COMPARISON OF POTASSIUM VALUES BEFORE AND AFTER PATIROMER INITIATION AMONG PATIENTS RECEIVING CHRONIC HEMODIALYSIS IN THE UNITED STATES

Christopher G. Rowan[1], Csaba P. Kovesdy[2], Charles Du Mond[3], Nina Oestreicher[3,4], David M. Spiegel[3], Wolfgang C. Winkelmayer[5]

[1]COHRDATA, Santa Monica, CA; [2]University of Tennessee Health Science Center, Memphis, TN; [3]Relypsa, Inc., a Vifor Pharma Company, Redwood City, CA; [4]University of California San Francisco, San Francisco, CA; [5]Baylor College of Medicine, Houston, TX, USA

INTRODUCTION AND AIMS

- In December 2015, the U.S. Food and Drug Administration approved patiromer for the treatment of hyperkalemia.
- We aimed to study serum potassium (K^+) concentration trajectories in hemodialysis (HD) patients who newly initiated patiromer in real world practice.

METHODS

- In a retrospective observational study, we identified patients receiving HD at a large U.S. dialysis provider who initiated patiromer between 12/21/2015 and 9/30/2016.
- K^+ values (mmol/L) were summarized in 6 sequential 30-day periods, 3 preceding and 3 following patiromer initiation.
- We used summary statistics to describe K^+ values and calculated the percentage of patients with $K^+ \geq 6.0$ in each baseline (BL) and follow-up (FU) period.
- Change in K^+ before *vs.* after patiromer initiation was assessed using the last K^+ value prior to patiromer initiation, to which the last K^+ value in each of the three FU periods was compared.
- Change in K^+ (before *vs.* after patiromer initiation) was analyzed using paired *t*-tests and McNemar's tests to assess changes in the percentage of K^+ values ≥ 6.0.

RESULTS

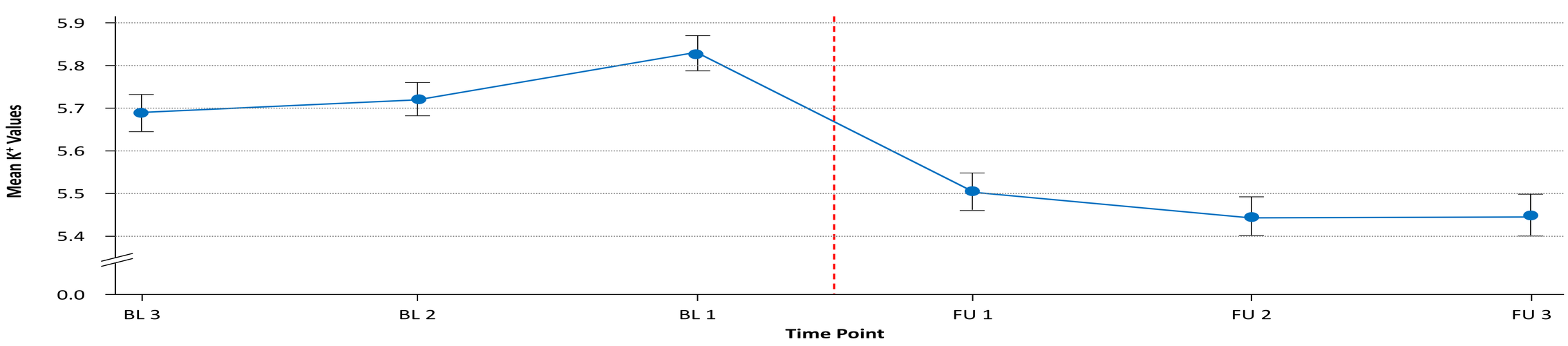
- Of 403 patients studied, the mean age was 59 years, 56% were men, 67% were White/Hispanic, and 18% were Black. K^+ values in each of the BL and FU periods are summarized in Table 1 and Figure 1.

Table 1. Study Schema and Summary of K^+ Data Before and After Patiromer Initiation

