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Study of Improvement in Quality of Life with Recombinant Erythropoietin in Chronic End Stage Renal Failure Patients.

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ABSTRACT

Out of 110 cases of Chronic End Stage Renal Failure on maintenance hemodialysis 89 cases opted for recombinant human erythropoietin therapy & 21 opted for multiple blood transfusion. 100% of cases had severe degree of anemia. 41 cases in group A and 9 cases in group B had Iron deficiency which was corrected with I.V. iron sucrose in 4 weeks, but with marginal improvement in hemoglobin level. 12 weeks after erythropoietin therapy 74 cases showed significant rise of hemoglobin and 15 cases showed poor response. With multiple blood transfusions there was no significant improvement of rise in hemoglobin. High PTH level, high CRP positivity and protein calorie malnutrition interfered with response. The initial erythropoietin level in CRF cases with severe anemia was marginally higher than control. However there was exponential rise of erythropoietin level in other cases of anemia with normal renal function. Minor side effects like rise in BP, rise in potassium level were noticed with erythropoietin therapy which could be tackled. But with multiple blood transfusions there was high incidence of Hepatitis B & Hepatitis C infection.

Keyword: Chronic End Stage Renal Failure, Anaemia, Erythropoietin, Multiple blood transfusion, Quality of life)

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INTRODUCTION

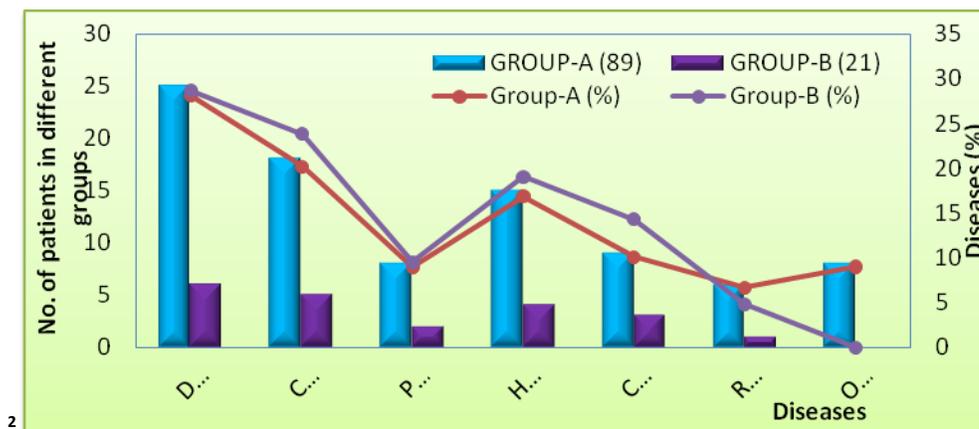
In the end stage renal failure patients on hemodialysis, 100% of patients have severe degree of anemia which increases the morbidity and mortality due to its impact on cardio vascular function and it influences quality of life .The correction of anemia in these patients has been associated with substantial improvement in quality of life. Till 1989, main treatment was by multiple blood transfusions (B.T), which had adverse effects like iron overdose, Hepatitis B & C infections. Once recombinant erythropoietin was introduced in 1989, principle of treatment of anemia has been revolutionised. In 1997, KDOQI guidelines recommended a target range of hematocrit with hemoglobin level from 11-12 gm%¹. Keeping this in mind, a study was undertaken to observe the effect of recombinant human erythropoietin (EPO) on the improvement of quality of life in our patients of Chronic Renal Failure End Stage on maintenance hemodialysis.

