Reply to Letter to the Editor

Peter A McCullough*

Baylor University Medical Center, Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas, TX, The Heart Hospital, Plano, USA

Patiromer Sorbitex Calcium: Author Response

We respect the comments in the letter to the editor concerning mention of the novel product patiromer sorbitex calcium for the treatment of hyperkalemia. The authors point out that at the minimum dose of patiromer, 8.4 g, patients will receive 1600 mg of calcium while at the minimum dose of sodium zirconium cyclosilicate 5 g, patients will receive ~400 mg of sodium as the counter exchange ion. The package insert for this product recently released in the United States indicates: "The active ingredient is patiromer sorbitex calcium which consists of the active moiety, patiromer, a non-absorbed potassium-binding polymer, and a calcium-sorbitol counterion. Each gram of patiromer is equivalent to a nominal amount of 2 g of patiromer sorbitex calcium." Accordingly the Medication Guide for patients states: "The most common side effects of Veltassa include: constipation, diarrhea, nausea, stomach-area (abdominal) discomfort, and gas [1]." The per capita daily consumption of sorbitol as a food additive is 200 mg [2]. The threshold for sorbitol to induce diarrhea is ~20 g. Thus in our view some of the gastrointestinal side effects could conceivably be related to the sorbitol component of the product. The placebo-controlled study in patients with chronic heart failure (the PEARL-HF) trial tested RLY5016 30 g per day total dose which is higher than the maximum 25.2 g per day of patiromer sorbitex calcium recommended in the package insert [3]. The rates of gastrointestinal adverse events were 21% with 30 g of RLY5016 and 6% with placebo. Inferences on how lower doses of commercially available patiromer sorbitex calcium would perform in the same population are limited.

References


*Corresponding author: Peter A McCullough, Baylor Heart and Vascular Institute, 621 N. Hall St., #H4030, Dallas, TX 75226, USA, Tel: (214) 820-7500 (O), (214) 820-7997; E-mail: Peter.McCullough@baylorhealth.edu

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