Original Article

Sevelamer Carbonate and Lanthanum Usage Evaluation and Cost Considerations at a Veteran's Affairs Medical Center

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ABSTRACT

Background: Hyperphosphatemia is a common problem in patients with chronic kidney disease (CKD). Calcium-containing phosphate binders are typically used as first-line therapy, primarily due to cost considerations. Non-calcium phosphate binders such as sevelamer and lanthanum may be considered in the appropriate setting. It is hypothesized that lanthanum is less costly and has a lower pill burden compared to sevelamer carbonate.

Objective: Determine the difference in cost (outcome 1) and tablet burden (outcome 2) between sevelamer carbonate and lanthanum within the Veteran population.

Methods: Patients with an active prescription for lanthanum or sevelamer carbonate on October 22, 2014 were evaluated. Chi-square analysis was used to analyze categorical data, and 2-sided *t* test was used for continuous data. An α of 0.05 determined significance.

Results: One hundred fifty patients were included in the evaluation. Patients were predominately male (96%) and had a diagnosis of end stage renal disease (ESRD; 78%). The combined rate of non-dialysis CKD (ND-CKD) stage 5 and ESRD was similar between lanthanum and sevelamer carbonate groups. Both groups achieved similar phosphorus control (56% vs 65%, with phosphorus level less than or equal to 5.5 mg/dL, respectively; *P* = .23). Lanthanum prescriptions required significantly fewer tablets per day (4 lanthanum tablets daily vs 7 sevelamer carbonate tablets daily; *P* < .001). A potential prescription cost savings of approximately \$4,500 monthly or \$54,000 annually was seen when considering conversion of patients in this study population from sevelamer carbonate to lanthanum therapy, with appreciable savings beginning at sevelamer daily doses of at least 4,800 mg.

Conclusions: Compared to sevelamer carbonate, lanthanum use was associated with reduced pill burden and lower absolute drug cost while maintaining similar phosphorus control.

Key Words—kidney, lanthanum, phosphorus, sevelamer

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Insufficient control of serum phosphorus is a common problem in patients with chronic kidney disease (CKD). The prevalence of hyperphosphatemia ranges from 9% to 23% in patients with CKD stage 3 or 4¹ and nearly 70% in patients with end stage renal disease (ESRD).^{2,3} Hyperphosphatemia is associated with increased morbidity as well as increased

all-cause and cardiovascular mortality.^{2,3} Kidney Disease: Improving Global Outcomes (KDIGO) guidelines recommend the use of phosphate-binding agents in the treatment of hyperphosphatemia in patients with CKD stage 3-5.⁴ A meta-analysis of 60 randomized controlled trials by Navneethan et al assessed the effects of various phosphate binders on serum

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phosphorus reduction, all-cause mortality, and cardiovascular endpoints in CKD patients.⁵ Authors concluded that data did not demonstrate superiority of non-calcium phosphate binders such as lanthanum or sevelamer carbonate over calcium-based phosphate binders.⁵ Additionally, all available phosphate binders significantly reduced serum phosphorus compared to placebo.⁵ KDIGO guidelines highlight that novel, non-calcium phosphate binders such as lanthanum and sevelamer carbonate cost more than calcium-based alternatives, but do not recommend one agent over the other.⁴

Calcium-containing phosphate binders are typically used as first-line therapy for the treatment of hyperphosphatemia, primarily due to cost considerations. National Veterans Affairs (VA) criteria for use developed in September 2011 allow the transition to a non-calcium, non-aluminum phosphate binder in patients with CKD stage 3-5 and/or ESRD with at least one of the following: persistently elevated serum phosphorus despite dietary restriction and adherence to a calcium-based phosphate binder, intolerance of calcium-based phosphate binder, elevated corrected calcium (based on trend values) despite reduction of vitamin D supplementation to lowest effective dose, low intact plasma parathyroid hormone (iPTH) level with normal or elevated serum calcium level associated with adynamic bone disease.⁶

It is hypothesized that lanthanum therapy is less costly per month within a greater than 500-bed VA medical center and has a lower pill burden than sevelamer carbonate while maintaining similar phosphorus control.^{2,7} Cost savings and decreased pill burden have been associated with lanthanum therapy in the literature, but there are limited data comparing these agents within the Veteran population.^{2,7} The purpose of this evaluation is to compare lanthanum and sevelamer carbonate therapies on the basis of direct drug acquisition cost, pill burden, dose comparison, and phosphorus control within the medical center.