MATERIALS AND METHODS

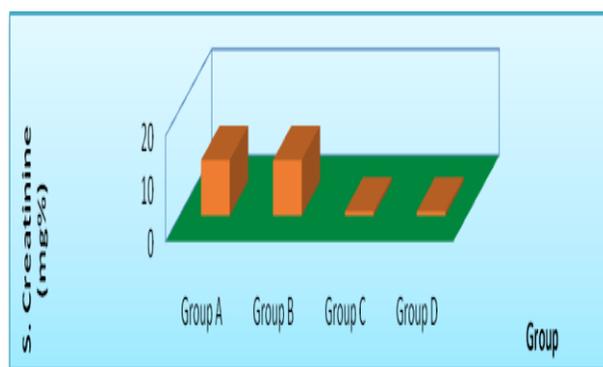
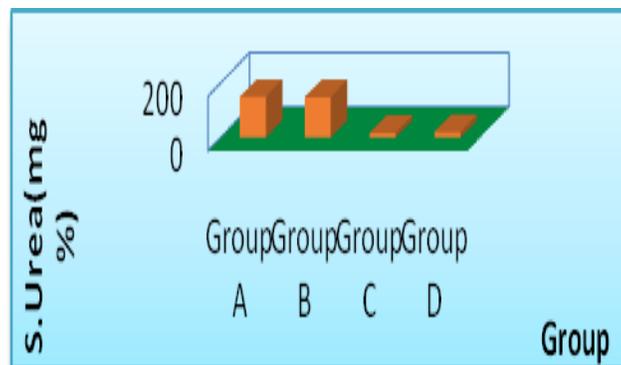
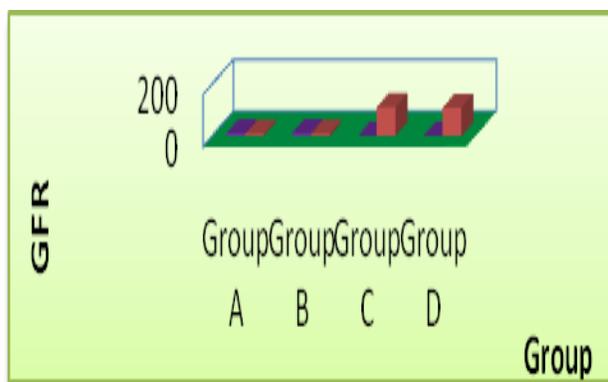
110 cases of Chronic Renal Failure (CRF) End stage Renal Disease were the materials of the study. 89 cases (Group A) agreed to take EPO and 21 cases (Group B) opted for multiple B.T. instead of EPO for correction of anemia. 20 healthy controls were taken as Group C. To see the EPO response to severe anemia with normal renal function 20 other cases of anemia (Group D) were taken. In addition to routine investigations (CBC, FBS, PPBS, S.Urea, S.Creatinine, S.Albumin, S.Protein, S.Electrolytes, S.Calcium, S.Phosphorous) special tests like CRP, S.Iron, S.Ferritin, Transferrin Saturation(TSAT), S.Vit B12,S.Folic acid & S.Parathyroid hormone levels were estimated before start of treatment of anemia. S.Erythropoietin level was estimated in all patients before and after treatment of anemia. Quality of life was assessed in relation to physical functioning, role limitation due to physical health, role limitation due to emotional problem, energy/fatigue, emotional well being, social functioning and pain by SF-36 questionnaire. Scoring was done as per Rand Scale. This was tested before and 12 weeks after anemia was corrected. A 6-minute walk test was done before and 12 weeks after correction of anemia to assess exercise tolerance capacity. Quality of life was also assessed regarding sleep disturbance, difficulty to concentrate, depression and loss of libido. Adverse reactions to both EPO and multiple B.T were noted. The data were compiled and statistically evaluated.

