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ASSESSING PHARMACOTHERAPEUTIC MANAGEMENT OF ANEMIA IN VARIOUS STAGES OF CHRONIC KIDNEY DISEASE AND POST RENAL TRANSPLANT PATIENTS

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ABSTRACT: Introduction: Anemia in CKD occurs when the kidneys are damaged or diseased. They cannot make enough EPO, which stimulates the bone marrow to produce RBC. It is associated with increased cardiovascular diseases, hospitalization, reduced quality of life, cognitive impairment, and mortality. **Materials and Methods:** A prospective observational study was conducted on CKD patients. Demographic details, treatment information, SES, and performance of daily activities were collected from the patients. Anemia was confirmed in patients by observing laboratory investigations, SES was collected by using the Modified Kuppuswamy scale, and the performance of patients for the treatment was analyzed by using the Karnofsky performance index. **Results:** The majority of the patients affected with anemia belong to UL Class. The performance of patients was improved as well as an increase in hemoglobin levels and decreases in Serum Creatinine levels were observed. P-value calculated for Haemoglobin, and serum creatinine was < 0.0001, which indicates the treatment was statistically significant. **Conclusion:** The pharmacotherapeutic treatment prescribed for anemia in various categories of CKD patient's shows significant improvement in the levels of Haemoglobin and serum creatinine.

INTRODUCTION: Chronic kidney disease is a multifactorial disorder that is continuously increasing worldwide [1]. It is characterized by kidney damage or dysfunction as well as an increased risk of cardiovascular disease [2].

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Anemia is defined as Hemoglobin (Hb) level less than 13.5 g/dl for men and less than 12.0 g/dl for women [3]. Anemia is one of the complications in CKD, which develops gradually and increases in severity as kidney disease progresses [4].

The major causes of anemia in CKD patients are Iron and erythropoietin deficiencies and hypo-responsiveness to the actions of erythropoietin. Other causes for anemia are decreased Half-life of RBC, blood loss, Nutritional deficiency, inflammation, erythropoiesis Inhibition which occurs due to the accumulation of uremic toxins [5].

Immuno suppressive medications, gastrointestinal blood loss, Iron deficiency, etc., are the causes of anemia in renal transplant patients. After successful kidney transplantation, erythropoietin levels increase rapidly, and after 3 months, most patients will achieve Hb levels > 12g/dl [6]. The GBD 2015 ranks, CKD as the 17th in the world and 5th in India [7]. The approximate prevalence of CKD in India is 800 per million population, and the incidence of ESRD is 150 – 300 pmp [8]. Anemia affects 60 – 80 % of renal impairment patients and is commonly seen in both predialysis and dialysis, which leads to reduced quality of life, decreased exercise tolerance, and an additional risk factor for early death [9]. The prevalence for anemia increases with ESRD, from 8.4% in stage 1, followed by 14.6% in stage 2, 26.4% in stage 3 – 4, and 53.4% in stage 5 in US [10].

Potential consequences of anemia include cardiorenal anemia syndrome, angina, a triad of worsening anemia, worsening CKD, worsening congestive heart failure [11]. Medical costs for anemic patients are as much as twice for non-anemic patients with the same comorbid conditions [12]. Untreated anemia in Non-Dialysis Dependent (NDD) – CKD patients showed increased cardiovascular risk, hospitalization, diminished health-related quality of life, exercise capacity, and mortality. Thus, the management of anemia throughout the CKD continual is essential [13]. The rate of cardiovascular events and death were greater among Erythropoiesis Stimulating Agents (ESA) treated patients and those with lower Hb levels [14]. The prevalence of anemia in CKD, the need for the use of ESA, and the high cost associated with anemia treatment in CKD calls for assessing the management of anemia for these patients [15]. This article will provide the treatment prescribed and medication cost for anemia in various stages of CKD [NDD, HD(Hemodialysis), PD(Peritoneal Dialysis)] and Tx (Renal Transplantation).

