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J Nephrol Ther 2018, Volume 8
DOI: 10.4172/2161-0959-C3-058

Ferric Pyrophosphate Citrate (Triferic®), a novel therapy that treats anemia of inflammation and overcomes functional iron deficiency

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Ferric Pyrophosphate Citrate (FPC) is a novel, highly soluble iron salt for parenteral delivery *via* hemodialysis solution. FPC donates iron directly and rapidly to transferrin, avoiding iron sequestration in the reticuloendothelial system. Randomized, placebo-controlled clinical trials in chronic hemodialysis (CKD 5HD) patients have demonstrated that FPC delivery by hemodialysis can maintain iron balance by replacing regular iron losses, while reducing ESA use and maintaining hemoglobin (Hgb). In the double-blind PRIME study, 104 iron replete (serum ferritin, 200 1000 µg/L) CKD 5HD patients received FPC or placebo for 36 weeks. The ESA dose was titrated to maintain Hgb in the target range; intravenous (IV) iron was administered for serum ferritin <200 µg/L. Prescribed ESA and IV iron doses were reduced by 35% (p=0.045) and 45% (p=0.028), respectively, in the FPC group, without increases in levels of serum ferritin, hepcidin or markers of oxidative stress/inflammation. In two single blind phase 3 studies (CRUISE), iron replete CKD 5HD patients received FPC (N=299) or placebo (N=300) for 48 weeks; changes in ESA and IV/oral iron doses were prohibited. Hgb was maintained at baseline levels in FPC treated patients in both studies, whereas placebo treated patients developed iron restricted erythropoiesis. Mean change in Hgb from baseline to end of treatment was 3.6 g/L lower for placebo than for FPC (p=0.011). The safety profile of FPC was similar to placebo, with no anaphylaxis. No increases in incidence of intradialytic hypotension, cardiovascular events, or infections were observed with FPC compared with placebo. FPC is effective in treating functional iron deficiency in states of inflammation, including CKD 5HD.

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