OBSERVATIONS AND DISCUSSION

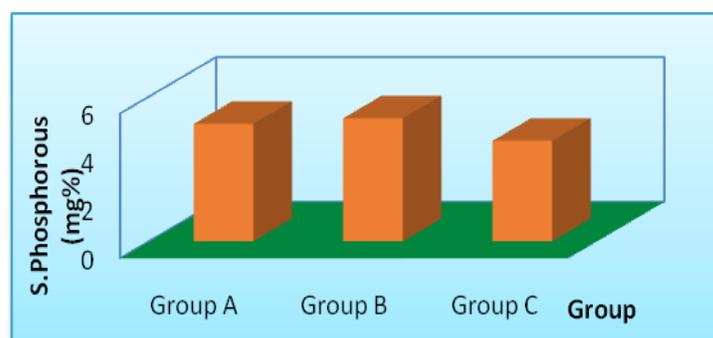
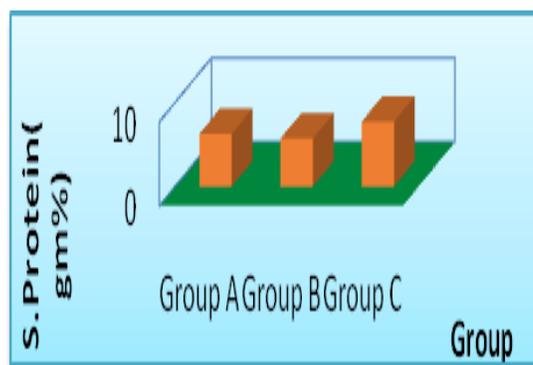
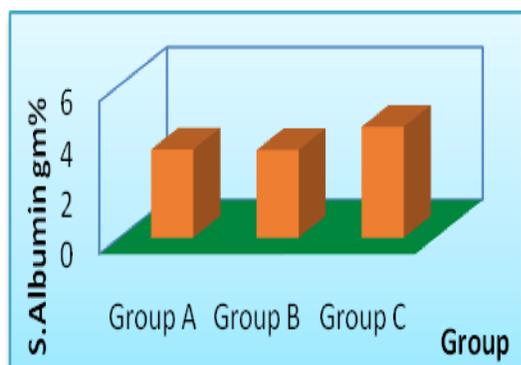
Maximum number cases were in the age group of 40-60 years. 100% of cases had severe degree of anemia. In the series of Agarwal & Dash et al, Diabetic nephropathy was the number one cause of CRF followed by chronic glomerulonephritis and hypertensive nephropathy.



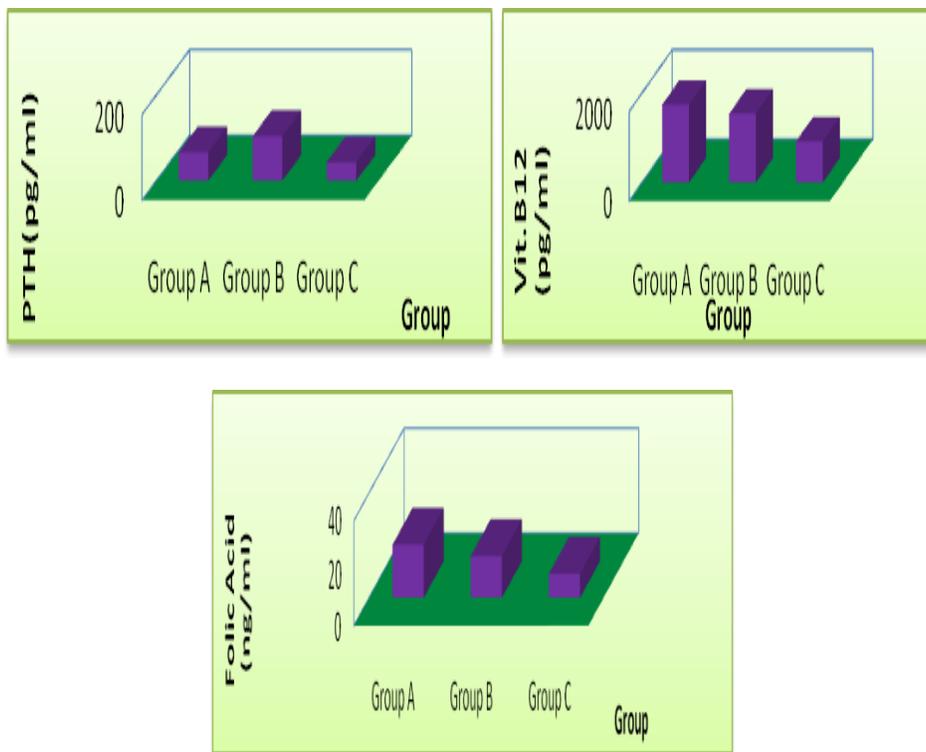
The GFR was less than 15 ml/min with very high S.Urea & S.Creatinine . As per Levey et al ESRD patients have GFR less than 15ml/min³.



