

Oxylanthanum Carbonate Achieves Serum Phosphate Control with Significantly Lower Pill Burden in Dialysis Patients with Hyperphosphatemia

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BACKGROUND

- High pill burden and gastrointestinal side effects from phosphate binders (PB) contribute to low adherence to treatment of hyperphosphatemia (HP)^{1,2}
- Oxylanthanum carbonate (OLC), a lanthanum-based PB in development for treating HP in chronic kidney disease (CKD), uses proprietary nanoparticle technology and is formulated in small, swallowable tablets
- In a pivotal open-label clinical trial, OLC was safe and well tolerated

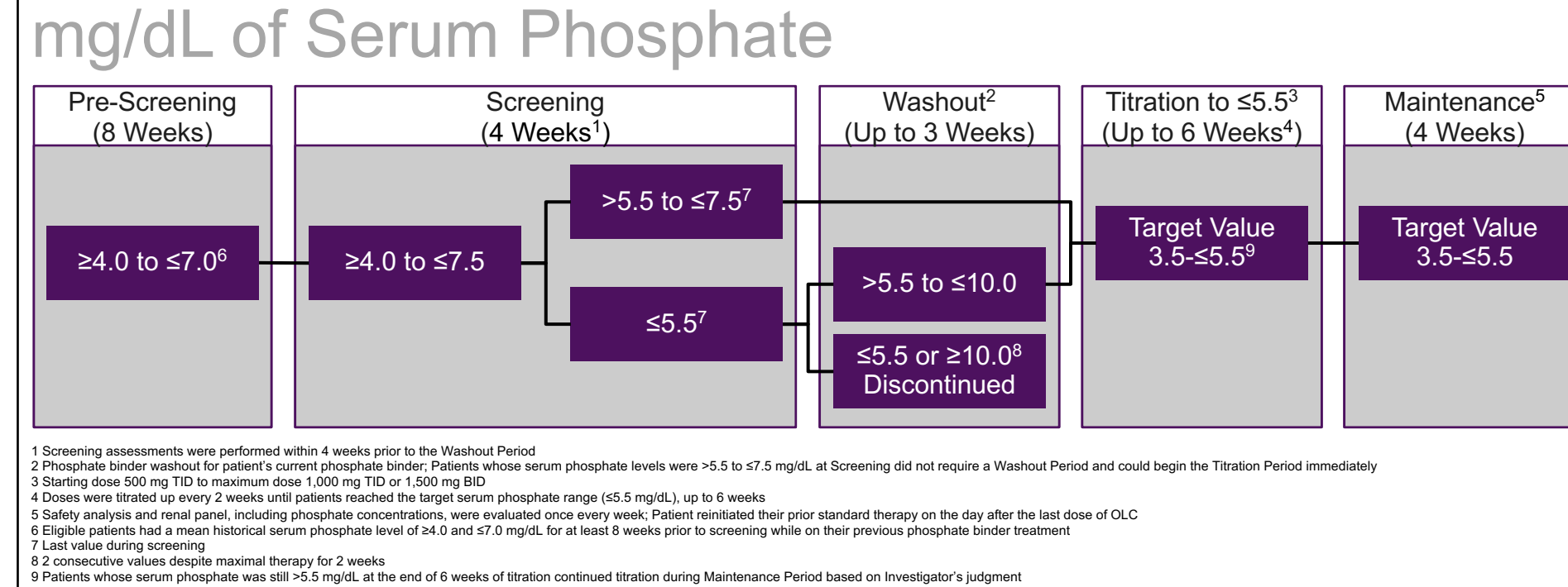
OBJECTIVE

We present new findings on sP levels, pill volume, and pill quantity in patients (pts) with HP treated with OLC compared to their pretrial PB regimen

METHODS

- This open-label, single-arm, multicenter, multidose study enrolled CKD pts on dialysis with mean historical sP ≥ 4.0 and ≤ 7.0 mg/dL for ≥ 8 weeks
- The study consisted of screening, washout, titration, and maintenance periods (**Figure 1**)
- After washout, pts received OLC 500mg TID, titrated to a max of 1000mg TID over 6 weeks followed by a 4-week maintenance period
- Daily pill volume was calculated by multiplying the pill volume per tablet by the number of tablets per day of pretrial PBs at screening and of OLC tablets at the end of study³
- Pretrial PBs included sevelamer carbonate, calcium acetate, ferric citrate, and sucroferric oxyhydroxide

