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Efficacy And Safety Of Sodium Zirconium Cyclosilicate In Hyperkalemia: A Subgroup Analysis In The Korean Population From The HARMONIZE Global Study

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Objectives : Sodium zirconium cyclosilicate (SZC) is a selective potassium (K^+) binder for hyperkalemia, which received regulatory approval in Korea in November 2025. This post-hoc subgroup analysis of the phase 3 HARMONIZE-Global study (NCT02875834) evaluated the efficacy and safety of SZC specifically in Korean patients to establish clinical evidence for its use in Korean patients and support localized treatment strategies.
Methods : Korean patients with hyperkalemia (serum $K^+ \geq 5.1$ mmol/L) were included in this phase 3, randomized, double-blind, placebo-controlled study. Following open-label treatment with SZC 10 g three times daily during a 48-hour correction phase, patients achieving normokalemia (3.5–5.0 mmol/L) were randomized to maintenance treatment with SZC 10 g, SZC 5 g, or placebo once daily for 28 days. The primary endpoint was mean serum K^+ during Days 8–29 of the maintenance phase.
Results : In the Korean subgroup (n=121), 84.3% of patients had chronic kidney disease and 78.5% were receiving RAAS inhibitors at baseline. During the correction phase, mean serum K^+ significantly decreased by 1.32 mmol/L at 48 hours compared to baseline ($p < 0.0001$), with 90.9% of patients achieving normokalemia. During the maintenance phase, SZC effectively maintained normokalemia; the least square mean serum K^+ was significantly lower in the SZC groups than in the placebo group (SZC 10 g: 4.51 mmol/L; SZC 5 g: 5.00 mmol/L; Placebo: 5.59 mmol/L; $p < 0.001$ for both). On Day 29, the proportion of patients maintaining normokalemia was significantly higher with SZC 10 g (66.7%) compared to placebo (8.7%; $p < 0.001$). SZC was generally well tolerated with no reported deaths. The most common adverse events were mild or moderate constipation.
Conclusions : SZC demonstrated rapid correction and effective maintenance of normokalemia in

Korean patients, consistent with global findings. These results support SZC as a prompt, sustained, and well-tolerated therapeutic option for hyperkalemia management in Korea.