BACKGROUND

Sevelamer is available in 2 salt forms: hydrochloride (HCl) and carbonate. The majority of studies use the HCl formulation since sevelamer carbonate did not become available until 2000. Sevelamer carbonate contains the same active ingredient as sevelamer HCl. It was developed as a pharmaceutical alternative to avoid the metabolic acidosis often seen with sevelamer HCl.⁸ The VA transitioned from sevelamer

hydrochloride to sevelamer carbonate in March 2009, providing this study with a unique population for comparison. In June 2010, a national VA therapeutic interchange guidance was released to assist with transitioning Veterans from sevelamer carbonate to lanthanum.⁹ The interchange was an effort to reduce pill burden and cost while maintaining similar phosphorus control as demonstrated in a crossover trial of sevelamer hydrochloride and lanthanum by Sprague et al published in 2009.^{9,10}

There are limited published data directly comparing lanthanum and sevelamer. A prospective randomized crossover trial of non-VA patients by Kasai et al assessed the safety and efficacy of lanthanum compared to sevelamer hydrochloride in 42 dialysis patients.¹¹ It showed similar efficacy in reduction of serum phosphorus with an average daily dose of 945 ± 449 mg for lanthanum and $2,971 \pm 1,464$ mg for sevelamer hydrochloride. Commonly reported adverse events in the literature are similar between lanthanum and sevelamer carbonate, with cumulative incidence of gastrointestinal intolerance and constipation at roughly 10% to 13%.^{3,7} The only significant difference seen in the study by Kasai et al was an increased rate of constipation in the sevelamer hydrochloride group compared to lanthanum (27% vs 5%, respectively; $P < .05$).¹¹

Most providers typically target a phosphorus goal between 3.5 and 5.5 mg/dL (1.13 and 1.78 mmol/L), which is consistent with the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines.¹² This target differs from the more recent KDIGO guidelines, which recommend lowering levels toward the “normal range” but do not specify a target threshold.⁴ In this study, we chose a general phosphorus goal of <5.5 mg/dL to determine whether it was or was not controlled. The recommendations for frequency of monitoring also differ between guidelines as well as stage of CKD.

Comparing the drug acquisition cost of lanthanum and sevelamer hydrochloride, a post hoc evaluation of cost-effectiveness in non-VA patients was compiled by Keith et al based on a 16-week (phase IV) trial converting sevelamer hydrochloride to lanthanum by Vemuri et al.^{2,7} The analysis of 691 patients showed an average savings for lanthanum of \$11.03 per day based on average wholesale price (AWP) while still maintaining phosphorus control.² This cost savings was directly proportional to the dose of sevelamer hydrochloride, with savings beginning with doses greater than or equal to 4,905 mg/day.²

Within the VA, lanthanum is available as 500 mg, 750 mg, and 1,000 mg chewable tablets and sevelamer carbonate is available as an 800 mg tablet. Sevelamer carbonate is also available as a powder for oral suspension, but it was not used in this study. While comparison studies by both Prajapati et al and Kasai et al did not detect differences in tablet burden between lanthanum and sevelamer hydrochloride, a study by Vemuri et al determined that lanthanum therapy required significantly fewer tablets per day.^{3,7,11} The decrease in tablet burden of lanthanum appeared to have a positive influence on patient adherence.^{3,7,11}