Figure 1. Study Design



RESULTS

- Of 128 pts screened, 86 were enrolled; 72 completed the study and had pretrial binder data (**Table 1**)
- The sP was ≤ 5.5 mg/dL at screening in 59% of pts and at the end of OLC titration in 91% of pts (**Figure 2**)
- The mean daily pill volume of pretrial binders at screening was 9.3 cm³ with a mean of 8.3 pills/day, compared to mean daily pill volume at study end with OLC of 1.3 cm³ with a mean 3.8 pills/day (**Figures 3&4**)
- Severe AEs, as assessed by investigators, were reported in one patient with upper abdominal pain and one with diarrhea
- Reasons for discontinuation during maintenance included adverse events (n=3), investigator decision (n=2), and consent withdrawal (n=1) (**Table 2**)

Table 1. Baseline Demographics (n=86)

Characteristics	Safety Population	Characteristics	Safety Population
Age (Years) Mean (SD)	62 (10.7)	Ethnicity, n (%) Hispanic or Latino	34 (39.5)
Gender, n (%) Male	47 (54.7)	Sevelamer	45 (52.3)
White	57 (66.3)	Calcium Acetate	17 (19.8)
Race, n (%) Black or African American	18 (20.9)	Phosphate Medication, n (%) Ferric Citrate	13 (15.1)
American Indian or Alaska Native	8 (9.3)	Sucroferric Oxyhydroxide	12 (14.0)
Other	3 (3.5)	Tenapanor	1 (1.2)

Figure 2. Proportion of Patients by Serum Phosphate (mg/dL) Levels – Pretrial Phosphate Medications vs OLC – All Patients (n=78)¹

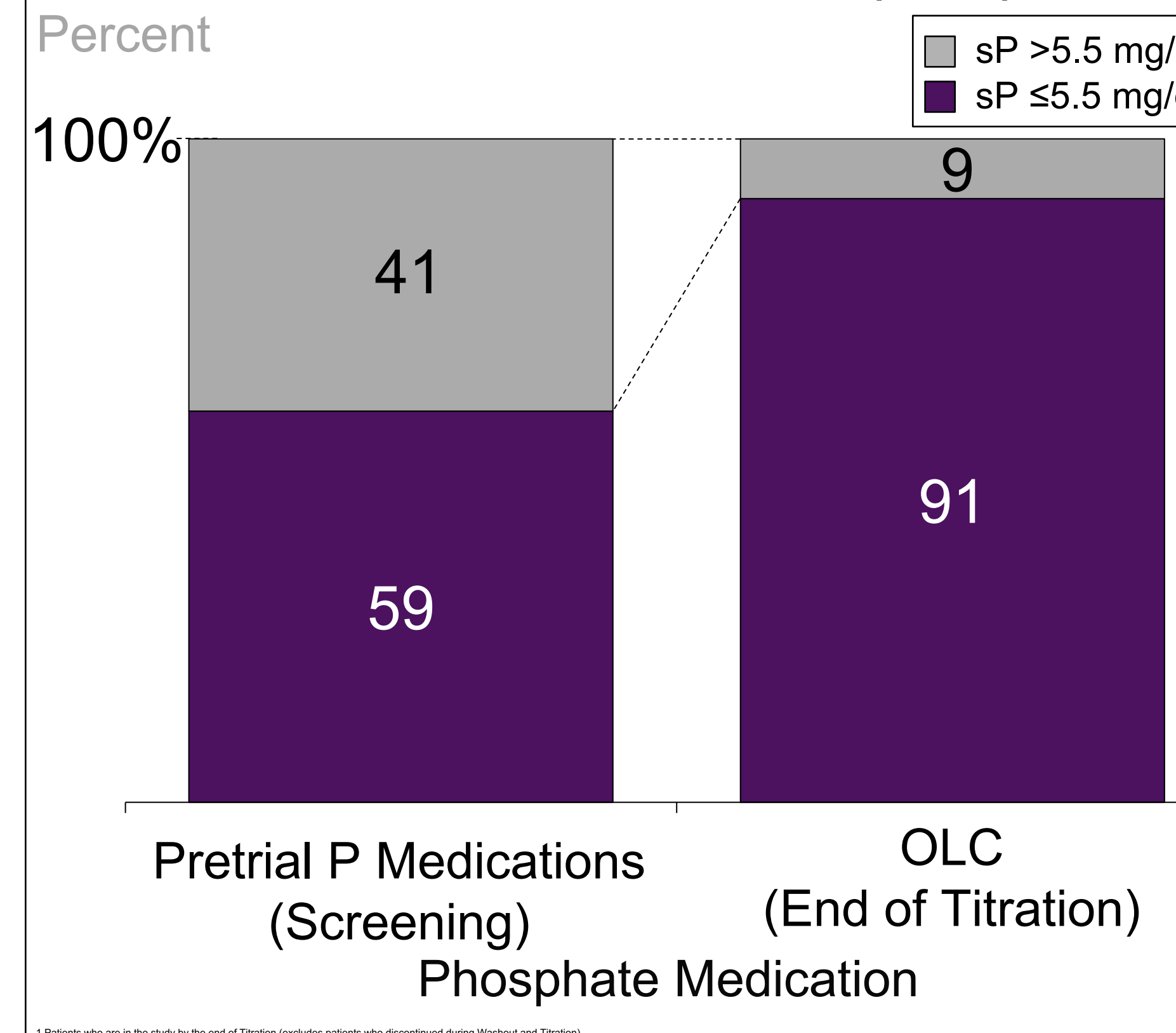


Figure 3. Mean (SE) Daily Pill Volume and Daily Quantity – Pretrial Phosphate Binders vs OLC – All Patients (n=72)¹

