 0.5	0.14

- Appetite ranges 1 (very good) to 5 (very poor)
- Appetite change/desire ranges from 0 (no) to 1 (yes)

Demographics

- ❖ The mean (SD) age was 55 ± 13 years
- ❖ Dialysis vintage 3.8 ± 2.7 years.
- ❖ Male (65%), white (82.4%) and non-Hispanic (64.7%).
- ❖ 88% of patients were on a phosphate binder at baseline (73% were on sevelamer)





- ➢ Twelve patients completed the study.
  - ➢ Two patients withdrew due to side effects (diarrhea),
  - ➢ One patient changed to hemodialysis
  - ➢ Two patients died (unrelated to the study).
- ➢ Results are shown in Table 1 and Figure 1.

- ➢ Serum phosphate decreased significantly from baseline but there was no significant change in serum albumin (Table 1).
- ➢ There was no significant change in appetite with SO (Table 1).
- ➢ Phosphate binder pill burden significantly decreased from:
  - ➢ Median (IQR) 11.0 (9.0-12) pills/day at baseline to 4.0 (3-5.50) pills/day at month 6.
- ➢ No significant Δ's in dietary intake

	Time-point: 0M	3M	6M	P-value
Kcal	1621 ± 648	1383 ± 868	1575 ± 567	0.42
Protein, g	77 ± 35	62 ± 38	74 ± 39	0.16
Phos, mg	1159 ± 525	973 ± 685	1097 ± 419	0.36
Kcal/kg	20.9 ± 11.1	18.1 ± 13.6	20.2 ± 9.0	0.53
Pro, g/kg	1.0 ± 0.6	0.8 ± 0.6	1.0 ±0.6	0.21

- All table values reported as mean ±SD

Conclusions

- Serum phosphate significantly ↓ w/ fewer phosphate binder pills/day after switching to SO.
- There was no change in serum albumin, **<u>however</u>** a trend existed in the analysis per-protocol.
- **SO did not dramatically impact appetite, albumin, or diet. However, patients did maintain albumin & a subset did ↑ serum albumin.**