METHODS

Data were obtained through an electronic review of the Veteran's Health Information Systems and Technology Administration (VISTA) and Computerized Patient Record System (CPRS). Data consist of demographics, active lanthanum and sevelamer carbonate prescriptions, most recent laboratory values recorded in CPRS within 1 year, allergies, and pertinent concomitant prescription therapy. Phosphorus lab was a one-time, point value at the time of data collection. Serum phosphorus less than or equal to 5.5 mg/dL was considered controlled. Cost analyses were based on ingredient cost as shown in **Table 1**, and patients who were prescribed less than or equal to 9,600 mg per day of sevelamer were assessed for potential cost savings in the transition to lanthanum. Chi-square analysis was used to analyze categorical data, and 2-sided *t* test was used for continuous data. An α was set at 0.05 to determine significance. Patients included were those with an active prescription for lanthanum or sevelamer carbonate tablets on October 22, 2014 (*N* = 150). Patients were included on an intention-to-treat basis and were not required to have a specific number of doses prior to inclusion and analysis. The primary objective was to compare lanthanum and sevelamer carbonate on the basis of

cost to the medical center and the secondary objective was to compare pill burden of the 2 agents.

RESULTS

The 150 patients in the evaluation had a mean age of 68 years, were predominately male (96%), and had a diagnosis of ESRD (78%) (**Table 2**). There were significantly more ND-CKD stage 5 patients in the lanthanum group compared to the sevelamer carbonate group (12% vs 3%, respectively; *P* = .03). However, when rates of ND-CKD stage 5 and ESRD were combined, there was not a significant difference between groups. There were only 3 allergies documented; nausea with vomiting and taste disturbance with lanthanum and 1 patient experiencing constipation with sevelamer.

Both lanthanum and sevelamer carbonate groups achieved similar phosphorus control defined as less than or equal to 5.5 mg/dL (56% vs 65%, respectively; *P* = .23). There was no significant difference in corrected calcium levels. Prescription fill history was assessed by the timeframe of the most recent fill (0-6 months and >6 months). Patients at the medical center are given up to a 3-month supply of medication at a time. Proportions of prescription fills within given timeframes were similar between the 2 groups. On average, lanthanum prescriptions required significantly fewer tablets per day (4 lanthanum tablets daily vs 7 sevelamer carbonate tablets daily; *P* < .001).

Average daily doses of lanthanum and sevelamer carbonate in this population were 2,777 mg and 5,979 mg, respectively. Fourteen percent of lanthanum doses and 41% of sevelamer carbonate doses were greater than the highest listed doses represented on VA therapeutic interchange guidance.⁹ Three patients in the lanthanum group and 2 patients in the sevelamer carbonate group were prescribed daily doses greater than the maximum daily doses studied in ESRD patients on dialysis (> 4,500 mg/day and >14,000 mg/day, respectively).^{8,13-15} Notably, 15% of patients in the lanthanum group and 11% of patients in the sevelamer carbonate group had concomitant prescriptions for calcium acetate, which is used for its phosphate-binding capacity.¹⁶

Prescription Review and Phosphorus Levels of Medical Center Patients

Active lanthanum and sevelamer carbonate prescriptions are represented by **Table 3** and **Table 4**, respectively. These tables delineate phosphorus

Table 1. Contracted prices^a of sevelamer carbonate and lanthanum

Drug name	Price per dispensed unit
Sevelamer carbonate 800 mg tablet	\$1.028
Lanthanum 500 mg, 750 mg, 1000 mg tablets	\$1.514

^aMcKesson contracted price as of August 2014.

