



DCOR Study: Assessing economic impact of sevelamer vs calcium binders on hospitalization & morbidity in hemodialysis patients using CMS data

Introduction

- Mortality, morbidity, and hospitalization rates in dialysis patients are high and the cost of care is enormous.
- The DCOR (Dialysis Clinical Outcomes Revisted) study was a U.S. multi-center, randomized, open-label, parallel design trial of sevelamer hydrochloride versus calcium-containing phosphate binders on mortality (primary end-point), hospitalization, morbidity, and costs (secondary end-points).
- Calcium-based binders were calcium acetate (predominantly) and calcium carbonate.
- In order to obtain hospitalization, morbidity, and cost outcomes, DCOR patient data were linked with end-stage renal disease (ESRD) data from the Centers for Medicare and Medicaid Services (CMS).
- Economic results are presented here.

Methods

- The cohort consisted of 2,101 (99.9%) DCOR study subjects who were linked, via Social Security Number, name, and demographics, to the Centers for Medicare and Medicaid Services (CMS) ESRD database. In this cohort, 2,038 (97.0%) subjects began treatment with either sevelamer or a calcium-containing binder.

- Because costs were assessed from claims, included subjects had Medicare as the primary payer (MPP) during ≥90% of the follow-up period. 1,895 (93.0%) of dosed patients had MPP status.
- Follow-up extended from dosing until death, transplant, change in dialysis modality, withdrawal of consent, loss to follow-up, end of 2004, or 90 days following study discontinuation (90-day rule).
- Costs were defined by Medicare allowable expenditures on submitted claims and were adjusted for inflation during the time-span of the DCOR trial (i.e. 2001-2004), using 2001 as the reference year.
- Per member per month (PMPM) costs were calculated for total, inpatient (IP), outpatient (OP), skilled nursing facility (SNF), and other medical claims. Sevelamer or calcium-binder costs are not included. ICD-9-CM diagnosis codes were used to categorize hospitalization cause (cardiovascular (CV), infection, vascular access (VA), fracture, and other).
- For OP costs, morbidity type was defined by procedure codes. Non-specific OP costs in claims with procedures were included proportionately to the cost of the relevant procedure, when multiple procedure types were present on one claim.
- Multiple linear regression models of log PMPM costs were used to assess the effects of sevelamer on relative cost (RC). Patients with zero IP or OP-event related costs were excluded. Models were adjusted for demographics, dialysis vintage, diabetes, and pre-study CV comorbidities.

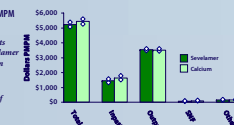
Results

- Total and IP average (median) PMPM inflation-adjusted costs were \$199 (\$280) and \$183 (\$235) less in sevelamer vs calcium groups, and OP costs were \$14 (\$63) more.
- About 25% of subjects in each group had \$0 IP costs. Regression models adjusting for baseline characteristics and comorbidities showed that IP costs were lower in sevelamer group as compared with calcium (RC=0.85, 0.76-0.95; p=0.006) with a trend towards significance in total costs (RC=0.96, 0.92-1.00; p=0.057) and no difference in OP costs (RC=1.02, 0.99-1.04; p=0.213).
- CV, infection, VA, fracture and "other" IP costs were \$28, \$62, \$-1, \$3, and \$89 less, respectively, among sevelamer vs calcium-treated subjects. Adjusted differences for IP costs showed that "other" hospitalization costs were lower in the sevelamer vs. calcium group (RC=0.86, 0.75-0.99; p=0.042).
- CV-related OP cost among subjects randomized to sevelamer vs calcium were marginally lower (\$2.15 vs. \$3.23 PMPM).
- Inflation-adjusted differences in VA-related (\$45.91 vs. \$45.79 PMPM) and infection-related (\$2.19 vs. \$2.13 PMPM) costs were nearly equivalent.

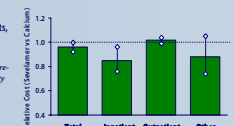
Inflation-adjusted PMPM Costs

	Total (N = 934)			Inpatient (N = 961)			Outpatient (N = 934)		
	Sevelamer (N = 961)	Calcium (N = 934)	p-value*	Sevelamer (N = 961)	Calcium (N = 934)	p-value*	Sevelamer (N = 961)	Calcium (N = 934)	p-value*
• Wilcoxon rank sum test									
• Mean PMPM costs	5,236	5,435	0.06	1,461	1,644	0.05	3,535	3,521	0.15
• Mean PMPM costs weighted by length of follow-up	(5,075, 5,398)	(5,208, 5,613)		(1,338, 1,584)	(1,503, 1,784)		(3,471, 3,598)	(3,463, 3,598)	
• Median	4,653	4,933		969	1,144		3,297	3,234	
• Std Dev	2,550	2,748		1,937	2,189		1,000	1,064	
• 25th - 75th	3,446 - 6,810	3,556 - 7,247		111 - 2,510	139 - 3,020		2,846 - 3,888	2,780 - 3,899	
• Min - Max	1,071 - 42,286	809 - 100,169		0 - 40,015	0 - 100,169		1,071 - 15,972	0 - 11,697	

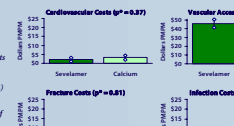
Inflation-adjusted PMPM Costs, by type



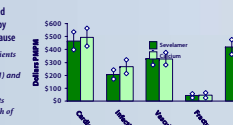
Inflation-adjusted Relative PMPM Costs, by type



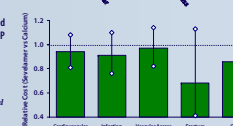
Inflation-adjusted PMPM OP Costs, by Morbidity Type



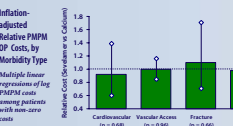
Inflation-adjusted PMPM IP Costs, by hospitalization cause



Inflation-adjusted Relative PMPM IP Costs, by hospitalization cause



Inflation-adjusted Relative PMPM OP Costs, by Morbidity Type



Conclusions

- Total and IP average PMPM costs were \$199 and \$183 less and OP PMPM costs were \$14 more among sevelamer-treated subjects than subjects treated with calcium-based binders (excluding all oral medication costs).
- Extrapolating average PMPM total costs to per patient per year total costs showed that sevelamer-treated subjects had \$2,388 less cost than calcium-binder treated subjects.
- Hospitalization costs drove the cost differential between treatment groups.
- These data are consistent with results showing a significant reduction in rates of multiple hospitalizations and hospital days in subjects treated with sevelamer versus calcium-based binders.
- Outpatient, SNF, or "other" costs were not significantly affected by binder choice.
- Sevelamer appears to reduce the hospitalization rate, hospital days, and inpatient costs as compared to calcium-based binders.
- In order to determine sevelamer's effect on total health care expenditures, the cost of oral medications (including phosphate binders) needs to be considered.

funded in part by an unrestricted grant from Genzyme Corporation