

Anemia Management in Dialysis Dependent and Non-Dialysis Dependent Chronic Kidney Disease Patients - Prospective Observational Study in a Tertiary Care Hospital in South India

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ABSTRACT

Background: Anemia is a common and significant complication of Chronic Kidney Disease (CKD). This study focuses on the change in haemoglobin levels of CKD patients during treatment with Erythropoietin stimulating agent (ESA)/Hypoxia Inducible Factor-Prolyl Hydroxylase Inhibitors (HIF-PHI) with or without Haematinics. Hypertension is a common adverse effect of erythropoietin treatment. **Materials and Methods:** A prospective study was conducted in Nephrology department of a tertiary care teaching hospital for six months. Patients were recruited based on inclusion and exclusion criteria. **Results:** The total sample in our study was 117, which is characterized by a male preponderance with 72 (61.5%). Among study population majority of patients 76 (65%) were undergoing Haemodialysis. Among four types of anaemia management drugs in non-dialysis patients a higher mean Hb change was noted in ESA+Hematinics in Hb range (9.1-10 g/dL), which is 1.4. Whereas in ESA alone, the higher Hb change in the range (9.1-10 g/dL), was 0.86. In case of dialysis, a higher mean Hb change was noted in ESA+Hematinics in the Hb range (7.1 - 8 g/dL), which is 1.43, Whereas in ESA alone, the Hb change in the baseline range (7.1 - 8 g/dL), was 0.8. In case of dialysis patients, a statistically significant elevation was observed between pre and post systolic/diastolic BP (p value 0.01). The twice weekly ESA therapy required more modification in antihypertensive therapy than once weekly ESA dosing. In dialysis patients, majority of patients were prescribed with ESA+Hematinics and in non-dialysis, a greater number of patients were prescribed with hematinics alone. **Conclusion:** Anemia management was found to be better if Erythropoietin is supplemented with haematinics both in dialysis dependent and non-dialysis dependent CKD patients. ESA treatment required increases in the doses/frequency/ and add-on therapy of antihypertensive agents.

Keywords: Chronic Kidney Disease, Anemia, Erythropoietin Stimulating Agents, Hematinics.

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INTRODUCTION

Patients with moderate to severe cases of Chronic Kidney Disease (CKD) typically develop anemia (National Kidney Foundation definition of anemia: adult males <13.5 g/dL and adult females <12.0 g/dL).¹ The prevalence of anemia increases with CKD severity, anemia also imparts a substantial healthcare burden in early-stage CKD.² The management of anemia in CKD includes Erythropoiesis stimulating agents, oral and Intravenous (IV) iron formulations, Hypoxia Inducible Factor-Prolyl Hydroxylase Inhibitors and

red blood cell transfusions when not possible to avoid.³ It has also a greater prevalence among older persons, persons with diabetes, cardiovascular disease, and hypertension than persons without these conditions.⁴ A study by Zaawari *et al.*, reports that about 82.4% of CKD patients had anemia.⁵ Prevalence of anemia increases with CKD severity. Therefore, the need to normalize hemoglobin level in CKD patients is necessary to reduce associated adverse cardiovascular outcomes. Anemia treatment should be prioritized in order to reduce the need for RBC transfusion and associated risk from transfusion related reactions, also to reduce further hospitalization and cost. Hypertension is a common adverse effect of erythropoietin treatment among patients with CKD. Therefore, it is necessary to determine whether the use of ESA was associated with higher BP and antihypertensive treatment. This study is aimed to evaluate



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overall anemia management trends in Dialysis Dependent (DD) and Non Dialysis Dependent (NDD) CKD patients.

MATERIALS AND METHODS

Study design

A prospective observational study was conducted in the Nephrology department of a 600-bedded tertiary care teaching hospital for six months. The minimum sample size required was found to be 77.

Study population

Inclusion Criteria: This study included Patients with age ≥ 18 years with chronic kidney disease and anemia. (Hemoglobin level is lower than 11.0g/dL in both males and females).

Exclusion Criteria: We excluded Cancer patients, Pregnant women and Patients who received blood transfusion within 2 months.

Methodology

The data relevant to the study were gathered using a specially designed data collection form. Patient demographics, past medical and medication history, prescribed medication, pertinent laboratory parameters, anemia management details, concomitant drug details were analyzed.

