

# Lowering Serum Phosphorus without Compromising Nutritional Status: A Phosphate Management Program

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## INTRODUCTION

The goal of this pilot study was to assess the effectiveness of a phosphorus management program in improving phosphorus outcomes without negatively impacting other markers of bone & mineral metabolism or nutritional status. The program supports patients with proper diet and phosphorus management through in-center phosphorus educational materials, direct-to-patient adherence communications, education and access support specific to adherence to lanthanum carbonate.

## METHODOLOGY

- This was a single arm, pre/post pilot study.
- Eight geographically diverse dialysis centers were assigned to receive phosphorus disease management in the form of staff training, and regular phosphorus monitoring, and direct patient education as described in the box to the right.
- We calculated the percentage of patients with serum phosphorus <5.5mg/dL for each clinic at baseline as the mean across the 6 months pre-intervention, providing stability in the baseline estimate (Table 1).
- We also calculated the mean serum phosphorus level for each clinic at each month post intervention, with baseline defined as a weighted (by clinic population) mean serum phosphorus across the 6 months prior to intervention. A repeated measures general linear model was used to compare least squares mean values for each measure at each month, and no significant differences were found among baseline months.
- The change in percent of patients with phosphorus (< 5.5 mg/dL) , PTH (150-300 pg/mL) and calcium (<9.6 mg/dL) and mean levels per center were analyzed using a paired t-test with statistical significance set at p < 0.05. For serum albumin and nPCR no target range was defined thus percent in range was not calculated.

## RESULTS

Table 1. Individual Facility Characteristics

Baseline Measure	Center								Overall
	NJ	CA	GA	IL	FL	TX	NJ	PA	
<b>Patients (n)</b>	75	91	87	75	83	82	68	141	
Mean±SD									88±23
Total									702
<b>Age (mean±SD)</b>	64±16	62±15	63±14	60±14	59±15	61±14	64±13	58±15	61±15
<b>Dialysis vintage in yrs (mean±SD)</b>	3.0±4.2	4.2±3.4	3.0±2.9	3.0±2.5	2.5±2.9	4.0±3.9	4.1±5.1	3.1±3.2	3.3±3.6
<b>Male (%)</b>	43%	54%	44%	61%	61%	65%	68%	55%	56%
<b>Diabetes (%)</b>	44%	66%	21%	48%	35%	41%	51%	30%	41%
<b>Race/ethnicity (%)</b>									
White	43%	7%	37%	4%	42%	37%	38%	0%	23%
Black	49%	0%	60%	23%	51%	49%	46%	93%	50%
Hispanic	3%	84%	2%	73%	5%	9%	2%	2%	21%
Asian/Pacific Islander	3%	9%	1%	0%	2%	0%	2%	1%	2%
Other/Unknown	3%	1%	0%	0%	0%	6%	13%	4%	3%
<b>Baseline biomarkers (mean ± SD)</b>									
Albumin (g/dL)	3.8±0.5	3.8±0.4	3.8±0.5	3.9±0.4	3.8±0.4	3.8±0.4	3.8±0.4	3.8±0.5	
nPCR (g/kg/day)	1.0±0.4	1.1±0.3	1.0±0.4	1.1±0.3	0.9±0.3	0.9±0.3	1.0±0.3	0.9±0.3	
Phosphorus (mg/dL)	4.9±1.5	5.0±1.7	5.4±1.6	5.6±1.7	5.4±1.5	5.1±1.6	4.8±1.7	5.8±2.0	
cCalcium (mg/dL)	9.1±0.7	9.0±0.6	9.1±0.7	8.8±0.6	9.2±0.7	8.9±0.7	8.9±0.7	8.8±0.8	
PTH (pg/mL)	303±201	387±507	466±345	379±255	261±202	386±384	331±353	508±569	
<b>% of patients achieving &lt;5.5 mg/dL phosphorus</b>	68%	70%	60%	56%	53%	67%	68%	54%	61%

### Phosphorus Management Program Interventions

- Staff in-service training on hyperphosphatemia including diet, dialysis, and phosphate binder therapy
- Regular monitoring of phosphorus with patient
- Renal diet and phosphorus binder education for all patients
- Additional options offered to patients prescribed lanthanum carbonate:
  - Medication (lanthanum carbonate) access support including benefit verification and prior authorization
  - Direct to patient communication program covering topics on managing diet and lanthanum carbonate-specific adherence support
  - Renal nurse direct-to-patient call center

Table 2. Biometric Measures Before and After Program Implementation

Biomarker	Baseline		Month 6		Change*		Change p-value	
	Mean ±SD	Percent in range#	Mean ±SD	Percent in range	Mean ±SD	Percent in range	Mean	Percent in range
<b>cCalcium (mg/dL)</b>	8.9 ±0.1	86.2% ±4.2%	8.9 ±0.09	90.3% ±3.3%	0.01 ±0.14	4.1% ±6.4%	0.92	0.12
<b>PTH (pg/mL)</b>	377.1 ±52.9	39.1% ±2.4%	368.8 ±65.7	44.5% ±7.0%	-8.3 ±70.9	5.5% ±6.1%	0.75	0.04
<b>Phosphorus (mg/dL)</b>	5.3 ±0.2	61.6% ±5.2%	5.1 ±0.3	71.3% ±9.0%	-0.2 ±0.2	9.6% ±5.9%	0.01	<0.01
<b>Albumin (g/dL)</b>	3.8 ±0.04	N/A	3.8 ±0.06	N/A	0.01 ±0.07	N/A	0.58	N/A
<b>nPCR (g/kg/day)</b>	0.98 ±0.07	N/A	0.97±0.07	N/A	-0.01 ±0.03	N/A	0.35	N/A

