EFFICACY AND SAFETY OF SUCROFERRIC OXYHYDROXIDE IN HAEMODIALYSIS PATIENTS WITH MINERAL BONE DISEASE

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INTRODUCTION: Hyperphosphatemia is a hallmark of advanced chronic kidney disease (CKD) and associated with adverse outcomes. Preclinical and epidemiological studies strongly support a causal relationship between hyperphosphatemia and mortality as well as cardiovascular complications, especially including vascular, valvular and soft-tissue calcifications. Actually, management of phosphate is strongly linked with the management mineral bone disease (MBD). Thus, appropriate phosphate lowering is considered to play a major role in health and longevity of CKD patients. In this respect, phosphate binders are the most powerful therapeutic option, while dietary phosphate restriction and intensified dialysis are valuable supportive approaches.

AIMS: We aimed to investigate sucroferric oxyhydroxide (PA21) in terms of efficacy and safety in haemodialysis (HD) patients with MBD.

METHODS: In this prospective study HD stable patients with hyperphosphataemia were received PA21 for 24 weeks. The primary outcome was estimation of serum phosphate concentration at the end of treatment. Secondary outcomes were corrected serum calcium and intact-parathyroid hormone (PTH) concentrations. Ferritin levels were monitored also during our study period. Adverse events (AEs) and adverse drug reactions (ADRs) were evaluated.

RESULTS: 27 HD patients were enrolled in our study protocol with mean age 64. 19 years (range: 40-86). 13 patients were naïve regarding phosphate medication, 7 were receiving sevelamer before starting PA21 and 6 lanthanum. All of the patients were taken 2-3 pills of PA21 during study period. 5 patients were totally withdrawn from the study (4 after 2 months due to diarrhea and one with discolored feaces after also 2 months of treatment). We noticed significant reduction of the phosphate levels even from the first month of treatment (from 6.50±1.26 to 4.94±0.89 mg/dl , $p<0.05$). This trend carried out until the end of the study period (4.55±1.48 mg/dl, $p<0.05$). Remarkable finding was the significant reduction of PTH levels in all of our patients even from the first month without interfering in vitamin D supplementation during the whole 6 months period (PTH at first 714±648 pg/ml, 1st month 447±+384 pg/ml, 6th month 285±241 pg/ml, $p<0,05$). Ferritin levels remained stable (from 460±254 to 524±256 mg/dl in the end, p=NS). Calcium levels had also unremarkable differences.

CONCLUSIONS: In conclusion, sucroferric oxyhydroxide is a valuable treatment option for hyperphosphataemia in CKD patients on dialysis, providing an effective and generally well tolerated noncalcium-based phosphate binder therapy with a low pill burden and the potential for improved treatment adherence in MBD in general.

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