Study variables

Background variables of each patient include age, gender, stage of CKD, Clinical profile and comorbidities. Other parameters such as Hemoglobin level, Blood pressure and creatinine level.

Statistical Analysis

The collected data were compiled using Microsoft Excel and were presented using tables and graphs. The data were tabulated, analysed and compared with relevant studies. Analyses were carried out at 5% level of statistical significance. Calculation of mean, standard deviation, paired *t*-test were carried out using statistical calculators. The Statistical Package for Social Sciences (SPSS) was used for the analysis of data. The differences between the two categories were analysed using paired *t*-test. The differences were regarded as significant with a $p \leq 0.05$.

RESULTS

Demographic details of patients enrolled in the study

The total sample in our study was 117, which is characterized by a male preponderance with 72 (61.5%). In this study a greater number of patients belong to age group of 51-60 years 37 (31.6%), followed by 61-70 years 35 (29.9%) and least number of patients were in group of 21-30 years with 3 (2.6%). Among the study population majority of the patients 76 (65%) were undergoing Haemodialysis and 41 (35%) were not undergoing dialysis.

Comorbidities observed in study population

A total of 42 patients had one comorbidity; out of this, 32 were on dialysis. About 51 patients had two comorbidities; among them, 32 were on dialysis. Also, 24 patients had three or more comorbidities: 13 were on dialysis.

Evaluation of change in hemoglobin value during anemia treatment

Among the four types of anaemia management drugs, a higher mean Hb change was noted in ESA+Hematinics in the baseline Hb range (7.1-8 g/dL), which is 1.43 in dialysis dependent patients. In case of Non dialysis dependent patients, higher mean Hb change was noticed in ESA+Haematinics in the baseline Hb range of (9.1-10 g/dL), which is 1.4 (Table 1). The average weekly dose of ESA, in patients on ESA alone was 4,545U, whereas in ESA + hematinics the dose was 4,800U. The average weekly dose of ESA, in patients on ESA alone was 6,500 U, whereas in ESA+hematinics the dose was 6,896 U.

The doses of ESAs and HIF-PHIs administered to the study population were recorded. ESAs (2000-4000 U) were administered subcutaneously once or twice weekly to both dialysis and non-dialysis patients, with dose adjustments made every 2-4 weeks based on hemoglobin response. HIF-PHIs were administered orally, with dosing frequency 50 mg thrice weekly.

All three treatment groups-Haematinics alone, ESA alone, and ESA combined with Haematinics-showed statistically significant improvements in Hemoglobin (Hb) levels. The HIF-PHI-based treatments did not reach significance, likely due to very small sample sizes.

Effect of Epo therapy in blood pressure

Mean change in blood pressure during Erythropoietin therapy was analysed in both dialysis dependent and non-dialysis patients. Modification in antihypertensive therapy including drug frequency, escalation of dose or addition of a new antihypertensive was analysed in patients Not on antihypertensive therapy, Mono, Dual or triple antihypertensive therapies. Though there were elevation in blood pressure in dialysis dependent and Non dialysis patients during erythropoietin therapy statistically significant elevation in blood pressure was observed only in patients on dialysis in paired *t*-test (Table 2).

Antihypertensives drugs in patients with and without EPO therapy

More number of antihypertensive drugs were prescribed in patients with EPO. The mostly prescribed antihypertensive drug in patients on EPO was alpha 2 agonist (clonidine 52.9%), followed by calcium channel blockers (Nifedipine 40.2% and cilnidipine 21.8%), beta blockers (metoprolol 18.4%, and bisoprolol 18.4%). The least prescribed drugs were ACE inhibitors and ARBs. In case of patients Not on EPO therapy, the

most prescribed antihypertensive drug was similar as patients on EPO therapy, that is alpha 2 agonist (clonidine 16.7%), followed by beta blockers (metoprolol 6.7% and bisoprolol 13.3%) calcium channel blockers (Nifedipine 3.3% and cilnidipine 13.3%). The least prescribed drugs were ACE inhibitors and ARBs.

Association between frequency of ESA and antihypertensive treatment

In our study, hypertension emerged as an adverse drug reaction associated with ESA therapy. Rather than reducing or withholding the ESA dose, we managed elevated blood pressure by adjusting the frequency and dosage of antihypertensive medications. This approach allowed for continued ESA administration without compromising hemoglobin correction, highlighting the importance of proactive hypertension management to maintain treatment efficacy.