MATERIALS AND METHODS: The study was conducted in the department of Nephrology at Sri Venkateswara Institute of Medical Sciences (SVIMS). This was a prospective observational study containing 150 subjects for a period of 6 months from June 2019 to December 2019. This study was approved by SVIMS institutional ethical committee, the IEC No.917. Subjects were taken into the study by considering the inclusion criteria [Patients with CKD (stage 1 - 5), Patients on Maintenance Dialysis (HD and PD), Post Tx and Age > 18 years] and exclusion criteria [Patients not willing to participate in study, Pregnant and Pediatric Patients, Patients with active bleeding, infection, inflammation, blood transfusion within 3 months of enrolment, HIV infection and Patients with known Hemoglobinopathies]. Study Materials include Informed consent form (ICF), Patient data collection Proforma, Modified Kuppuswamy SES scale, and Karnofsky performance scale index. Patient proforma was used for collecting data which includes patient demographic details, past medical history, family and social history, economic status, diagnosis, laboratory investi-gations, and present medications prescribed for anemia to each patient. We measure the SES of the patients by using the Modified Kuppuswamy SES scale, and the performance of the patient was measure by using the Karnofsky performance scale index, which was an assessment tool to assess the prognosis in individual patients.

Statistics Analysis: Data were recorded in a predesigned pro forma and managed using Microsoft Excel 2007. Data were expressed by mean ± standard deviation (SD). Performed normality in Graphpad prism Version 5 and not passed in normality. Thus, we selected the Paired T-test equivalent test, *i.e.*, Wilcoxon signed-rank test (nonparametric test), to obtain a P-value. P-value < 0.05 considered as significant. All the data was assessed according to the statistical criteria.

RESULTS: In our study, 150 subjects were included; among them about 98 (65.3%) were male and 52 (34.6%) were female. Out of them, 27 patients were of age group 54-59, 20 patients were of age group 60-65, 19 patients belongs to the age of 42-47 and >65, the least was found in the age of 18-23. Among 120 patients, the majority 66 of patients were in the UL (Upper Lower) class followed by 20 patients in LM (Lower Middle), 19 patients in L (Lower) and at last 15 patients were in UM (Upper Middle) class, there were no patients in U (Upper) class. The renal transplant patient's SES (Socio economic status) was not collected because we collected the transplant patient's data retrospectively, which was given in **Table 1**.

TABLE 1: CORRELATION BETWEEN HB LEVELS AND SES

SES	Hb levels (g/dl)				
	<5	5-7	7-9	9-11	>11
U	0	0	0	0	0
UM	0	1	10	4	0
LM	0	6	11	3	0
UL	0	13	34	19	0
L	1	0	10	8	0
Total	1	20	65	34	0

Note: SES: Socio Economic Status, U: Upper class, UM: Upper Middle class, LM: Lower Middle class, UL: Upper Lower class, L: Lower class

Out of 30 patients in CKD (1-3), 9 were seen in the UL class. In CKD (4-5), half of the patients were present in UL Class, in HD 23 patients, in PD 19 patients belong to UL Class respectively. Most of the patients were having Hb levels in the range of 7 – 9 g/dl irrespective of any SES class, followed by which more of patients were having Hb levels of 9 – 11 g/dl, and in U Class there were no patients.

Comparison of mean Hb levels of various categories of CKD, which was started in **Table 2**. In the same way comparison of mean serum creatinine values among various categories of CKD, was showed in **Table 3**.

TABLE 2: COMPARISON OF MEAN HB LEVELS OF VARIOUS CATEGORIES OF CKD

Categories	Mean Hb g/dL		
	First time	Follow-up 1	Follow-up 2
CKD (1-3)	8.82 ± 0.81	9.22 ± 0.74	9.37 ± 0.70
CKD (4-5)	8.7 ± 1.29	9.06 ± 0.8	9.44 ± 1.10
HD	7.55 ± 1.15	7.94 ± 1.25	8.25 ± 1.44
PD	7.93 ± 1.2	7.73 ± 1.36	8.4 ± 1.79
Tx	8.6 ± 1.1	10.4 ± 1.5	11.3 ± 1.4

Note: CKD: Chronic Kidney Disease, HD: Hemodialysis, PD: Peritoneal Dialysis, Tx: Renal Transplantation. Each category consists of 30 patients

