Disparities in Real-World Utilization Patterns of Potassium Binders in US Veterans with Hyperkalemia

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BACKGROUND

- Hyperkalemia (HK) is a potentially life-threatening metabolic disorder and a challenging clinical problem for clinicians caring for patients with chronic kidney disease (CKD), diabetes mellitus (DM), or heart failure (HF).
- The management of chronic HK has always been limited to renin-angiotensin-aldosterone system inhibitor (RAASi) dose reduction or discontinuation, diuretic therapy, dietary potassium (K^+) restriction, or the use of sodium polystyrene sulfonate (SPS).
- Patiromer (PAT) is a sodium-free, non-absorbed, K^+-binding polymer approved for the treatment of HK, including in the United States,[1] the European Union,[2] Switzerland,[3] and Australia,[4] among others.
- Little has been reported about the real-world utilization of this medication.

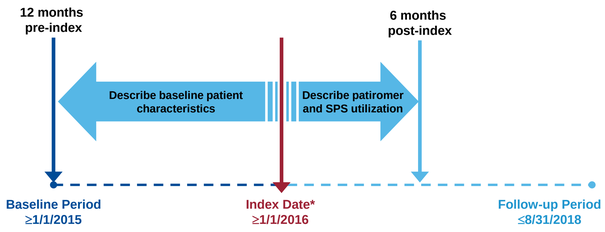
OBJECTIVE

- This historical cohort study aimed to describe K^+ binder treatment patterns in US Veterans with HK.

METHODS

- PAT and SPS utilization were evaluated using the Veterans Health Association (VHA) Corporate Data Warehouse (CDW) database from 1/1/16 to 8/31/18 (**Figure 1**).
- Two HK cohorts were identified: PAT cohort and SPS cohort.
- The index date is the date of the first pharmacy dispensing claim for PAT or SPS during the study period. Index date may have started anytime between 1/1/16 and 8/31/18.
- Patients were included who had a pre-index serum K^+ ≥5.1 mEq/L, a pre-index diagnosis of HF, DM, or CKD.
- We evaluated two exposure classification groups: Intent-to-treat (ITT) and continuous exposure (CE). CE was defined as ≤30 days of a gap in exposure to binder therapy.
- Follow-up began at index date and ended at first censoring event.
  - ITT: death, end of follow-up, or 6 months post-index.
  - CE: discontinuation or switch of index K^+ binder, death, end of follow-up, or 6 months post-index.

FIGURE 1. STUDY SCHEMA



*The index date is the date of the first pharmacy-dispensing claim for PAT (PAT cohort) or SPS (SPS cohort) during the study period. Index date may have started anytime between 1/1/16 and 8/31/18.

RESULTS

- Baseline patient characteristics (12 months before index date) (**Table 1**):
  - Mean ages were 69 years (PAT) and 72 years (SPS) with the majority of patients being male (>97%) and 28%/22% African-American (PAT/SPS).
  - Comorbidities: higher percentage of CKD, HF, end-stage renal disease (ESRD), and peripheral vascular disease (PVD) in the PAT cohort.
  - Medications: PAT cohort observed a higher percentage of beta blocker, cyclosporine/tacrolimus, loop diuretic, insulin, and SPS use and a lower percentage of NSAID and RAASi use.

TABLE 1. PATIENT CHARACTERISTICS

	PAT n=386	SPS n=11,604
Demographics (as of index date)		
Age years, mean	69	72
Age ≥75 years, n (%)	79 (21)	3747 (32)
Male, n (%)	376 (97)	11,382 (98)
Caucasian, n (%)	250 (65)	8162 (70)
African American, n (%)	108 (28)	2505 (22)
Comorbidities (12 months before index), n (%)		
Cardiac dysrhythmias	113 (29)	3000 (26)
Cerebrovascular disease	66 (17)	1633 (14)
CKD	370 (96)	7864 (68)
Congestive HF	136 (35)	3158 (27)
Coronary artery disease	151 (39)	4272 (37)
DM	308 (80)	9122 (79)
ESRD	98 (25)	1482 (13)
Myocardial infarction	25 (7)	771 (7)
PVD	113 (29)	2455 (21)
Baseline medications (12 months before index), n (%)		
Beta blocker	264 (68)	7263 (63)
Cyclosporine/tacrolimus	26 (7)	435 (4)
Loop diuretic	220 (57)	4309 (37)
Thiazide diuretic	73 (19)	1770 (15)
Insulin	194 (50)	5019 (43)
NSAID	19 (5)	1501 (13)
ACEi	144 (37)	5348 (46)
ARB	74 (19)	1901 (16)
SPS	169 (44)	908 (8)

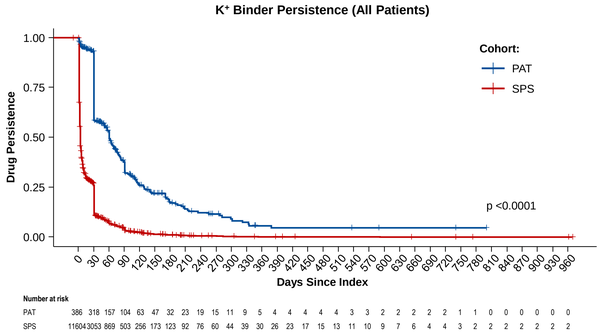
- Mean estimated glomerular filtration rate (eGFR) was lower in the PAT cohort (25 mL/min/1.73m^2) vs SPS (37 mL/min/1.73m^2) (**Table 2**).
- Mean serum K^+ for PAT and SPS were 5.9 and 5.8 mEq/L, respectively.