Table 2. Baseline demographic data in Veterans Affairs patients receiving lanthanum vs sevelamer carbonate

Demographic data	Lanthanum ^a (<i>n</i> =74)		Sevelamer car- bonate ^b (<i>n</i> =76)		<i>P</i> value
Age, years ($\pm SD$)	67.6	(± 10.5)	68.9	(± 9.6)	.43
Weight, kg ($\pm SD$)	89.5	(± 20.9)	85.4	(± 19.9)	.47
Sex, male	97%		95%		.42
CKD stage based on eGFR, <i>n</i> (%)					
3	0	(0)	0	(0)	—
4	10	(14)	11	(14)	.84
5	9	(12)	2	(3)	.03
ESRD	55	(74)	62	(83)	.22
Concomitant outpatient medications, <i>n</i> (%)					
Cholecalciferol	12	(16)	4	(5)	.03
Ergocalciferol	5	(7)	5	(7)	.96
Calcitriol	10	(14)	7	(9)	.41
Calcium acetate	11	(15)	8	(11)	.42
Laboratory data					
Corrected serum calcium, mg/dL ($\pm SD$)	9.6	(± 0.9)	10.1	(± 0.7)	.67
Serum phosphorus (<5.5 mg/dL), <i>n</i> (%)	40	(56)	49	(65)	.23
Serum phosphorus lab within 1 year, <i>n</i> (%)	53	(74)	52	(69)	.57
Prescription fills (most recent), <i>n</i> (%)					
< 3 months	69	(93)	72	(95)	.70
> 6 months	5	(7)	4	(5)	.70
Average daily dose, mg ($\pm SD$)	2,777	($\pm 1,074$)	5,979	($\pm 3,071$)	<.001
No. of tablets per day ($\pm SD$)	4	(± 1.3)	7	(± 3.8)	<.001
Allergy/adverse reaction, <i>n</i> (%)					
Calcium acetate	1	(1)	0	(0)	
Lanthanum	0	(0)	2	(3)	
Sevelamer carbonate	0	(0)	1	(1)	

Note: CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; ESRD = end stage renal disease.

^aTwo patients had no documented serum phosphorus.

^bOne patient had no documented labs on file.

control based on daily dose of lanthanum or sevelamer carbonate. Cost per day is calculated using pricing data at the time of evaluation.

Conversion Factor Data When Comparing Lanthanum and Sevelamer Carbonate

Approximate therapeutic equivalent lanthanum doses to sevelamer carbonate are listed in the last 2 columns of Table 4. Of note, the conversion factors are based on sevelamer carbonate potency compared

to lanthanum. They are reciprocals of those defined in literature commonly citing conversion factors of lanthanum potency compared to sevelamer carbonate. For example, with a conversion factor of 2, it could be said that “lanthanum is two times more potent than sevelamer carbonate in terms of phosphorus reduction.” Several conversion factors have been cited in the literature: 2.13,^{9,10} 2.33,¹⁷ 2.6-2.8,¹⁸ 2.67,¹⁹ 3.05.¹¹ Use of higher ratios (3.1-4.2) has been suggested with sevelamer carbonate doses exceeding 7,200 mg.¹⁸

Table 3. Active lanthanum prescriptions in Veterans Affairs patients ($n = 74$)

Lanthanum dose/day, mg	Cost/day	Patients	Serum phosphorus ≤5.5 mg/dL
6,000	\$ 9.06	3 (4%)	1 (33%)
4,500	\$ 9.06	4 (5%)	1 (25%)
4,000	\$ 6.04	3 (4%)	1 (33%)
3,750	\$ 12.08	1 (1%)	0 (0%)
3,000	\$ 4.53	35 (47%)	18 (51%)
2,500	\$ 7.55	0 (0%)	0 (0%)
2,250	\$ 4.53	9 (12%)	6 (67%)
2,000	\$ 6.04	1 (1%)	1 (100%)
1,500	\$ 4.53	17 (23%)	11 (73%)
1,000	\$ 3.02	1 (1%)	1 (100%)

Note: Shaded portion is a daily dose higher than the maximum studied doses (>4,500 mg lanthanum).¹⁶

Table 4. Active sevelamer carbonate prescriptions ($n = 76$)