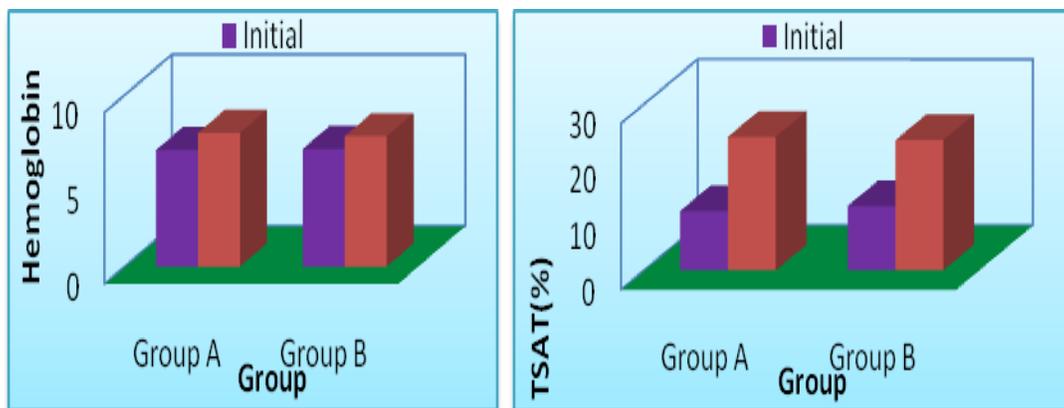
The S. Protein & S. Albumin were lower than the control group. Phosphate levels were within normal range as most patients were taking phosphate binders. 54.5% cases were CRP +ve indicating inflammation/infection.



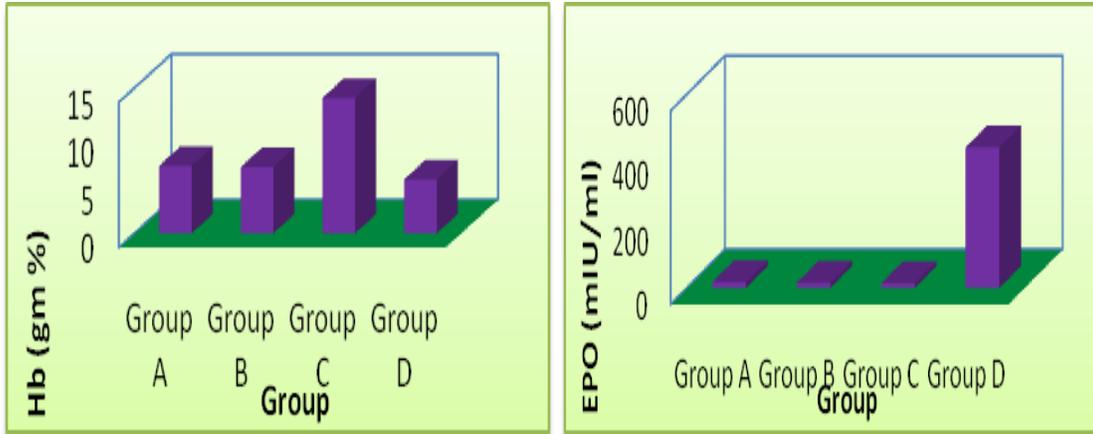
41 cases of group A and 9 cases of group B had iron deficiency with TSAT below 20%. Dialysis Outcomes & DOPPs study stated that 31-38 % of hemodialysis cases have iron deficiency.⁴ S.PTH levels were high in group A & B. S.Vit.B12 and folic acid levels were in normal range.



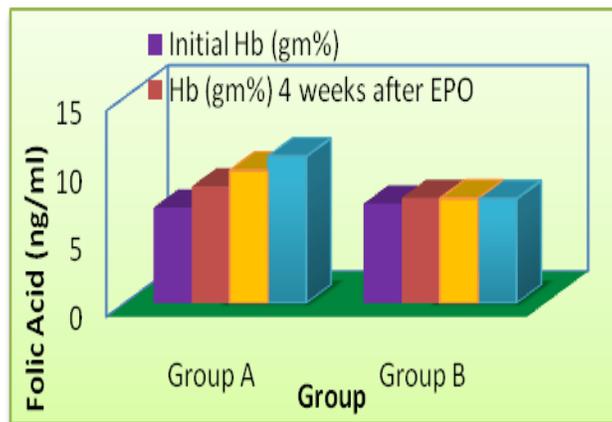
Iron deficiency was corrected with I.V. Iron Sucrose supplementation and it got corrected in a period of 4 weeks. However hemoglobin improved marginally.



