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Effect of Finerenone on the Incidence of Hypokalemia in Patients With Type 2 Diabetes and Chronic Kidney Disease: A FIDELITY Analysis

Authors:
Bertram Pitt, MD;[1] Rajiv Agarwal, MD;[2] Stefan D. Anker, MD;[3] George L. Bakris, MD;[4] Peter Rossing, MD;[5,6] Luis Ruilope, MD;[7-9] Charles A. Herzog, MD;[10] Barry H. Greenberg, MD;[11] Robert Pecoits-Filho, MD;[12,13] Faiez Zannad, MD;[14] Marc Lambelet, Dipl Math;[15] Robert Lawatscheck, MD;[16] Andrea Scalise, MD;[17] Gerasimos Filippatos, MD;[18] Asia Quan, PharmD;[19] on behalf of the FIDELIO-DKD and FIGARO-DKD Investigators

Organizations/Affiliations:
[1]Department of Medicine, University of Michigan School of Medicine Ann Arbor, MI, USA
[2]Indiana University School of Medicine and Richard L. Roudebush VA Medical Center, Indianapolis, IN, USA
[3]Department of Cardiology (CVK), and Berlin Institute of Health Center for Regenerative Therapies, German Centre for Cardiovascular Research Partner Site Berlin, Charité–Universitätsmedizin, Berlin, Germany
[4]Department of Medicine, University of Chicago Medicine, Chicago, IL, USA
[5]Steno Diabetes Center Copenhagen, Herlev, Denmark
[6]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[7]Cardiorenal Translational Laboratory and Hypertension Unit, Institute of Research imas12, Madrid, Spain
[8]CIBERCV, Hospital Universitario 12 de Octubre, Madrid, Spain
[9]Faculty of Sport Sciences, European University of Madrid, Madrid, Spain
[10]Cardiology Division, Department of Internal Medicine, Hennepin Healthcare/University of Minnesota, Minneapolis, MN, USA
[11]University of California San Diego, La Jolla, CA, USA
[12]Arbor Research Collaborative for Health, Ann Arbor, MI, USA
[13]School of Medicine, Pontifícia Universidade Católica do Paraná, Curitiba, Brazil
[14]Henri Poincaré University, Nancy, France
[15]Chrestos Concept GmbH & Co. KG, Essen, Germany
[16]Cardiology and Nephrology Clinical Development, Bayer AG, Berlin, Germany
[17]Pharmaceutical Development, Bayer Hispania S.L., Barcelona, Spain
[18]National and Kapodistrian University of Athens, School of Medicine, Department of Cardiology, Attikon University Hospital, Athens, Greece
[19] Bayer US LLC, Whippany, NJ, USA

Abstract

Background: Hypokalemia is associated with CV events and mortality in patients with CKD, however the prevalence and impact may be underrecognized.

Objectives: To investigate the incidence and effect of low serum potassium in patients treated with finerenone, a non-steroidal MRA, versus placebo in the FIDELITY dataset.

Methods: In FIDELITY, a pooled analysis of the FIDELIO-DKD (NCT02540993) and FIGARO-DKD trials (NCT02545049), patients with CKD and T2D who were optimally treated with RASi were randomized to finerenone or placebo. Key outcomes included serum potassium levels <4.0 or <3.5 mmol/L, a CV composite outcome (CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF), and an arrhythmia composite outcome (new diagnosis of atrial fibrillation/atrial flutter, hospitalization due to arrhythmia, or sudden cardiac death).

Results: Of 12,859 patients, 41.1% and 7.5% experienced a treatment-emergent potassium level of <4.0 and <3.5 mmol/L, respectively. Compared with placebo, finerenone reduced the incidence of potassium levels <4.0 (33.9% vs 48.3%) and <3.5 mmol/L (4.8% vs 10.1%). Incidences of CV and arrhythmia composite outcomes were highest in patients with a baseline potassium level of <3.5 mmol/L (15.7% and 7.3%, respectively, for <3.5 mmol/L vs 13.5% and 6.3%, respectively, for ≥3.5 mmol/L). Risk of the CV and arrhythmia composite outcomes was reduced with finerenone by 14% (HR=0.86; 95%CI=0.78-0.95) and 13% (HR=0.87; 95%CI=0.76-1.00), respectively, versus placebo.

Conclusions: Low serum potassium levels are common in patients with CKD and T2D despite treatment with RASi. Finerenone was associated with protection from hypokalemia and reduction in the risk of CV and arrhythmia outcomes.

Keywords: Chronic kidney disease, Cardiovascular, Finerenone, Hypokalemia
Abbreviations: chronic kidney disease (CKD), mineralocorticoid receptor antagonist (MRA), renin–angiotensin system inhibitor (RASi), type 2 diabetes (T2D)

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Both the FIGARO-DKD and FIDELIO-DKD studies complied with the Declaration of Helsinki and approval was obtained from the required ethical committees and regulatory authorities. All patients provided written informed consent.

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AQ is an employee of Bayer.