A total of 26 patients were on once-weekly ESA therapy, out of which BP was elevated in 16 patients, the frequency of antihypertensive drugs was increased in one patient, and a new drug was added for three patients. In case of twice-weekly ESA therapy ($n=60$), BP was elevated in 50 patients, out of which dose was escalated in two patients, frequency was escalated in six patients, and a new drug was added for 12 patients.

Difference in anemia management in dialysis and non-dialysis patients

A total of four types of anaemia management therapy were given to the study population. In dialysis dependent cases a majority of patients were given ESA+hematinics treatment ($n=58$), followed by ESA alone ($n=8$), hematinics alone ($n=7$), and HIF-PHI+hematinics ($n=3$). In cases of non-dialysis, a greater number of patients were given hematinics alone ($n=17$), followed by ESA alone ($n=11$), ESA+hematinics ($n=10$), and HIF-PHI alone ($n=3$).

Distribution of different types of haematinics Prescribed

In this study population, the most commonly prescribed oral iron formulation was ferrous fumarate (34.1%), followed by ferric ammonium citrate (8%), ferrous ascorbate (7.3%), and ferrous bisglycinate (2.4%). Inj. iron sucrose was prescribed for only 4 patients in non-dialysis patients. The majority of patients on dialysis was prescribed with cyanocobalamin (Vit B12), (76.3%), followed by Inj. iron sucrose (13.2 %).

DISCUSSION

Anaemia is very common complication among CKD patients worldwide. The overall anemia management trends in CKD patients were assessed. The present study describes the outcome of 117 patients suffering from CKD anemia. Initially 120 patients

were enrolled but out of the 3 were excluded from the study due to blood transfusion in the middle.

In our study male were predominating than female, so males are under high risk of CKD as compared to female patients which was found to be parallel to the study conducted by Abdullah zawari *et al.*, on “prevalence of anemia among CKD patients” in India, a single centered study.⁵ In our study, majority of participants aged between 51-60 years followed by 61-70 years and least in 21-30 years. More number of CKD patients were undergoing dialysis in our study It underscores a study conducted by Swaraj Sathyam *et al.*, on “prevalence of anemia and cardiovascular disease in chronic kidney disease” a single centered tertiary care centre study.⁶ Clinical characteristics of sample in our study was assessed. The most common comorbidity was hypertension followed by diabetes mellitus and cardiovascular disease, which correlate with the study conducted by Haeusak Park *et al.*, on “Trend in anemia care in non-dialysis depended CKD patients in US”. More number of comorbidities were among dialysis patients than non-dialysis patients because most of the patient's undergoing dialysis were at stage of 4 and 5 with worsening of CKD.¹

In our study the hemoglobin values (g/dL) of patients taking different anemia treatment were assessed from their baseline and followed up for 5 months to obtain mean change in Hb values, which is then compared. More mean change from baseline (g/dL) was in patients taking ESA+ Hematinics than ESA alone. The patients in stage 1-3 were mostly prescribed with ESA alone and hematinics alone, but in stages of 4-5 the management of anemia is mostly with ESA+ Hematinics. By prescribing ESA along with hematinics more beneficial change in Hb value were noted than ESA alone. ESA alone was prescribed in patients with a baseline of 8.1-9 g/dL and 9.1-10 g/dL and in these patients, they were recommended to consume iron rich foods along with ESA for iron utilisation. In our study population the dose and frequency of ESA found to be different, but majority of patients were prescribed with 4000U and twice weekly frequency. The average weekly dose of ESA alone and ESA with hematinics were assessed to check whether Hb mean elevation in ESA+Hematinics were contributed by Hematinics. The average weekly dose of ESA alone and ESA+Hematinics were almost similar. It suggests that hematinics contribute positively to the elevation of Hb.

A Study conducted by Shoichiro Daimon *et al.*, on “Effect of oral and intravenous iron therapy on hemoglobin levels in hemodialysis patients according to serum ferritin level”. Data from the study shown that for hemodialysis patients with serum ferritin levels less than 100 ng/mL, oral iron therapy could decrease the needed ESA dose which is equivalent or superior to that by IV iron. Moreover, although long-term safe range of serum ferritin levels is not known, oral iron therapy may also help to avoid iron toxicity and reduce the morbidity related to iron overload. Oral iron therapy without the use of IV iron is effective for the treatment of anemia in hemodialysis patients with low

serum ferritin levels.⁷ In our study also majority of patients received haematinics as oral preparations rather than injectable Iron preparations.