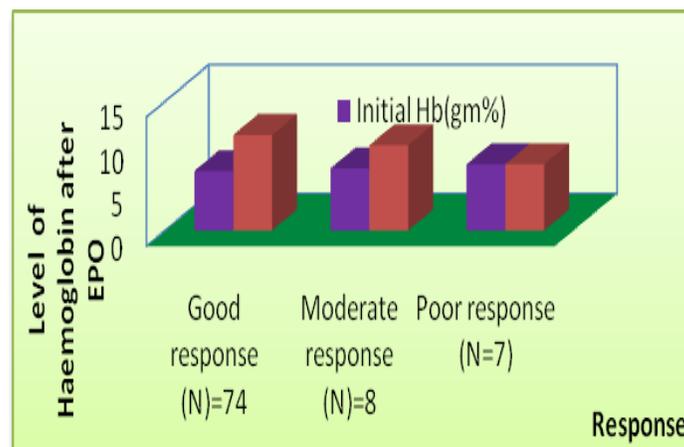
S.EPO level was slightly higher in both group A & B from control (group C). However there was exponential rise of EPO in group D who had severe anemia with normal renal function. These findings of the level of EPO in cases of CRF with anemia & in other cases of anemia with normal renal functions were in agreement with the findings of Akio Urabe et al. [5]



The hemoglobin response was noted 4 weeks, 8 weeks, 12 weeks after EPO/B.T. therapy in both group A & B. There was substantial statistically significant rise of hemoglobin after 12 weeks in group A which was not noticed in group B.

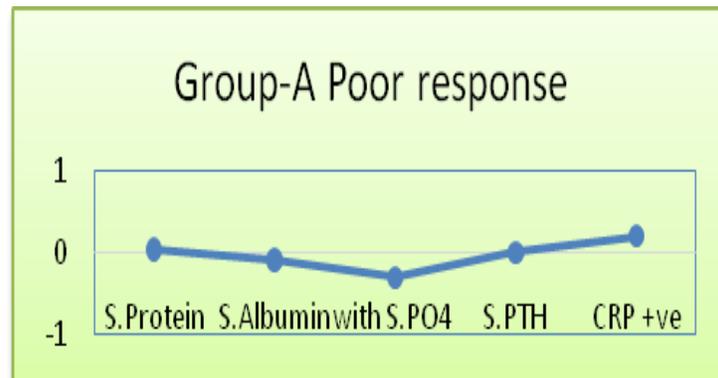
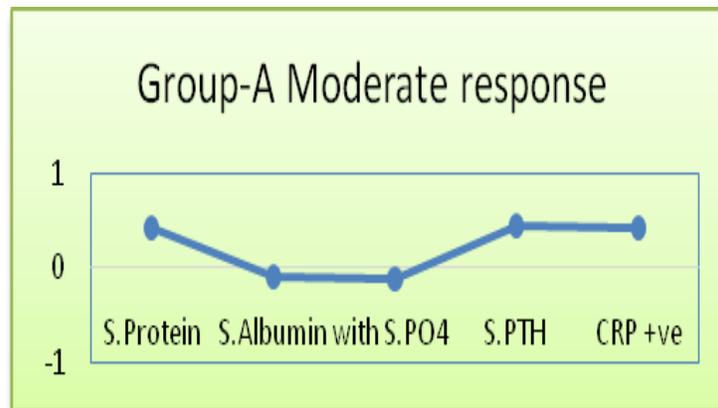
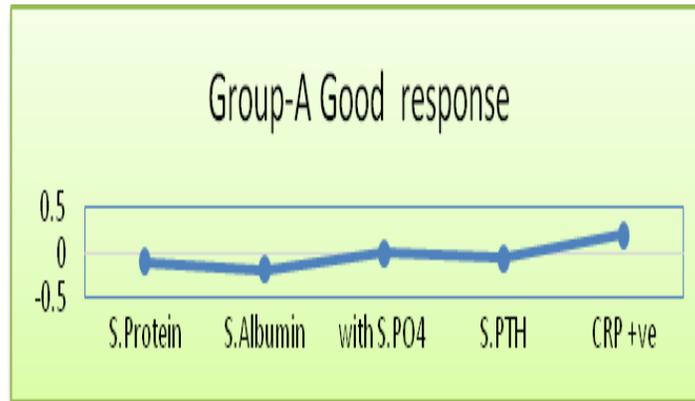


