

Efficacy and Safety of Erythropoietin and Darbepoetin for Treatment of Anemia in Chronic Kidney Disease Patients: A Comparative Observational Study

Brajesh Kumar¹, Lalit Kumar², Jeetendra Kumar³

¹Tutor, Department of Pharmacology, Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar.

²Tutor, Department of Pharmacology, Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar.

³Professor and HOD, Department of Pharmacology, Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar.

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Corresponding author: Dr. Lalit Kumar

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Abstract

Background: One common outcome of chronic kidney disease (CKD) is anemia. Darbepoetin and erythropoietin are the main medications used to treat it. This study compared the safety and effectiveness of darbepoetin against erythropoietin injection for the treatment of renal anemia in patients with chronic kidney disease.

Methods: The study included patients of any gender with hemoglobin levels less than 12 g/dl who were diagnosed with anemia owing to chronic kidney disease (CKD), regardless of dialysis. The laboratory results of hemoglobin (Hb), red blood cells (RBCs), haematocrit (PCV), and adverse events were used to compare the safety and effectiveness of erythropoietin and darbepoetin.

Results: Of the 216 patients who satisfied the inclusion criteria, 108 received erythropoietin treatment and 108 received darbepoetin treatment. In the group of patients receiving erythropoietin, the changes in Hb, RBCs, and PCV were 1.16, 0.49, and 3.76, respectively. Similarly, the group of patients using Darbepoetin showed changes in Hb, RBCs, and PCV of 1.19, 0.42, and 3.52, respectively. The variations in Hb, RBCs, and PCV between the two patient groups were 0.04, 0.07, and 0.24, respectively. 48 (44.44%) patients in the erythropoietin group had four adverse events (HTN, vomiting, headache, and joint pain), while 38 (35.19%) patients in the darbepoetin group reported one adverse event (HTN).

Conclusion: For the treatment of anemia in CKD patients, erythropoietin and darbepoetin were found to be equally safe and efficacious.

Keywords: Anemia, Chronic kidney disease, Darbepoetin, Erythropoietin.

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Introduction

Interstitial fibrosis gradually replaces normal kidney architecture in chronic kidney disease (CKD), which is characterized by a progressive loss of function over several months to years.[1] With an incidence rate ranging from 8% to 16%, CKD is the 16th most common cause of years of life lost globally.

To avoid the negative consequences of chronic kidney disease (CKD), such as cardiovascular disease, end-stage renal disease, anemia, and death, primary care physicians must perform appropriate screening, diagnosis, and treatment. One of the most frequent side effects of CKD is anemia [2,8]. A decrease in one or more of the three main red

blood cell measurements hemoglobin concentration, hemocrit, or red blood cell count is referred to as anemia.[3] Red blood cell transfusions were the only treatment available in the past, but they were costly, time-consuming, risky for infection, might cause iron and fluid overload, and encouraged the production of antibodies that could cause issues if transplantation was later attempted.[9] The following are many forms of erythropoiesis-stimulating agents (ESAs) used in anemia brought on by chronic kidney disease.

The kidney produces the hormone erythropoietin (EPO), which encourages the bone marrow to

create red blood cells. Reduced oxygen levels in the blood passing through the kidney cause the kidney cells that produce erythropoietin to react. In reaction to low oxygen levels, these cells create and secrete erythropoietin. People with anemia (low blood count) associated with kidney disease are the most common users. Reduced erythropoietin production from malfunctioning kidneys can result in anemia, or low production of red blood cells. The bone marrow produces more red blood cells when erythropoietin is present. The blood's ability to carry oxygen is increased as a result of the increase in red blood cells.[4, 10]

Darbepoetin (DPO), a recombinant hyperglycosylated counterpart of epoetin, is a new erythropoiesis-stimulating protein (NESP) produced by recombinant DNA technology that promotes the synthesis of red blood cells by the same mechanism as the natural hormone. It is a 37 Kda glycoprotein with five N-linked oligosaccharide chains and 165 amino acids, while endogenous erythropoietin (EPO) and the shorter-acting recombinant human erythropoietin (rHuEPO) only have three.[6, 7]

Material and Methods

From March 2026 to May 2026, a comparative prospective and observational study on patients with chronic renal disease who had anemia was carried out in the pharmacology department associated with the medicine department of

Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar. The study comprised patients with CKD-related anemia who were either male or female, registered at JLNCH, between the ages of 18 and 97, and prescribed either erythropoietin or darbepoetin. Patients who were on red blood cell transfusions, had just had surgery, or were pregnant or lactating were not allowed to participate in the study.