TABLE 3: COMPARISON OF MEAN SERUM CREATININE VALUES AMONG VARIOUS CATEGORIES OF CKD

Categories	Mean Serum creatinine mg/dL		
	First time	Follow-up 1	Follow-up 2
CKD (1-3)	3.42 ± 1.66	3.45 ± 1.5	3.04 ± 1.43
CKD (4-5)	6.02 ± 1.78	5.34 ± 1.40	5.1 ± 2.01
HD	6.23 ± 3.96	5.25 ± 2.52	4.96 ± 2.60
PD	7.25 ± 2.23	6.7 ± 2.4	6.3 ± 2.25
Tx	3.8 ± 2.1	1.6 ± 1.26	0.99 ± 0.24

For 150 subjects, 104(69.3%) patients were prescribed with anemia treatment. Medical management was not given for 46(30.6%) patients depending upon their Hb levels. The most commonly prescribed drug for anemia in CKD was Cap. Nefita, Inj.EPO, T. Folvite. Out of 30 CKD (1 - 3) patients, 19 were prescribed for anemia, in those 6 patients were treated with Inj. Epo 4000IU, 4 patients have been prescribed with T. Ferrisome 30 mg, 2 were treated with T. Folvite 5 mg, and 2 were treated with Inj. Ferinject 500 mg and at last only 1 was treated with T. Livogen 150 mg and 1with Inj.Isofer 500 mg respectively. In CKD (4 - 5) patients, 25 were treated for anemia, in the 12 were prescribed with Inj. Epo 4000IU, and 8 were treated with Cap. Nefita and 5 with Inj. Ferinject 500 mg, 4 with T. Ferrisome and 1 with T. Folvite 5 mg, 1 with T. Celefer, 1 with Inj. Vitamin K 10 mg/ml. For HD patients, all were prescribed with Cap. Nefita and 16 were treated with Inj. Epo 4000 IU, 4 were treated with Inj. Darbepoietin 4000 IU, and 1 with T. Benadon 40 mg, 1 with T. Epogen 4000 IU, 1 with Inj. Venofer 20 mg/ml, 1 with Inj. Epoetin 4000IU. For PD patients, 24 were treated with Cap. Nefita , 13 with Inj .Epo 4000IU, 10 with T. Folvite 5 mg and 5 with T. Benadon and 5 with Inj. Mircera 30 mcg/0.3 ml. The details of medications overall of the study for various categories irrespectively, which was stated in **Table 4**. The average monthly expenditure of various categories of patients was shown in **Table 5**.

TABLE 4: MEDICATIONS FOR ANEMIA PRESCRIBED TO VARIOUS CATEGORIES OF CKD PATIENTS

Treatment	Male	Female	Total	Percentage
T. Nefita	45	20	65	39.6
Inj. Epo	36	8	44	26.8
T. Folvite	9	6	15	9.14
T. Ferrisome	5	3	8	4.87
Inj. Mircera	3	5	8	4.87
Inj. Ferinject	5	2	7	4.26
T. Benadon	3	3	6	3.65
Inj. Darbepoietin	4	0	4	2.43
Inj. Vitamin K	1	0	1	0.60
Inj. Epogen	1	0	1	0.60
Inj. Epoetin	0	1	1	0.60
Inj. Iron Sucrose	0	1	1	0.60
Inj. Isofer	0	1	1	0.60
T. Livogen	1	0	1	0.60
T. Celefer	0	1	1	0.60
Total	113	51	164	100

TABLE 5: AVERAGE MONTHLY EXPENDITURE IN VARIOUS CATEGORIES OF CKD

Categories	Average monthly expenditure
CKD (1-3)	2701.33
CKD (4-5)	2823
HD	11505
PD	9590

When coming to the prognosis, For CKD (1- 3) Stage, the mean Karnofsky performance score was improved from 86.6 ± 6.49 to 90.33 ± 8.35, for CKD (4-5) it was improved from 85.6 ± 1.02 to 88 ± 6.53. For HD, from 74.3 ± 10.22 to 75.6 ± 11.16. For PD, from 73.6 ± 16.82 to 78 ± 17.96. An overall improvement was seen in all patients in view of performance. Non-parametric Wilcoxon signed-rank test was performed, and we got P-value for Hb and serum creatinine was < 0.0001, which indicates the treatment was statistically significant. We observed in patients an increase in Hb levels and a decrease in serum creatinine levels, which indicates the treatment was clinically significant. **Fig. 1** and **2** explained the Haemoglobin and Serum creatinine mean with 95% CI in two different follow-ups, and both figures showing the improvement in haemoglobin levels and serum creatinine levels in patients.