\*Change may not add exactly due to rounding

#Ranges for calcium <9.6 mg/dL; PTH 150-300 pg/mL; phosphorus < 5.5 mg/dL

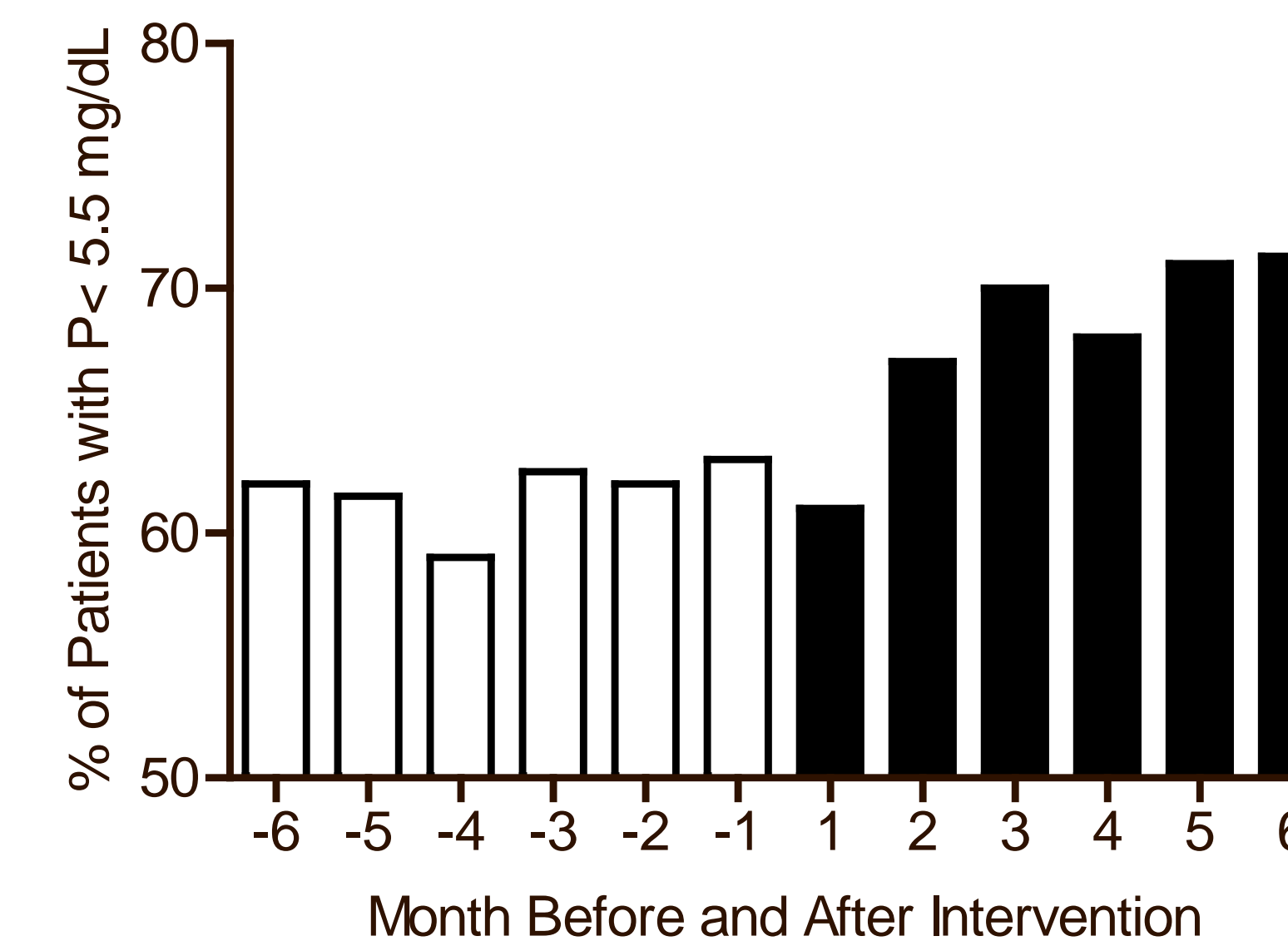


Figure 1. Proportion of Patients Achieving Phosphorus < 5.5 mg/dL by Month Before and After Intervention.

## SUMMARY of RESULTS

- The percent of patients achieving phosphorus <5.5 mg/dL increased significantly (mean 9.6 ± 5.9% increase; p<0.01; Table 2 and Figure 1).
- There was also a significant increase in the percent of patients per facility achieving PTH between 150 and 300 pg/mL (mean 5.5 ± 6.1% increase; p=0.04; Table 2).
- Over the course of the evaluation, mean calcium, albumin and nPCR did not change significantly (Table 2).

## KEY LEARNINGS

- ✓ These results show proof-of-concept that a focused phosphorus management program targeting both staff and patients can significantly improve patient outcomes without compromising nutritional status.

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