EFFECT OF ORAL SUCROSOMIAL® IRON IN CKD PATIENTS WITH ANEMIA

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BACKGROUND: Anemia is a common manifestation in patients with Chronic Kidney Disease (CKD) and is linked with iron deficiency. The optimum route of administration of iron is controversial in this group of patients since oral administration is easier, safer and less expensive, but may be linked to gastrointestinal side effects and suboptimal iron absorption. Sucrosomial® Iron is a new iron formulation in a phospholipid membrane with reported high bioavailability, low incidence of side effects and satisfactory tolerated.

OBJECTIVES: The purpose of this study was to investigate the efficacy and tolerability of oral Sucrosomial® Iron in CKD patients with anemia.

METHODS: 10 patients with CKD stage 3-5 (eGFR <60 mils/min, range: 12-48) and anemia (Hb<12 gr/dl, ferritin<200 ng/ml) were enrolled in our study. During the 6 months study period, all of the patients had stable renal function, did not need to be transfused or admitted to the hospital for any reason and received oral Sucrosomial® Iron (Sideral®) once daily. Hematological profile and renal function were recorded at the beginning of the study, 3 months later and at the end of the study protocol. The primary efficacy end points of the study included the change in Hb values from baseline to end of treatment. Adverse effects and compliance data were reported from the day of initial treatment to the end of treatment. Data were analysed using t-test (SPSS).

RESULTS: Hemoglobin levels were 9.82+/-2 g/dl at the beginning of the study and ended to be 10.36+/-0.97 g/dl, which represented a 5.5% increase (p=NS). At the same time Hct levels increased from 31.4+/-4.92% at the beginning of the protocol to 32.28+/-3.05% at the end (increase 3.12%, p=NS). Ferritin levels, which are one index of iron stores also increased from 91.9+/-75.74 mcg/L to 129.28+/-177.05 mcg/L (increase 40.67%, p=NS). Oral Sucrosomial® Iron was well tolerated and no significant adverse effects were recorded.

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. Further larger studies are needed to investigate Sucrosomial® Iron effects in complicated CKD patients and help scientific community to reach solid conclusions.