In a study conducted by Sonia SN *et al.*, on “An Overview of Safety and Efficacy Between Hypoxia-Inducible Factor-Prolyl-Hydroxylase Inhibitors and Erythropoietin-Stimulating Agents in Treating Anemia in Chronic Kidney Disease Patients” These Studies have shown that the newer oral therapy, HIF-PHI, was non-inferior to ESA to maintain serum Hb levels in CKD patients. Moreover, the adverse event profile was almost similar in both groups.⁸

In this study, a novel therapy for treating anemia in CKD were included. The HIF-PHI alone and combination of HIFPHI with hematinics were at initial stage of prescribing to patients in which 3 were in group of HIFPHI alone in non-dialysis and 3 were in combination of HIFPHI with hematinics in dialysis depended patients. Though the sample size was limited, the novel therapy shown positive response in our study site too.

In both dialysis and non-dialysis with ESA, mean change in systolic and diastolic blood pressure were determined and compared using a paired *t* test. Follow up data on BP in both non-dialysis patients and dialysis dependent patients showed a substantial mean change in systolic BP than diastolic BP, but in non-dialysis patients there was no statistically significant elevation for both systolic/diastolic BP. In case of dialysis dependent patients, a

statistically significant elevation was observed between pre and post systolic/diastolic BP. The association between frequency of ESA with antihypertensive therapy was evaluated and it shows that the twice weekly ESA therapy need more modification in antihypertensive therapy than once weekly ESA dosing. The twice-weekly ESA therapy patients were prescribed with an add on therapy along with other antihypertensives. Therefore, dose and frequency of ESA was directly related to the elevation of BP.

In a study conducted by Marit M. Suttrop *et al.*, on “Effect of erythropoiesis-stimulating agents on blood pressure in pre-dialysis patients” the authors reported that the hypertensive effect of ESA, since ESA treated patients received more antihypertensive agents. No relevant difference in BP was found between patients with and without ESA, thus the increase in BP seems to be controlled by antihypertensive medication.⁹

In this study the distribution of anemia drugs in dialysis and non-dialysis patients were assessed and categorised. A total of five types of anemia management treatments were given to the study population. In dialysis dependent patients, majority were prescribed with ESA+Hematinics, followed by ESA alone, hematinics alone, and HIFPHI+Hematinics. In this study population most commonly prescribed oral iron formulation was ferrous fumarate, least prescribed was ferrous bisglycinate. The parenteral formulation commonly used Inj. iron sucrose. In case of non-dialysis, a greater number of patients were prescribed with

Table 1: Mean Hb value change in Non dialysis dependent and dialysis dependent patients during Anaemia management.

Anemia management	No. of patients			Mean change from Baseline Hb Level (g/dL)			
	Dialysis status	CKD stages	N	7.1-8	8.1-9	9.1-10	10.1-11
Haematinics alone	NDD	1-3	17	Nil	0.63 (n=4)	0.42 (n=10)	0.43 (n=3)
	DD	4-5	7	Nil	0.60 (n=1)	0.50 (n=2)	0.65 (n=4)
ESA alone (Avg.Weekly dose 4,545U)	NDD	1-3	11	0.56 (n=3)	0.56 (n=3)	0.86 (n=5)	Nil (n=0)
	DD	4-5	8	0.8 (n=1)	0.5 (n=4)	0.95 (n=2)	0.2 (n=1)
ESA (Avg.Weekly dose 4,800U) + Heamatinics	NDD	1-3	10	1.03 (n=6)	1.16 (n=3)	1.4 (n=1)	Nil
	DD	4-5	58	1.43 (n=11)	1.06 (n=21)	0.23 (n=18)	0.43 (n=8)
HIF-PHI alone	NDD	1-3	3	Nil	1.2 (n=1)	1.1 (n=1)	0.4 (n=1)
	DD	4-5	0	Nil	Nil	Nil	Nil
HIF-PHI + Hematinics	NDD	1-3	0	Nil	Nil	Nil	Nil
	DD	4-5	2	Nil	0.6 (n=2)	Nil	Nil

Table 2: Mean Blood pressure change in patients on Erythropoietin therapy.