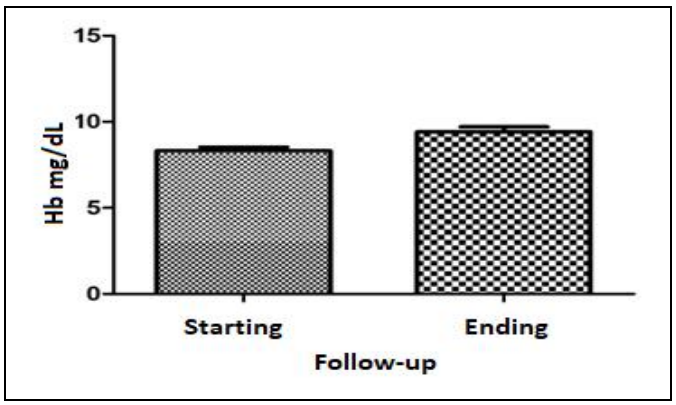

FIG. 1: HAEMOGLOBIN MEAN WITH 95% CI IN TWO DIFFERENT FOLLOW-UPS Note: Using non-parametric wilcoxon signed-rank test, we compared haemoglobin follow-ups and we got P-value for Haemoglobin was < 0.0001. *p < 0.05 considered significant, **p < 0.0001

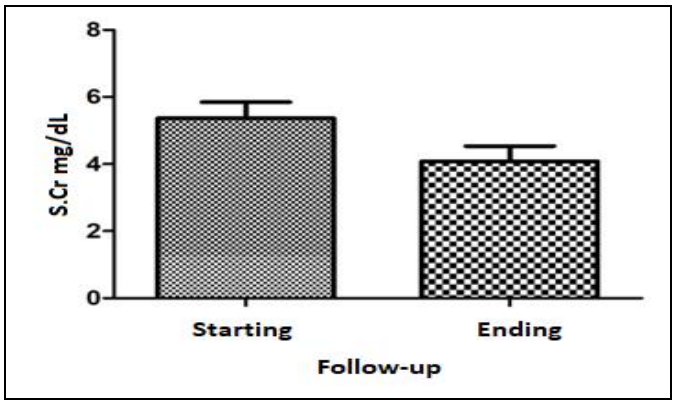

FIG. 2: SERUM CREATININE MEAN WITH 95% CI IN TWO DIFFERENT FOLLOW-UPS Note: Using non-parametric wilcoxon signed-rank test, we compared serum creatinine follow-ups and we got P-value for serum creatinine was < 0.0001. *p < 0.05 considered significant, **p < 0.0001

DISCUSSION: Anemia is one of the complications in CKD patients, which leads to high morbidity, mortality, and enormous financial cost. The pharmacotherapeutic management for anemia in various stages of CKD [pre dialysis, dialysis (HD, PD), and post-Tx] patients was treated with iron supplements, ESA and Vitamins. During the study period, we observed an increase in Hb levels and a decrease in serum creatinine levels which indicates the treatment was clinically significant, and we got P-value for Hb and serum creatinine was < 0.0001, which states that the study was statistically significant.

In our study males (65.3%) were more affected than females (34.6%). Bibek Poudel et al. had reported in his study, anemia was found in male CKD patients, female CKD patients, and total CKD patients were found to be 41.3%, 56.34%, and 47.8%, respectively [16]. The mean age group of 49.04 ± 14.93 years was more affected with anemia in our study. Aishatu Mohammad Nalado *et al.*, had reported that the mean age of anemia in CKD participants was 55.3±15.0 years [17]. By the Kuppuswamy SES scale, we have observed that UL class patients were more affected with anemia. J Y Kim et al. had concluded in his study that lower SES is associated with the prevalence of anemia and Iron Deficiency Anemia in Korean adolescent girls, and higher SES seems to have a protective effect on anemia and IDA [18].

