ABSTRACT BOOK

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EFFICACY AND TOLERABILITY OF ORAL SUCROSOMIAL® IRON IN CKD PATIENTS WITH ANEMIA.
Ioannis Griveas, MD, PhD
Consultant Nephrologist 417 Veterans Army Administration Hospital Of Athens, Medical Director Private Dialysis Unit "Nefroiatriki", Athens, Greece, Private Renal Clinic “Athens-Nephrology”, Athens, Greece

Introduction: Iron deficiency is one of the main causes of anemia in patients with Chronic Kidney Disease (CKD), and iron supplements along with the erythropoietin constitute the basis of its therapy. The clinical consequences of untreated severe anemia in non-dialysis CKD patients can be significant, but disparities exist in the anemia treatment guidelines and position papers issued from working groups and associations across the world. These differ in hemoglobin target and iron levels and they focus on various iron markers and other clinical outcomes. Moreover, there is an ongoing debate regarding oral versus intravenous administration of iron. The above facts led new oral compounds to arise, which show different rates of absorption with possibly different efficacy and improved tolerability. The main representative is oral Sucrosomial® iron, a preparation of ferric pyrophosphate carried inside a phospholipid and sucrester membrane, which is characterized by higher gastrointestinal absorption and bioavailability than other oral formulations, as well as lower incidence of side effects.

Objective: The study purpose was to assess the efficacy and tolerability of the treatment with Sucrosomial® iron in iron deficiency anemic non-dialysis CKD patients.

Methods: 30 patients (mean age 74.21 years, range: 39-86 years) with CKD stage 3-5 (not in dialysis, eGFR <60 mils/min, range: 12-48) and anemia along with iron depletion (ferritin<200 ng/ml) not attributable to other causes (neoplasms, infections, bleeding, hemopathies, hepatopathies), were enrolled in our prospective study. During a study period of 18 months, all patients had stable renal function, did not need transfusion or admission to hospital for any reason and received oral Sucrosomial® iron (Sideral®) once daily, according to the therapeutic protocols of the clinic. Hematological profile, renal function and bone-mineral data were recorded at the beginning of the study and every 2 months until the end of the study protocol. The primary efficacy end points of the study included the change in Hct values from baseline to the end of the treatment. Secondary endpoints were an estimation of iron repletion and bone–mineral parameters. Adverse effects and compliance data were reported from the beginning to the end of treatment. Data were analyzed using t-test (SPSS).

Results: During our study period of 18 months, Hct levels increased from 33.3 ± 1.87% at the beginning of the protocol to 36.61 ± 2.72% (p<0.05). Hemoglobin levels were 10.98 ± 0.73 g/dl at the beginning of the study and ended to be 11.86 ± 0.71 g/dl (p=NS). Ferritin levels, which are one index of iron stores, also increased from 42.73 ± 24.47 mcg/dl to 98.89 ± 126.99 mcg/dl (p=NS). Renal function (eGFR) of our patients remained stable, without significant changes during the 18 months period of the study. PTH levels declined over the study period from 359.05 ± 447.24 pg/ml to 163.72±89.12 pg/ml (p=NS). Ca, K and Na levels remained stable without significant changes. We separated our population in 2 groups: one with eGFR over 30 mils/min and another with eGFR below 30 mils/min and we
compared their clinical-laboratory behavior regarding all the parameters of the protocol. We did not notice any significant changes concerning Hct, Hb and ferritin fluctuations during protocol period. Oral iron was well tolerated and no significant adverse effects were recorded. None of our patients dropped out from the study for any reason. It is noticeable that its behavior related to GI effects seems to differ favorably compared to other iron compounds.

**Conclusions:** Oral Sucrosomial® iron seems to be a safe and efficacious alternative in managing CKD patients with anemia. Despite the small amount of patients in our study protocol, the low rate of adverse events with Sucrosomial® iron and its practicality suggest that this formulation has all the potential to be the first step to correct anemia in stable CKD patients. Along with the other follow-up parameters in CKD patients, it might be somehow of help for the stabilization of renal function. Further larger studies are needed to investigate Sucrosomial® iron effects in complicated CKD patients and help scientific community to reach solid conclusions.