	Pre-patiromer K^+ assessments*			Index Date† (Day 0)	Post-patiromer K^+ assessments*		
	Days −91 to −61 BL 3	Days −60 to −31 BL 2	Days −30 to −1 BL 1		Days 1 to 30 FU 1	Days 31 to 60 FU 2	Days 61 to 91 FU 3
Descriptive	**BL 3**	**BL 2**	**BL 1**		**FU 1**	**FU 2**	**FU 3**
N (≥1 K^+ test)	390	386	401		387	328	274
Number of K^+ tests							
Total number of K^+ tests	1,222	1,205	1,357		1,186	1,000	850
Mean number of K^+ tests per patient	3.1	3.1	3.4		3.1	3.0	3.1
SD per patient	1.7	1.6	1.6		1.4	1.5	1.6
Median number of K^+ tests per patient	3.0	3.0	4.0		4.0	3.0	3.0
K^+ values (mmol/L)							
Mean	5.69	5.72	5.83		5.51	5.45	5.45
SD	0.70	0.68	0.75		0.75	0.72	0.75
50th	5.70	5.70	5.80		5.50	5.40	5.40
K^+ categories, %							
K^+ <5	13.8%	12.0%	11.5%		20.1%	24.9%	23.7%
K^+ ≥5 – <5.5	22.4%	20.9%	16.2%		26.4%	27.6%	28.0%
K^+ ≥5.5 – <6.0	29.5%	31.7%	27.8%		27.3%	24.0%	23.9%
K^+ ≥6.0 – <6.5	21.2%	22.7%	25.7%		17.2%	14.3%	14.9%
K^+ ≥6.5	13.1%	12.8%	18.8%		9.0%	9.2%	9.5%

*In each baseline (BL) and follow-up (FU) period, all potassium (K^+) values were included. †The index date is the date of the first patiromer order during the study period 12/21/2015–9/30/2016. SD, standard deviation.

Figure 1. Mean K^+ Values (95% CI) Before and After Patiromer Initiation*



*The dashed red line represents the time of patiromer initiation.
BL, baseline; FU, follow-up; K^+, potassium.

- Compared with BL 1, the mean K^+ changes (in mmol/L) were −0.48 in FU 1; −0.51 in FU 2; and −0.55 in FU 3 (all $P<0.001$) and are summarized in Table 2.

Table 2. Study Schema and Summary of K^+ Change Data Before and After Patiromer Initiation

		Pre-patiromer K^+*	Index Date‡ (Day 0)	Post-patiromer K^+†		
		Days −30 to −1 BL 1		Days 1 to 30 FU 1	Days 31 to 60 FU 2	Days 61 to 91 FU 3
Descriptive				**BL *vs.* FU 1**	**BL *vs.* FU 2**	**BL *vs.* FU 3**
N				367	320	267
K^+ Δ values						
K^+ Δ Mean				−0.48	−0.51	−0.55
K^+ Δ SD				0.91	0.92	0.91
K^+ Δ 50th				−0.50	−0.50	−0.50
K^+ Δ by BL K^+				**K^+ Mean Δ**	**K^+ Mean Δ**	**K^+ Mean Δ**
K^+ <5				0.47	0.46	0.44
K^+ ≥5 – <5.5				0.16	-0.04	0.05
K^+ ≥5.5 – <6.0				−0.24	−0.24	−0.33
K^+ ≥6.0 – <6.5				−0.83	−0.74	−0.73
K^+ ≥6.5				−1.15	−1.36	−1.40
Analytic (pre *vs.* post)				**BL 1 *vs.* FU 1**	**BL 1 *vs.* FU 2**	**BL 1 *vs.* FU 3**
Paired *t*-test (H0: Δ=0)				**K^+ Mean Δ=0**	**K^+ Mean Δ=0**	**K^+ Mean Δ=0**
K^+ Δ mean				−0.48	−0.51	−0.55
95% CI				−0.57, −0.39	−0.62, −0.41	−0.66, −0.44
P value				*P*<0.001	*P*<0.001	*P*<0.001
McNemar's§				**K^+ ≥6.0**	**K^+ ≥6.0**	**K^+ ≥6.0**
Before *vs.* after				0.50 *vs.* 0.24	0.49 *vs.* 0.21	0.51 *vs.* 0.21
Before *vs.* after Δ				−0.26	−0.28	−0.30
95% CI				−0.33, −0.19	−0.35, −0.21	−0.38, −0.22
P value				*P*<0.001	*P*<0.001	*P*<0.001

*The last K^+ value closest to the index date in BL 1 was used. †The K^+ values farthest from the index date in FU 1, FU 2, and FU 3 were used. ‡The index date is the date of the first patiromer order during the study period 12/21/2015–9/30/2016. §McNemar's test is a within-subjects *z*-test of equality of proportions for correlated data. BL, baseline; FU, follow-up; K^+, potassium.

- The percentages of patients with K+ ≥6.0 were: BL 3=34.3, BL 2=35.4, BL 1=44.5, and FU 1=26.2, FU 2=23.5, FU 3=24.5.
- The absolute percent reductions (vs. BL 1) of patients with K+ ≥6.0 were: −26% for FU 1, −28% for FU 2, and −30% for FU 3 (all $P<0.001$).

CONCLUSIONS

- Statistically significant reductions in mean K^+ concentrations and the percentage of patients with $K^+ \geq 6.0$ were observed in HD patients initiating patiromer in this typical practice setting.
- Given the limitations of retrospective research, these findings merit additional investigation using prospective designs and longer follow-up.

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