In our study 104 (69.3%) patients were treated for anemia, and 46(30.6%) were not treated. Out of 46 untreated patients, 30 were Tx patients. Melissa E. Stauffer and Tao fan had reported that a total of 22.8% of patients are treated for anemia with CKD 10. The highest average monthly expenditure for treatment of anemia was seen in HD followed by PD, then CKD(4-5), CKD(1-3). The highest improvement in Mean Hb levels was seen in Tx patients, and the least improvement was seen in PD patients. A more decrease in serum creatinine was observed in Tx patients, and the least decrease was seen in CKD (1-3) stage. Simon D. Roger *et al.*, the study has shown that C.E.R.A with Darbepoetin Alfa once weekly successfully corrects anemia and maintains Hb levels in patients with CKD [19]. Gert. Jensen *et al.*, the study showed that iron Isomaltoside was effective in predialysis CKD and had a good safety profile [20].

In our findings out of 104 patients who have received treatment for anemia, the majority (39.6%) patients were prescribed with Cap. Nefita, 26.8% were given with Inj. EPO, 9.14% of patients were treated with Tab. Folvite 5 mg respectively. Elizabeth V. Lawler in their study, reported that among 89000 patients with anemia and CKD, 7.1% initiated ESA within a year, while 30.8% initiated Iron therapy and 16.5% used blood transfusion [21]. Out of all the medications, ESA was the most commonly prescribed drug for the treatment of anemia. Iron therapy was given to CKD (1-3) and (4-5) patients, Vitamins and Inj. EPO was prescribed for both HD and PD patients. Marwan Akel *et al.,* had reported that mean Hb levels increased from 10.16 to 11.96 g/dL, and 55.3% of patients have reached the target Hb of 12 g/dL [22].

In our collected data, for CKD(1-3) the mean Hb level was increased from 8.82 ± 0.81 to 9.37 ± 0.70, 6 patients were treated with Inj. Epo 4000 IU Twice monthly, For CKD (4-5) the mean Hb level was increased from 8.7 ± 1.29 to 9.44 ± 1.10, 8 patient was treated with Inj. Epo 4000 IU twice monthly, 4 patients were treated with a frequency of weekly once, for HD patients the mean Hb level was increased from 7.55 ± 1.15 to 8.4 ± 1.79, 24 patients were treated with Cap. Nefita, 16 patients were treated with Inj. Epo 4000IU thrice weekly and for PD patients, the mean Hb level (g/dL) was increased from 7.93 ± 1.2 to 8.4 ±1.79, 13 patients were treated with Inj. Epo 4000 IU thrice weekly and at last Tx patients mean Hb level was increased from 8.6 ± 1.1 to 11.3 ± 1.4 without treatment. Benjamin O. Varnoff *et al.* had reported for CKD (3-4) patients; anemia treatment was most cost-effective when targeting Hb level of 10.5 g/dl [23]. In our findings, when targeting a Hb level of 10g/dl in various stages of CKD shows that the average monthly expenditure for treating anemia is more for HD and PD patients, in which most of the patients were in UL Class. Tilmon B. Drueke *et al.,* had concluded that early correction of Hb levels in anemia with CKD does not reduce the risk of cardiovascular events [24]. In our study, we had observed an increase in the Hb levels shown improvement in doing their daily activities by Karnofsky performance scale.

Strength and weakness of the study: The major strength of our study was, we have mainly focussed on the pharmacotherapeutic management for anemia in CKD. We have done two follow-ups in our study to show the results. As our study is prospective, we have collected the SES and laboratory investigations from every patient to show the significant improvement from the first time to the second follow-up. The main limitation of our study was, we did not include the co-morbidities.

Implementation: For future research, one can calculate both direct non-medical and indirect costs for treating anemia with CKD and also can calculate the treatment cost for both anemia and CKD.

CONCLUSION: Treatment given to the patient by considering their SES class, affordability by the patient for treatment, their haemoglobin levels, and counselling on their diet can increase compliance and improves the treatment outcome. Pharmacotherapeutic management for anemia in various categories of CKD patients shows significant improvement in the levels of Hb and serum creatinine.

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