Randomized Clinical Trial of Sevelamer Carbonate on Serum Klotho and Fibroblast Growth Factor 23 in CKD

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Abstract

Background and objectives Epidemiologic studies suggest that higher serum phosphaturic hormone fibroblast growth factor 23 levels are associated with increase morbidity and mortality. The aim of the FGF23 Reduction Efficacy of a New Phosphate Binder in CKD Trial was to evaluate the effect of sevelamer carbonate on serum C-terminal fibroblast growth factor 23 levels in normophosphatemic patients with CKD stage 3b/4.

Design, setting, participants, & measurements Patients with CKD, eGFR between 45 and 15 ml/min per 1.73 m^2, fasting serum phosphate concentration >3.1 mg/dl, and serum C-terminal fibroblast growth factor 23 >80 relative units/ml were included in our double-blind, placebo-controlled, randomized multicenter study. All patients received 100,000 IU cholecalciferol at time of randomization. Participants received either placebo or sevelamer carbonate 4.8 g daily during a 12-week period. Biologic parameters, including serum C-terminal fibroblast growth factor 23, intact fibroblast growth factor 23, and α-klotho, were evaluated at baseline and 12 weeks after inclusion.

Results Of 96 screened patients, 78 (mean±SD age: 63±13 years old; 70% men; mean eGFR: 27±9 ml/min per 1.73 m^2) met the inclusion criteria. At baseline, mean eGFR was 27±9 ml/min per 1.73 m^2, mean serum phosphate level was 3.8±0.5 mg/dl, and median (interquartile range) serum C-terminal fibroblast growth factor 23 level was 157 (120-241) relative units/ml. After 12 weeks of treatment, urinary phosphate-to-creatinine ratio fell significantly in the sevelamer group. The sevelamer and placebo groups did not differ significantly in terms of median change in serum C-terminal fibroblast growth factor 23 levels: the median (interquartile range) change was 38 (−13-114) relative units/ml in the placebo group and 37 (−1-101) relative units/ml in the sevelamer group (P=0.77). There was no significant difference in serum intact fibroblast growth factor 23, α-klotho, or phosphate levels changes between the two groups. Serum total and LDL cholesterol levels fell significantly in the sevelamer group.

Conclusions In our double-blind, placebo-controlled, randomized study performed in normophosphatemic patients with CKD, a 12-week course of sevelamer carbonate significantly reduced phosphaturia without changing serum phosphorus but did not significantly modify serum C-terminal fibroblast growth factor 23 and intact fibroblast growth factor 23 or α-klotho levels.

chronic kidney disease | fibroblast | mineral metabolism | KLOTHO | FGF23 | phosphate binders | randomized controlled trials | sevelamer | fibroblast growth factor 23 | Phosphorus | Cholesterol, LDL | creatinine | Cholecalciferol | Double-Blind Method | glomerular filtration rate | Fasting | Random Allocation | Fibroblast Growth Factors | Hypophosphatemia, Familial | Renal Insufficiency, Chronic | Phosphates

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