TABLE 2. BASELINE LABORATORY DATA

	PAT n=386			SPS n=11,604		
Baseline laboratory values (3 months before index date)	Mean	SD	Med	Mean	SD	Med
Number of K^+ assessments	3.5	2.5	3.0	2.7	2.1	2.0
K^+ value, mEq/L	5.9	0.5	5.8	5.8	0.4	5.7
K^+ categories, n (%)						
K^+ 5.1–5.4, mEq/L	74 (19.2)			2201 (19.0)		
K^+ 5.5–5.9, mEq/L	184 (47.7)			5850 (50.4)		
K^+ ≥6.0, mEq/L	128 (33.2)			3553 (30.6)		
eGFR using the CKD-EPI formula	Mean	SD	Med	Mean	SD	Med
eGFR value, mL/min/1.73m^2	24.6	16.5	22.1	37.0	22.2	33.7
eGFR categories, n (%)						
eGFR ≥90, mL/min/1.73m^2	2 (0.5)			267 (2.3)		
eGFR 60–89, mL/min/1.73m^2	10 (2.6)			1509 (13.0)		
eGFR 30–59, mL/min/1.73m^2	103 (26.7)			4821 (41.5)		
eGFR 15–29, mL/min/1.73m^2	149 (38.6)			2997 (25.8)		
eGFR <15, mL/min/1.73m^2	115 (29.8)			1949 (16.8)		

CKD-EPI, chronic kidney disease epidemiology collaboration; Med, median; SD, standard deviation.

FIGURE 2. PAT AND SPS DURATION OF CONTINUOUS USE



Time to the first censoring event (censoring events in CE: discontinuation or switching of index K^+ binder, end of study, death, or end of FU–8/31/18)

- At 6 months post-index, ~20% and ~2% remained continuously exposed to PAT and SPS, respectively (**Figure 2**).

TABLE 3. DRUG UTILIZATION METRICS AT 6 MONTHS POST-INDEX

6 months after index date, ITT	N	Mean	SD	Median
Medication fills				
PAT	210	1.9	1	2
SPS	9028	1.3	0.7	1
Days supplied/fills				
PAT	210	37	19	30
SPS	9028	12	17	3
PDC*				
PAT	210	0.45	0.28	0.41
SPS	9028	0.11	0.18	0.02
Percent patients PDC ≥80%	No		Yes	
PAT, n (%)	172 (82)		38 (18)	
SPS, n (%)	8905 (99)		123 (1)	

*PDC: total number of "days supplied" for the Index KB (the numerator) divided by the total number of days in the analysis interval (the denominator)

- The median number of dispensed days supplied was 30 for PAT and 3 for SPS, and the median medication fills were 2 for PAT and 1 for SPS.
- The median PDC for PAT/SPS were 41%/2%, respectively; PDC ≥80% was 18% for PAT and 1% for SPS (**Table 3**).

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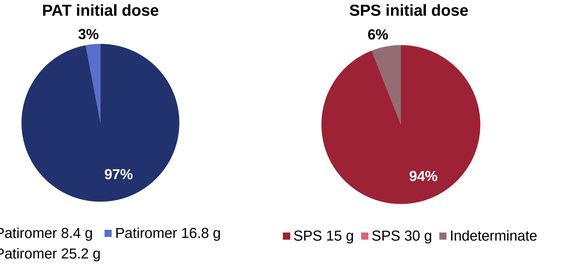
- The initial dose was 8.4 g (PAT) and 15 g (SPS) for 97% and 94%, respectively (**Figure 3**).
  - PAT and SPS dose increases and decreases were uncommon.

FIGURE 3. INITIAL BINDER DOSES



LIMITATIONS

- This is a descriptive, observational study; therefore, no causal or comparative claims can be derived.
- We have assumed that patients are taking their dispensed medications as directed.

CONCLUSIONS

- This descriptive analysis among US Veterans indicates a contrasting utilization pattern for patients exposed to PAT and SPS.
- At baseline, a greater percentage of patients had heart failure and more advanced kidney disease in the PAT cohort.
- The days supplied, number of prescription fills, and higher PDC suggest a more chronic treatment pattern for PAT and a more episodic treatment pattern for SPS.
- These findings warrant additional investigation as PAT use increases.

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DISCLOSURES

EOG reports consultant fees from Amgen and research support from Hope Pharmaceuticals and Cormedix; **CPK** reports consultant fees from AstraZeneca and Relypsa, Inc., a Vifor Pharma Group Company; **SDW** and **JF** report employment by Relypsa, Inc., a Vifor Pharma Group Company and stock in Vifor Pharma; **CGR** reports consultant fees from Corvidia, Keryx, Halozyme, and Relypsa, Inc., a Vifor Pharma Group Company, and founded COHRDATA; **JLH** and **BCS** report research support from COHRDATA.