Sevelamer dose/day, mg	Cost/day	Patients	Serum phosphorus ≤5.5 mg/dL ($n=75$)	Therapeutic equivalent lanthanum dose, a mg	
				Conversion factor ^{9,10} of 1/2.13	Conversion factor ^{11,18} of 1/3
16,800	\$ 21.59	1 (1%)	1 (100%)	7,896	5,600
14,400	\$ 18.50	1 (1%)	1 (100%)	6,768	4,800
12,800	\$ 16.45	1 (1%)	1 (100%)	6,016	4,267
11,200	\$ 14.39	2 (3%)	1 (50%)	5,264	3,733
10,400	\$ 13.36	1 (1%)	1 (100%)	4,888	3,467
9,600	\$ 12.34	9 (12%)	6 (67%)	4,512	3,200
7,200	\$ 9.25	16 ^a (21%)	8 (53%)	3,384	2,400
6,400	\$ 8.22	0 (0%)	0 (0%)	3,008	2,133
5,600	\$ 7.19	2 (3%)	2 (100%)	2,632	1,867
4,800	\$ 6.17	25 (33%)	15 (60%)	2,256	1,600
4,000	\$ 5.14	1 (1%)	0 (0%)	1,880	1,333
3,200	\$ 4.11	0 (0%)	0 (0%)	1,504	1,067
2,400	\$ 3.08	17 (22%)	13 (76%)	1,128	800

Note: Shaded portions are daily doses higher than the maximum studied doses (>4,500 mg lanthanum and >14,000 mg sevelamer carbonate).^{8,16}

^aOne patient had no phosphorus lab on file.

DISCUSSION

Doses of lanthanum and sevelamer carbonate noted in this study population were similar to those in Vemuri et al's study in which average daily doses of lanthanum and sevelamer hydrochloride were 2,800 mg and 7,200 mg, respectively.⁷ The average daily dose in the current review was significantly

higher when compared to Kasai et al's review where the average daily dose was 945 mg for lanthanum and 2,971 mg for sevelamer hydrochloride.¹¹ This dose disparity correlated to decreased tablet burden in favor of lanthanum as seen in this study, which has been associated with a potentially positive influence on patient adherence.⁷

Table 5. Estimated cost avoidance for transition from sevelamer carbonate to lanthanum at study hospital

Sevelamer dose/ day, mg	Lanthanum conversion dose/day, mg	Daily cost savings per patient	Estimated 30-day cost savings	Estimated annual cost avoidance
9,600	4,500	\$3.20	\$863.46	\$10,361.52
7,200	3,000	\$4.68	\$2,247.84	\$26,974.08
6,400	3,000	\$3.69	\$0.00	\$0.00
5,600	2,250	\$2.66	\$159.60	\$1,915.20
4,800	2,250	\$1.64	\$1,230.00	\$14,760.00
4,000	1,500	\$0.61	\$18.30	\$219.60
3,200	1,500	-\$0.42	\$0.00	\$0.00
2,400	1,500	\$0.06	\$32.64	\$391.68
			\$4,551.84	\$54,622.08

This study demonstrated a potential prescription cost savings for the medical center of approximately \$4,500 monthly or \$54,000 annually, if all study patients prescribed less than or equal to 9,600 mg of sevelamer carbonate per day were converted to lanthanum therapy. Patients with doses greater than 9,600 mg per day were excluded, as they would have required a larger dose of lanthanum than the maximum studied dose. Similar to the study by Keith et al, appreciable cost savings for this patient population began at sevelamer carbonate daily doses greater than or equal to 4,800 mg.² Notably, of the 52 patients on sevelamer carbonate daily doses between 4,800 mg and 9,600 mg in this review, 18 patients (35%) had a previous trial of lanthanum. These 18 patients may not be appropriate candidates for conversion to lanthanum as the reason for originally transitioning from lanthanum was unknown (provider preference, gastrointestinal intolerance, lack of dentition, etc).

