FERRIC CITRATE AS A PHOSPHATE BINDER MAY OFFER BETTER GLUCOSE CONTROL IN DIALYSIS PATIENTS

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Background: Dialysis patients require phosphorus binders to prevent hyperphosphatemia. Ferric citrate (FC) was studied as a phosphorus binder, iron source, and for its ability to maintain hemoglobin. Methods: 441 dialysis subjects were randomized to FC or active control (AC) (calcium acetate and/or sevelamer carbonate) in a 52-week open label Safety Period (SP), followed by a 4-week Efficacy Period (EP); subjects on FC at the end of the SP were re-randomized to FC or placebo. The primary analysis compared the mean change in phosphorus between FC and placebo during the EP. A gatekeeping strategy controlled study-wise Type 1 error for TSAT, ferritin, IV iron and ESA usage as pre-specified secondary outcomes in the SP. Results: EP mean baseline phosphorus was similar at baseline (5.1 ± 1.2 mg/dL) and 4 weeks (4.9 ± 1.3 mg/dL) on FC, but increased from 5.4 ± 1.5 mg/dL to 7.2 ± 1.8 mg/dL on placebo (P<0.001). SP phosphorus control was similar between FC and AC, with comparable safety profiles. FC subjects achieved higher iron parameters (ferritin 899 ± 488 ng/mL, TSAT 39%) vs. active control (ferritin 628 ± 367 ng/mL, TSAT 30%, p<0.001). FC subjects received less IV elemental iron (median 12.95 mg/week FC, 26.88 mg/week AC, P=0.001) and less ESA (median epoetin equivalent units per week, FC 5306 Units/week, AC 6951 Units/week, P=0.04). Hemoglobin levels were higher on FC (P=0.018). SP median blood glucose levels in the FC decreased from a baseline of 122 mg/dL to 107 mg/dL at week 52, while the median blood glucose level in the AC increased from a baseline of 115 mg/dL to 126 mg/dL at week 52. Conclusions/Discussion: Ferric citrate is an efficacious and safe phosphate binder. Ferric citrate increases iron stores and reduces IV iron and ESA while sustaining hemoglobin. Further research is warranted to support the supposition that the maintenance of hemoglobin in dialysis patients may lead to increased utilization of glucose and potentially better glucose control in dialysis patients who constantly lose blood and become anemic.