SUMMARY

Background to Study: The incidence of anaemia in pre dialysis patients with CKD is estimated to be around 68% with 61% having either absolute or functional iron deficiency. Intravenous iron therapy is now the standard modality of iron supplementation in hemodialysis patients, but its role in pre dialysis CKD patients is less well established and concerns remain about adverse events such as anaphylactic reaction. Low molecular weight iron dextran and iron sucrose have recently become available in Nigeria because of their better safety profile and ease of administration. It is necessary to evaluate the efficacy and safety profile of these intravenous iron preparations in our CKD patients.

Objective: The aim of the study was to compare the efficacy and safety profile of intravenous low molecular weight iron dextran and iron sucrose in the management of iron deficiency anaemia in pre dialysis chronic kidney disease patients.

Methodology: This study was an open label randomized trial. A total of sixty seven anaemic pre dialysis CKD patients with iron deficiency were randomized to one of the two treatment groups (Low molecular weight iron dextran n=33; or Iron sucrose, n=34). Complete blood count, serum creatinine, serum iron, Unsaturated Iron Binding Capacity (UIBC), serum ferritin and transferrin saturation were assessed in all the patients at baseline. Patients assigned to iron dextran arm received 1000mg of low molecular weight iron dextran intravenously in four divided doses of 250mg, each dose was given as an infusion in 250mls of 0.9% saline over a period of 3 hours. Patients assigned to iron sucrose arm of the study received 1000 mg of iron sucrose intravenously in five divided doses of 200mg. Each 200mg dose was administered in 250mls of 0.9% normal saline over a 2 hour period. The total dose was given over a 10-day period.
All the parameters were repeated in all the patients at day 24.

**Results:** Half of the study population (50.3%) had absolute iron deficiency and 6.3% had functional iron deficiency. Median serum ferritin (ng/ml) rose significantly from 71 at baseline to 241 on day 24 (P <0.01) in the iron sucrose group, and 121 at baseline to 234 on day 24 (P <0.01) in the low molecular weight iron dextran group. There was no significant difference between the iron sucrose and low molecular weight iron dextran groups in the proportion of patients achieving the primary end point (Hb increase ≥ 1g/dl) (34.4% vs 19.4% , P=0.15), as well as the mean change in haemoglobin concentration by day 24 ( 0.6g/dl vs 0.3 g/dl, P=0.26). The effect of potential covariates on the odds of achieving primary end point (a ≥ 1.0 g/dl Hb ) with the two parenteral preparations was evaluated. Baseline serum ferritin < 100ng/dl was associated with a 3-fold likelihood of achieving a ≥ 1.0g/dl rise in Hb.

A total of 19 reactions occurred in thirteen patients. The overall most frequently occurring adverse event was hypotension (26.3 %). The proportion of subjects who experienced at least one or more adverse events was higher in the iron dextran arm compared to the iron sucrose arm (14.3% versus 6.3%) however, this did not reach statistical significance ( P= 0.13).

**Conclusion:** Iron deficiency is common in anaemic pre dialysis CKD patients. Both intravenous low molecular weight iron dextran and iron sucrose are equally effective in the management of iron deficiency anaemia. Occurrence of adverse events was higher with low molecular weight iron dextran and hypotension being the most frequently occurring adverse event.