

**ABSTRACT – NKF APRIL 7, 2003 – DALLAS, TEXAS**

**EVALUATION OF THE ABILITY OF HEME IRON POLYPEPTIDE TO SUSTAIN RESPONSE TO rHuEPO IN PERITONEAL DIALYSIS PATIENTS: A PROSPECTIVE CLINICAL EVALUATION.**

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**BACKGROUND:** Maintenance of Hematocrit (Hct) in Peritoneal Dialysis (PD) patients is critical to maintain quality of life and prevent development of left Ventricular Hypertrophy (LVH). Use of recombinant human erythropoietin (rHuEPO) facilitates maintenance of target hemoglobin levels if sufficient available iron is present in circulation. Typical iron therapy in PD patients is a combination of oral non-heme iron supplements augmented by IV iron when oral supplements fail. Failure of oral non-heme iron is common due to side effects and inconvenient dosing regimens. Recent work by Hallberg et al and Skikne et al suggests that heme iron will be absorbed in states of elevated serum ferritin, has superior absorption rates, and has a lower incidence of gastrointestinal (GI) side effects.

**METHODS:** We identified 12 stable PD patients and administered a newly available heme iron supplement. After receiving Institutional Review Board approval, three months of baseline data were collected including Hct and serum iron indices as well as monthly rHuEPO dose and monthly IV iron dose. At time zero, patients were instructed to discontinue all non-heme oral iron supplementation and consume 24 mg elemental iron twice a day as heme iron polypeptide (HIP). HIP therapy continued for 4 months. A side-effect questionnaire was administered during the baseline period and once monthly while on HIP therapy.

**RESULTS:** No significant changes were seen in Hct or serum iron indices. Serum ferritin had a slight increase over the 4-month period but changes were not significant. IV iron was not used during either the baseline period or the experimental period. Average monthly rHuEPO dose decreased significantly during the first two months (-16,669 units/month,  $p = .015$ ) and by an average of -11,905 units/month during the second two month period when compared to baseline. One subject was removed from the study because his TSAT increased to 51% in month 3 and to 58% in month 4.

**CONCLUSIONS:** HIP was able to sustain response to rHuEPO in PD patients without concomitant use of IV iron over a four month period. Total elemental iron dose of HIP (24 mg/day) was significantly ( $p = .0001$ ) lower than the mean total iron dose from ionic iron during the Baseline Period (125 mg/day). We observed significant reductions in average monthly rHuEPO dose. Also, reduction in GI side effects and significant reduction in the frequency of gas ( $p = .03$ ) was noted suggesting a better pattern of patient compliance. HIP appears to be an excellent alternative oral iron supplement with reduced incidence of side effects and less dependence on rHuEPO to maintain target hematocrit values.

Pt. #	Ethnicity	Sex	Etiology of Kid. Failure	Age	Years on Dialysis	Baseline ionic Fe Dose
8	Pac. Is.	F	Glo Neph	51	1.2	195
10	Pac. Is.	M	HTN, DM	69	3.4	195
4	Asian	M	HTN, Cancer	85	1.3	195
9	Cau.	F	HTN	59	1.3	150
5	Afri-Am.	M	HTN, Diabetes	40	0.9	130
1	Cau.	M	HTN	75	8.8	130
3	Cau.	M	HTN, COPD	78	0.8	130
7	Pac. Is.	F	Glo Neph	35	3.9	65
11	Asian	F	Glo Neph	53	4.7	65
6	Cau.	M	Plycys Kid Dis	47	0.5	65
2	Asian	F	HTN	39	2.1	50
			Median	53.0	1.3	130
	male: 55%		Average	57.4	2.6	125
	female: 45%		STDEV	17.2	2.5	56

	Mean HCT (%)	Mean difference	p-values (to Baseline)	Mean TSAT (%)	p-values (to Baseline)	Mean Ferritin (ng/ml)	p-values (to Baseline)	Mean EPO/ month	p-values p to Baseline
Baseline	35.01			30.27		344.64		52255	
P I	35.96		0.13	32.73	0.25	346.95	0.48	35586	0.015*
P II	34.72		0.37	30.82	0.43	380.18	0.24	40350	0.071