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Pharmacology of patiromer, a nonabsorbed cross-linked polymer that lowers serum potassium concentration in patients with hyperkalemia

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Statement of the Problem: Hyperkalemia is a potentially life-threatening condition, and patients with chronic kidney disease, diabetes, or who are taking renin–angiotensin–aldosterone system inhibitors are at increased risk of this disorder. Colonic potassium secretion can increase to compensate when urinary potassium excretion is impaired, but this adaptation is insufficient and hyperkalemia still results. Patiromer is a novel, spherical, nonabsorbed polymer designed to bind and remove potassium, primarily in the colon. Patiromer has been found to decrease serum potassium in patients with hyperkalemia having chronic kidney disease who were on renin–angiotensin–aldosterone system inhibitors. Patiromer was approved in the United States in late 2015 as Veltassa® for the treatment of hyperkalemia. It is the first new therapy available for hyperkalemia management in over 50 years.

Methodology & Theoretical Orientation: Results of nonclinical studies and an early phase clinical study are reported here.

Findings: Studies with radiolabeled drug were conducted in rats and in dogs. This work confirmed that patiromer was not absorbed into the systemic circulation. Results of an in vitro study showed that patiromer was able to bind 8.5 to 8.8 mEq of potassium per gram of polymer at a pH similar to that found in the colon and had a much higher potassium-binding capacity compared with other resins, including polystyrene sulfonate. In hyperkalemic rats a decrease in serum potassium was observed associated with an increase in fecal potassium excretion. In a clinical study in healthy adult volunteers, a significant increase in fecal potassium excretion and a significant decrease in urinary potassium excretion were observed.

Conclusion & Significance: Overall, patiromer is a high-capacity potassium binder, and the chemical and physical characteristics of patiromer may lead to good clinical efficacy, tolerability, and patient acceptance.

Biography

Lingyun Li has her expertise in biotechnology and pharmaceutical preclinical development (focusing on pharmacology and toxicology) in the areas of Oncology, Cardiovascular, and Renal Diseases. As a Pharmacologist, she has previously worked at J&J and Sanofi in Drug Discovery and Development. She is currently the Director of Biology and Pharmacology at Relypsa, Inc. She has experience supporting all stages of drug development (preclinical, IND to phase 3, and NDA). She has experience working with small molecules, biologics, and polymer drugs, and has extensive regulatory experience interacting with FDA and EMA.

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