Ongoing, Open-Label Study of Sodium Zirconium Cyclosilicate in Patients with Hyperkalemia

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Hyperkalemia (HK; serum potassium [K+] >5.0 mEq/L) is a common electrolyte disorder in patients with chronic kidney disease (CKD). HK can lead to life-threatening, abnormal cardiac rhythms and is associated with poor outcomes in patients with CKD. Sodium zirconium cyclosilicate is an investigational agent that is a non-absorbed, selective cation exchange crystal that is thought to bind to K+ throughout the GI tract. Previous studies showed that sodium zirconium cyclosilicate lowers and maintains K+ in the normal range for up to 28 days in patients with HK. The current ongoing, open-label study assessed sodium zirconium cyclosilicate treatment for 12 months in 751 adult patients with HK (K+ ≥5.1 mEq/L). Patients received 10g sodium zirconium cyclosilicate three times a day for 24–72 hours (induction phase), and patients whose K+ levels normalized during the induction phase went on to receive 5g of drug once a day for 12 months (maintenance phase; with dose titrated as needed). There were no protocol-mandated restrictions on diet or concomitant medications, including RAAS inhibitors. As of December 7, 2015, 436 patients had completed ≥6 months of treatment; 73.6% had a baseline eGFR <60 mL/min/1.73m2. During the induction phase, 99.3% of patients achieved normal K+ levels, with average K+ levels decreasing from 5.6 mEq/L at baseline to 4.7 mEq/L at the start of the maintenance phase. Among patients treated for ≥6 months, the average K+ level was 4.7 mEq/L over months 3–12. The most common side effects in all treated patients were constipation (5.0%), peripheral edema (7.6%), and worsening hypertension (8.2%). No patient stopped treatment because of edema or hypertension; 2 patients (0.3%) stopped due to constipation. These initial study results suggest that daily treatment with sodium zirconium cyclosilicate maintained normal K+ levels in patients with HK treated ≥6 months. The nursing implications for treatment of the HK patient are promising.

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