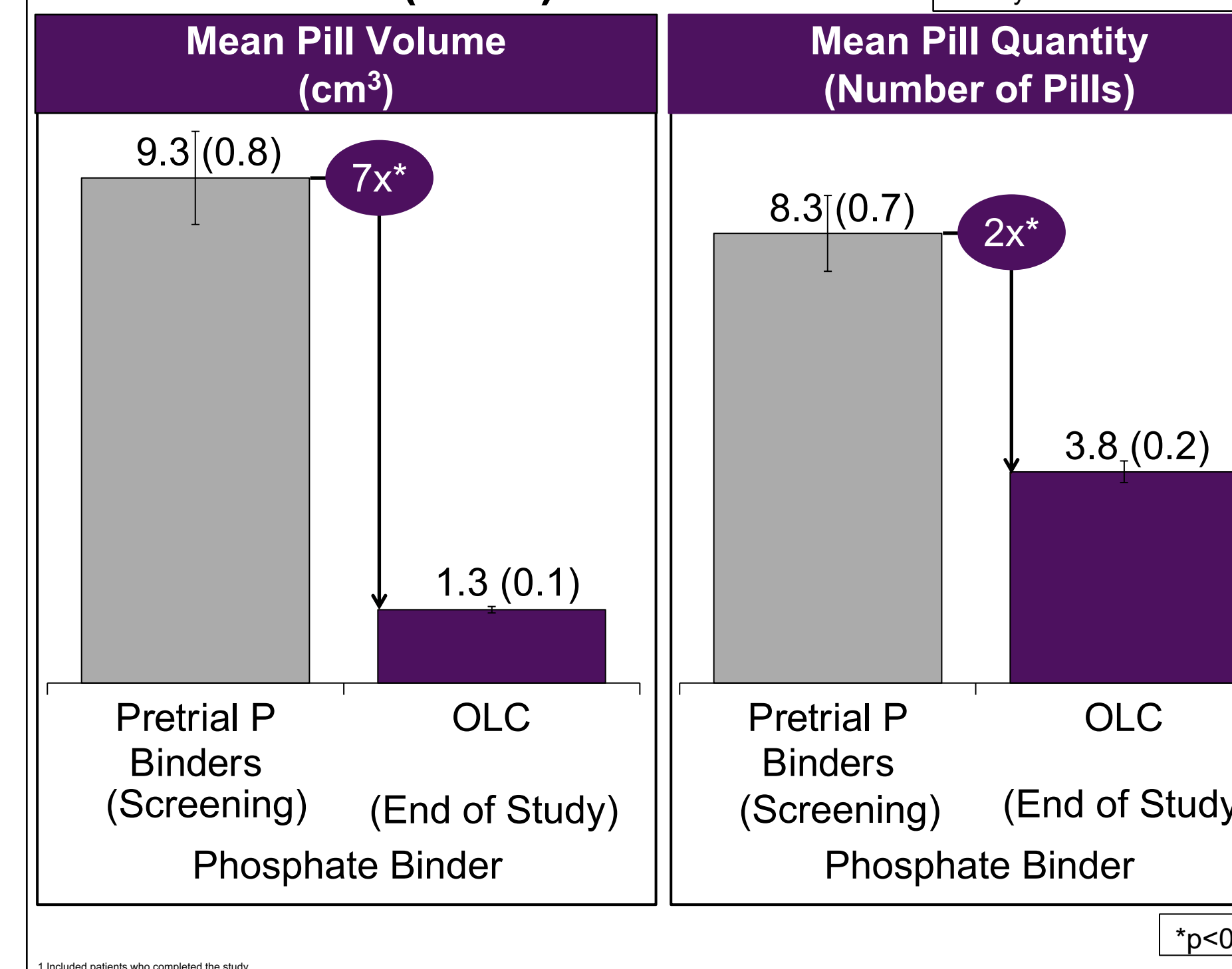


Figure 4. Mean Daily Pill Volume/Quantity by Phosphate Binders – All Patients

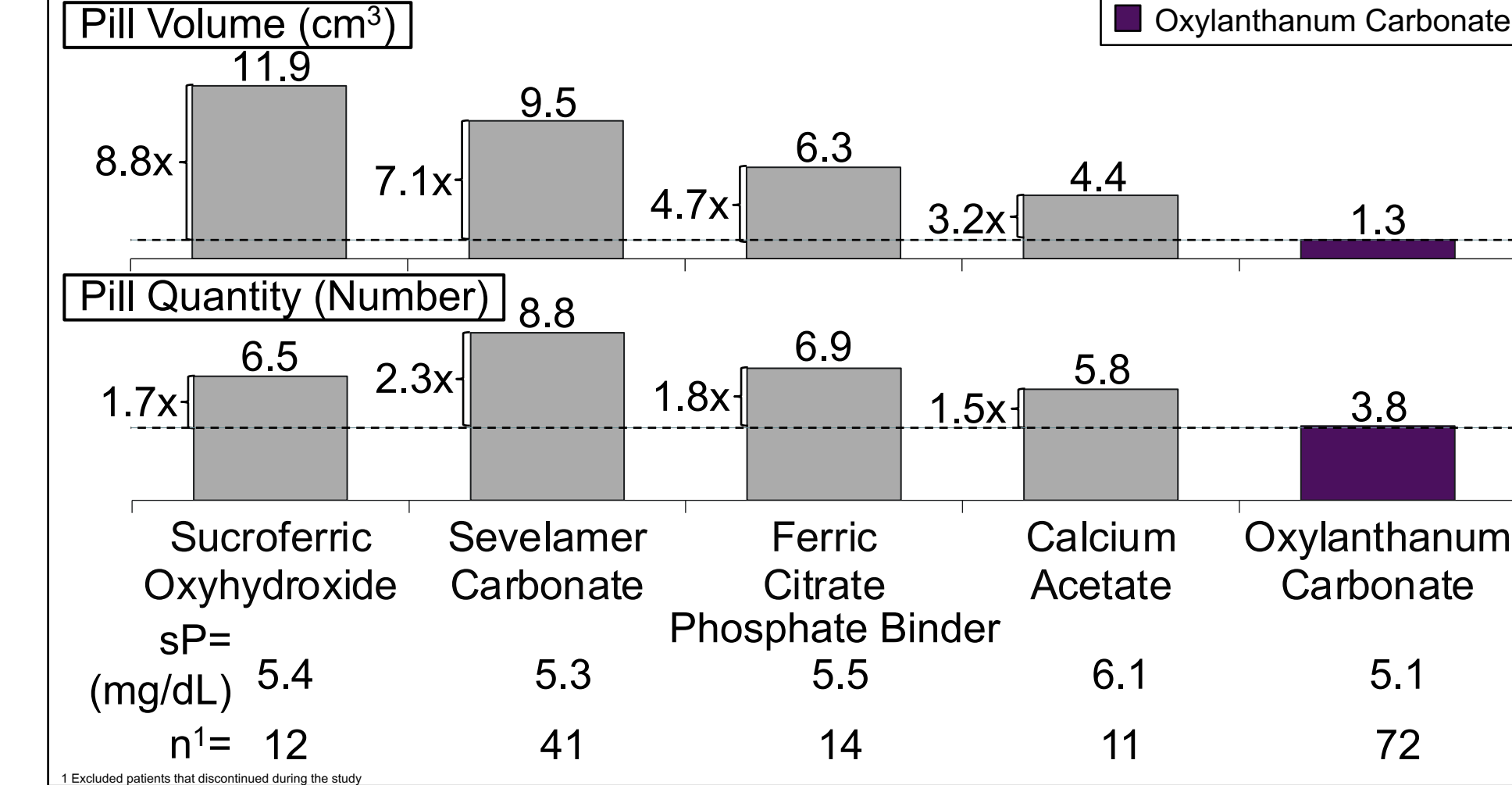


Table 2. Summary of Treatment-Related Adverse Events (AEs) – Safety Population (n=86)

Number of Patients (%)	Treatment-Related AEs
All Patients	15 (17.4)
Mild, Moderate, Severe	8 (9.3), 5 (5.8), 2 (2.3)
Serious AEs	0 (0.0)
Led to Discontinuation	3 (3.5)
Led to Death	0 (0.0)

CONCLUSIONS

- OLC reduced sP below 5.5 mg/dL in $> 90\%$ of pts by end of titration
- Mean daily pill volume and pill quantity were significantly reduced with OLC compared to pts' pretrial PBs

IMPLICATIONS

- Combined with previously presented safety data, these findings suggest that OLC is safe, effective, and well-tolerated
- Its small, easy-to-swallow formulation may be a welcome choice for pts with HP

References:

1. Chiu YW., et al. *Clin J Am Soc Nephrol.* 2009. Jun.
2. Wang S., et al. *J Ren Nutr.* 2014. Jan.
3. Sprague S., et al. *Am J Neph.* 2023. Jun.

Acknowledgments:

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