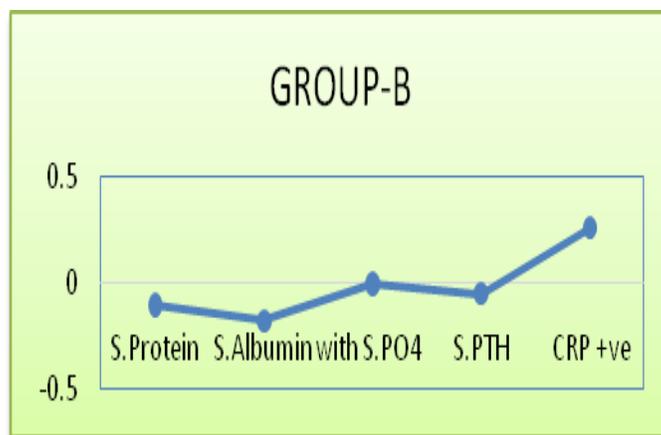
Out of 89 cases, 74 had good response to EPO and 15 cases had moderate to poor response to EPO.



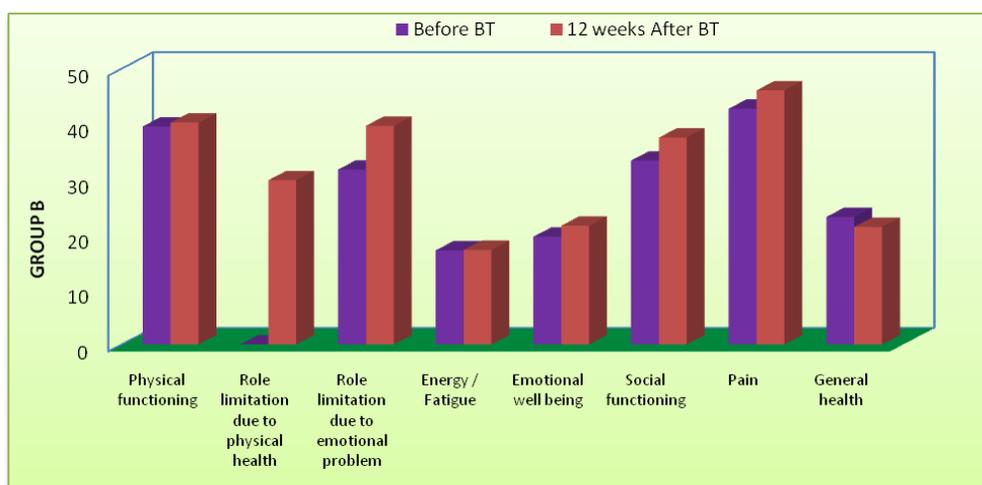
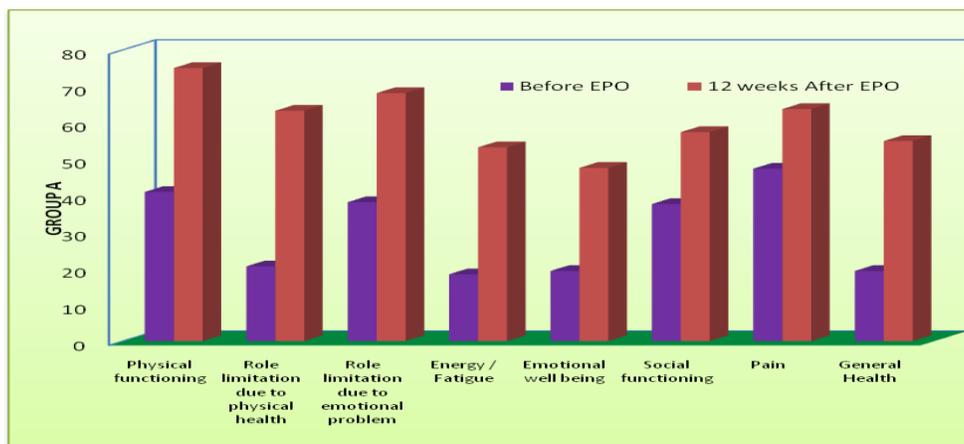
An attempt was made to establish co-relation of hemoglobin improvement to S.PTH, CRP +ve., S. Protein & S. Albumin levels. Increased PTH level and increased incidence of CRP interfered with EPO response. Rao et al