While phosphorus control trended in favor of sevelamer carbonate in this population, there was no statistically significant difference to refute conclusions of both agents achieving similar phosphorus control as shown in previous studies.^{5,10,11} Although lanthanum and sevelamer carbonate are only approved in ESRD patients, this evaluation along with previous literature support use in CKD stage 3-5 as well.^{5,17} Both groups included a similar portion of patients who had active prescriptions for calcium acetate. While this could represent a confounding variable given that calcium acetate is a first-line phosphate binder, this portion may be artificially elevated

because prescriptions remain active for 1 year from the date written. Therefore patients transitioned from calcium acetate to a non-calcium phosphate binder within 1 year may have an active prescription for calcium acetate but not actually be actively taking the medication. Many patients were on vitamin D agents (cholecalciferol, ergocalciferol, or calcitrol), which may cause increases in phosphorus levels. Active vitamin D prescriptions were noted in 36% of the lanthanum group and 22% of the sevelamer carbonate group.

There are several limitations to this study. It is a relatively small, single-center study with a predominately older, male demographic. Control of phosphorus was based on a single phosphorus lab recorded at the time of data collection; only 69% of patients in the sevelamer group and 74% of patients in the lanthanum group had a recorded phosphorus lab within the past year. Labs drawn at dialysis centers outside of our institution were not included in this analysis if they were not documented in the VA medical record. Though the proportion of phosphorus levels less than or equal to 5.5 mg/dL was similar between groups, it is difficult to extrapolate longitudinal phosphorus control based on a single lab value. The length of time on phosphate binder therapy up until lab draw was not collected, thus some patients may have only been on this course of therapy for a short time. The proportion of most recent prescription fill as shown in Table 2 was similar between groups, although refill history may not adequately represent patient adherence. Patients within the institution are not sent more

than a 90-day supply of medication, thus the time-frame of refill within 6 months may overestimate patient adherence. Patients with the same total daily dose may not have been prescribed identical regimens (ie, for a total daily dose of 3,000 mg: 1,000 mg tid vs 1,500 mg bid vs two 500 mg tablets tid). Only the most common regimens were assessed for the cost evaluation. Intolerance to sevelamer carbonate or lanthanum was assessed by allergies entered by providers. Often, drug allergies are only entered if they are true allergies, and drug intolerance might not be captured. Last, dietary phosphorus intake was not evaluated.

Sevelamer carbonate tablets must be swallowed whole and lanthanum tablets need to be crushed or chewed upon administration, which may be helpful for patients with difficulty swallowing pills. Neither may be partially administered, thus all dose conversions were rounded to the nearest available dose. Two patients had active prescriptions for both lanthanum and sevelamer carbonate. For the purposes of this analysis, they were represented as separate data points for both lanthanum and sevelamer carbonate groups.

The conversion factor between sevelamer carbonate and lanthanum varies in the literature and may be nonlinear.¹⁸ Data from the post hoc analysis of Vemuri et al's study by Wilson et al suggest that at higher doses, lanthanum may have a proportionally increased amount of phosphate-binding capacity when compared to sevelamer hydrochloride.¹⁸ This combined with a limited number of available tablet strengths makes it inherently challenging to develop a chart of lanthanum conversion regimens if intending to transition from sevelamer carbonate to lanthanum.

CONCLUSIONS

In this evaluation, phosphorus control did not favor one product over another. Compared to sevelamer carbonate, lanthanum exhibited a reduced pill burden and lower absolute monthly drug cost. The cost savings were directly proportional to sevelamer carbonate daily dose and became appreciable with doses of at least 4,800 mg/day. Given the reduction in pill burden, decreased monthly cost, and similar phosphorus control of lanthanum compared to sevelamer carbonate, an institution-specific review may be beneficial. To evaluate the utility of a transition from sevelamer carbonate to lanthanum, it may be most useful to focus on patients with sevelamer doses of at least 4,800 mg/day. A suggested conversion table would also be useful in facilitating

recommendations when transitioning from sevelamer carbonate to lanthanum.

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