Hypertension treatment	Dialysis status	Number of patients with Mean change in blood pressure from baseline				Mean change in BP from baseline
		NO modification in treatment	Drug Frequency increased	Dose Escalated	Add on drug	
No anti-Hypertensive	NDD (n=1)	1	Nil	Nil	0	Systolic NDD 8.095 (p->0.05)
	DD (n=3)	2	Nil	Nil	1	
Monotherapy	NDD (n=11)	10	Nil	Nil	1	DD 6.833 (p-<0.01)
	DD (n=20)	12	3	Nil	5	
Dual therapy	NDD (n=7)	7	Nil	Nil	Nil	Diastolic NDD 2.381 (p->0.05)
	DD (n=25)	20	0	1	4	
Triple Therapy	NDD (n=2)	2	Nil	Nil	Nil	DD 3.367 (p-<0.01)
	DD (n=18)	11	2	1	4	

hematinics alone, followed by ESA alone, ESA+Hematinics, and least with HIF-PHI.

In a study conducted by Marie Evans *et al.*, on “Contemporary management of anaemia, erythropoietin resistance and cardiovascular risk in patients with advanced chronic kidney disease: a nationwide analysis” showed that anemia remains highly prevalent in advanced CKD. DD patients used more erythropoiesis-stimulating agents and iron formulations than ND patients. Patients with anaemia received moderate ESA doses with a relatively low prevalence of iron use. The proportion of CKD patients receiving iron increased with CKD severity; the most frequent form of iron was oral in ND patients and IV in DD patients. ESA use also increased with CKD severity and was more common in HD.¹⁰ Our study results support this study except the Iron administration by the parenteral route.

CONCLUSION

Our study aimed at a better understanding of anaemia management in CKD patients. The study found that ESA therapy, along with the use of hematinics, is effective for the treatment of anaemia in both dialysis and non-dialysis patients. Our study confirms the hypertensive effect of ESA in our study site, since ESA treatment required modification in the doses, frequency, and add-on therapy of antihypertensive agents. Hypertension management became difficult as the dose of the ESA was increased.

This study also found a difference in anaemia management between dialysis and non-dialysis patients. In dialysis patients, the most commonly prescribed anaemia treatment was ESA in combination with hematinics, whereas in non-dialysis patients, it was either hematinics or ESA alone. The study also found a difference in the formulation of hematinics used in dialysis and non-dialysis patients. In dialysis patients, hematinics are typically administered parenterally, while non-dialysis patients receive them orally.

LIMITATION

Our study was conducted in a single setting and sample size was limited. We included a novel class of anemia management drug HIF-PHI in our study however due to the small sample size we were unable to accurately assess the mean change in hemoglobin. There are some confounding factors influencing hemoglobin values in dialysis and non-dialysis patients such as diet of patients which is not assessed in our study. Our study period was for a duration of 6 months and if the study duration was for a longer period more reliable data could be obtained. Larger, multicentre randomized trials with longer follow-up are needed to confirm these findings and improve anemia management.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CKD: Chronic Kidney Disease; **ESA:** Erythropoietin stimulating agent; **HIF-PHI:** Hypoxia inducible factor-prolyl hydroxylase inhibitors; **Hb:** Hemoglobin; **BP:** Blood pressure; **IV:** Intravenous; **RBC:** Red blood cell; **DD:** Dialysis dependent; **NDD:** Non dialysis dependent; **SPSS:** Statistical package for social sciences.

ETHICAL CONSIDERATION

The institutional ethics committee approved the study protocol entitled to Document Anemia management in chronic kidney disease patients-a prospective observational study for 6 months vide letter no. LH/EC/2023-33.dted 11 October 2023.

SUMMARY

Anemia is a common and significant complication of Chronic Kidney Disease (CKD). This study focuses on the change in haemoglobin levels of CKD patients during treatment with Erythropoietin stimulating agent (ESA)/hypoxia Inducible Factor-Prolyl Hydroxylase Inhibitors (HIF-PHI) with or without Haematinics. Hypertension is a common adverse effect of erythropoietin treatment.

A total of 117 patients were included in the study.

The Statistical Package for Social Sciences (SPSS) was used for the analysis of data. The differences between the two categories were analysed using paired *t*-test. The differences were regarded as significant with a $p \leq 0.05$.

Combining Erythropoietin (ESA) with haematinics improved haemoglobin levels more effectively than ESA alone in both dialysis and non-dialysis patients.

However, ESA treatment was associated with increased blood pressure, required increases in the doses/frequency/and add-on therapy of antihypertensive agents.

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