stated that high S.PTH affected EPO response by bone marrow fibrosis. [6] Kamyar et al stated that chronic inflammation affects EPO response. [7]



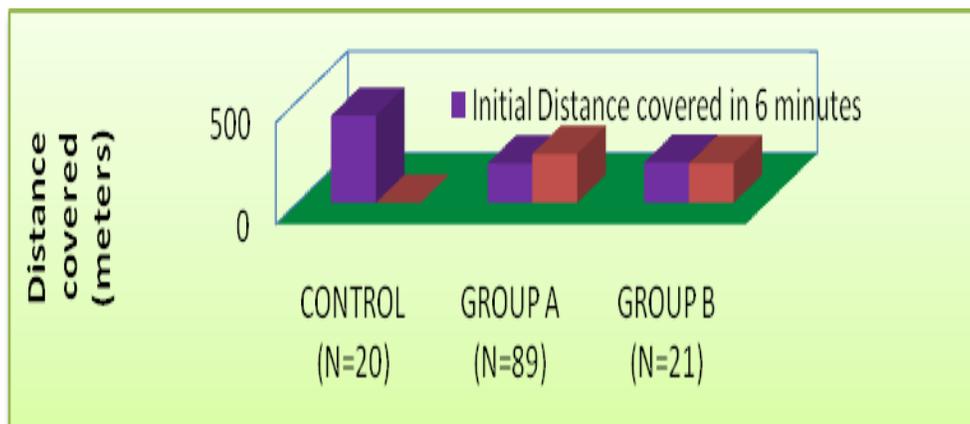


Quality of life in relation to 8 functions as per SF-36 questionnaire showed substantial improvement in group A with correction of anaemia where as it was not noticed in group B who opted for B.T. The Canadian Study 1990 stated that patients treated with EPO had improvement in the scores of fatigue, physical symptoms, relationship & depression, & improvement in sickness impact profile.

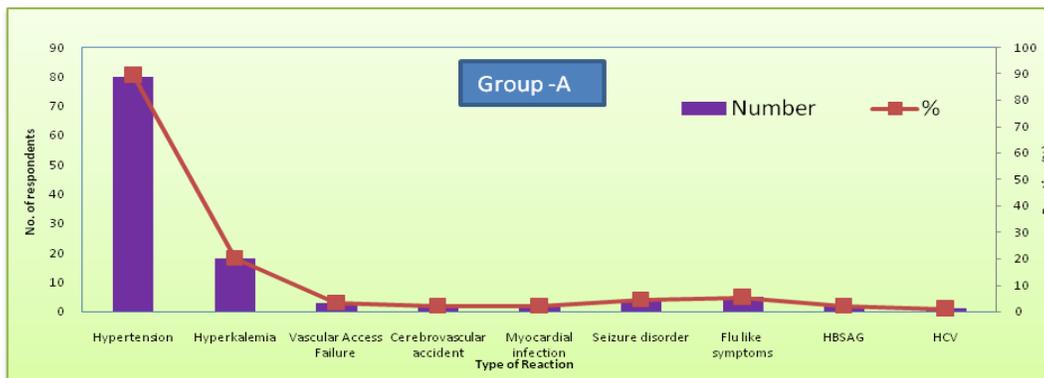
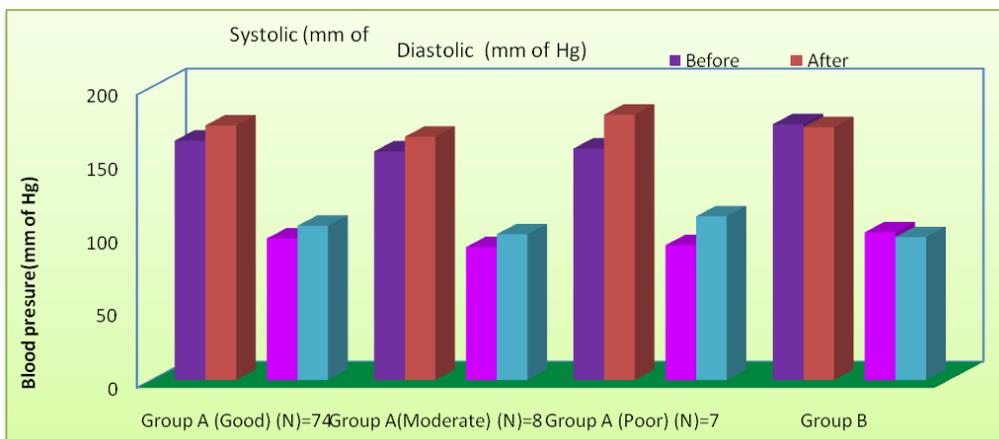


