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Safety, effectiveness and treatment pattern sodium zirconium cyclosilicate for hyperkalemia management in China: Final results from a multicenter, prospective real-world study (Actualize Study)

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Objectives : Sodium zirconium cyclosilicate (SZC) is a non-absorbed cation-exchanger and is approved in China for the treatment of hyperkalemia (HK). The study aimed to assess its effectiveness, safety, and treatment patterns in real-world clinical setting. The results of the final analysis are presented here.
Methods : This multi-center prospective non-interventional cohort study enrolled 1000 patients (aged ≥18 years), including new and ongoing SZC users from 34 sites. The treatment was categorized into the correction phase (FAS-P1) and maintenance phase (FAS-P2 new and ongoing users). Subgroup analysis was performed in patients on hemodialysis (FAS-H). The primary objective was to explore the safety and effectiveness of SZC in the treatment of HK patients in China, and the secondary objectives included the deemed as causally related adverse events (AEs), serious adverse events (SAEs), discontinuations of SZC due to adverse events (DAEs), and specific AEs.
Results : Of the 1000 enrolled patients, 442, 878, and 474 were included in FAS-P1, FAS-P2 and FAS-H subgroups, respectively. The most frequently used SZC dosage in FAS-P1, FAS-P2, and FAS-H was 5g QD in 186 (42.1%), 331 (37.7%) and 40 (8.4%) patients, respectively. In FAS-P1 group, 64% of patients reported AEs and 65.4% in FAS-P2; 26.9% and 30.8% of patients reported SAEs, respectively. The serum potassium (sK+) reduced from 5.8 mmol/L to 5.0 mmol/L with mean change in sK+ of -0.9mmol/L and was consistent throughout the maintenance phase. The proportion of patients with mean 'with-in' sK+ levels were slightly higher in ongoing [13.2 (95% confidence interval (CI): 8.5, 20.5)] than in new user group [7.7 (95% CI: 3.7, 16.1)] of FAS-P2 with mean sK+ of 5.0mmol/L and 5.1mmol/L, respectively. Further, SZC showed good efficacy in patients with CKD subgroups of FAS-P2.

Conclusions : In real-world clinical practice, SZC was effective in lowering sK^+ levels, and there were no concerns about the safety of using SZC.