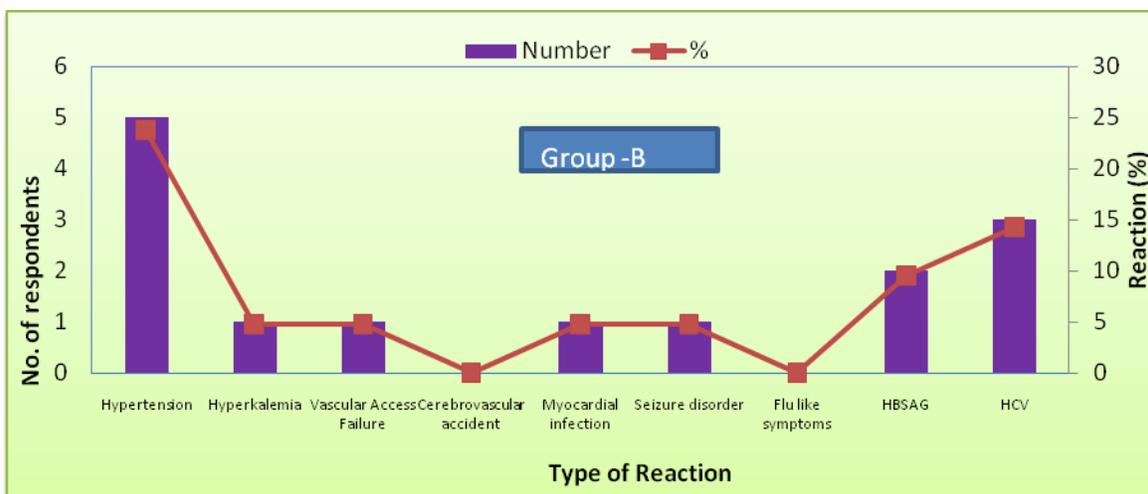
Depression improved statistically with correction of anemia with EPO in group A which was not noted in group B. Cognitive function improved in both groups. There was no improvement in loss of libido in both groups.

In six minutes walk test there was substantial improvement in group A which was absent in group B . The Canadian Study also showed improvement in 6 minute walk test which is a test for exercise tolerance. [8]



There was rise in both systolic and diastolic BP in group A which was not noticed in group B . Various literatures have confirmed rise in systolic and diastolic BP after EPO therapy. S.Potassium level was also high in group A after EPO therapy which was not seen in group B. Esbach et al 1989 stated that 35% of their cases showed increase in both systolic & diastolic B.P & increase in S.Pottassium after EPO. [9] There was not much difference between Group A & B in relation to CVA, MI, Vascular Clotting . However incidences of Hepatitis B & C infections were high in group B which was statistically significant. The available literatures are in agreement with our observations. Libyan Study recommended to reduce blood transfusion because of high incidence of Hepatitis B & C infections.[10]





CONCLUSION

It was observed that correction of anaemia improved the quality of life in all these patients.

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