216 cases in all were chosen using inclusion and exclusion criteria, and they were split into two treatment-based groups at random. Group A: 4000 units of erythropoietin subcutaneously twice a week (n = 108) and group B (darbepoetin): 40 mcg subcutaneously once a month (n = 108). Information about the medications, RBC, PCV, and hemoglobin lab findings was documented. Adverse pharmacological responses associated with the research medications were also recorded. The effectiveness of both medications was assessed using lab values of RBCs, PCV, and hemoglobin. Additionally, the safety of both medications was evaluated using the ADRs. The z-test was used for data collection and analysis.

Results

There were 216 patients in the study, 108 in each group. Variables related to demographics were evaluated. The majority of patients were male and ranged in age from 58 to 77. The majority of patients in both groups had stage 5 CKD (Table 1).

Table 1: Comparison of demographics data in the study groups

Parameters		Group EPO		Group DPO	
		No. of cases	Percentage	No. of cases	Percentage
Age group (in years)	18-37	18	16.67%	4	3.71%
	38-57	40	37.04%	36	33.33%
	58-77	42	38.89%	56	51.85%
	78-97	8	7.41%	12	11.11%
Mean±SD	54.72±16.16		60.74±13.17		
Gender	Male	74	68.52%	64	59.26%
	Female	34	31.48%	44	40.74%
Stages of CKD	Acute on CKD	14	12.96	30	27.78%
	3	4	3.7%	16	14.81%
	4	4	3.7%	6	5.56%
	5	72	66.67%	52	48.15%
	ESRD	14	12.96%	4	3.7%
Total		108	100%	108	100%

Table 2: Comparison of haemoglobin levels in the study groups

Drugs	Hb before, Mean±SD	Hb after, Mean±SD	Mean change in Hb	P value
Erythropoietin	7.84±1.33	9±1.48	1.16	P<0.0001
Darbepoetin	8.6±1.25	9.79±1.31	1.19	P<0.0001

Table 3: Comparison of RBCs levels in the study groups

Drugs	RBC before, Mean±SD	RBC after, Mean±SD	Mean change in RBC	P value
Erythropoietin	2.78±0.54	3.27±0.58	0.49	P<0.0001
Darbepoetin	3.08±0.65	3.5±0.63	0.42	P<0.0001

Table 4: Comparison of PCV levels in the study groups

Drugs	PCV before, Mean $\pm$ SD	PCV after, Mean $\pm$ SD	Mean change in PCV	P value
Erythropoietin	24.06 $\pm$ 4.22	27.83 $\pm$ 4.65	3.77	P<0.0001
Darbepoetin	26.25 $\pm$ 4	29.77 $\pm$ 4.03	3.52	P<0.0001

Table 5: Shows the adverse events reported by patients on erythropoietin

Adverse events	No. of patients	Percentage
HTN	21	38.89%
Headache	1	1.85%
Joint pain	1	1.85%
Vomiting	1	1.85%

Table 6: Shows the adverse events reported by patients on darbepoetin

Adverse events	No. of patients	Percentage
HTN	19	35.19%

Following treatment, improvements in PCV, RBCs, and hemoglobin were assessed. Prior to therapy, groups A and B had mean $\pm$ SD hemoglobin levels of 7.84 $\pm$ 1.33 and 8.6 $\pm$ 1.25, respectively. Similarly, following therapy, group A's and group B's mean $\pm$ SD hemoglobin levels were 9 $\pm$ 1.48 and 9.79 $\pm$ 1.31, respectively.

For groups A and B, the mean change in hemoglobin concentration prior to and following therapy was 1.16 and 1.19, respectively.

Both groups' mean improvements in hemoglobin concentration were substantially the same (Table 2). Prior to therapy, groups A and B had mean $\pm$ SD RBC levels of 2.78 $\pm$ 0.54 and 3.08 $\pm$ 0.65, respectively. In a similar vein, following therapy, groups A and B had mean $\pm$ SD RBC levels of 3.27 $\pm$ 0.58 and 3.5 $\pm$ 0.63, respectively. For groups A and B, the mean change in RBC concentration before and after therapy was 0.49 and 0.42, respectively. Both groups' mean improvements in RBC concentration were substantially the same (Table 3). Prior to therapy, groups A and B had mean $\pm$ SD PCV levels of 24.06 $\pm$ 4.22 and 26.25 $\pm$ 4, respectively. Similarly, following treatment, group A's mean $\pm$ SD PCV level was 27.83 $\pm$ 4.65, while group B's was 29.77 $\pm$ 4.03. In groups A and B, the average change in PCV levels prior to and following therapy was 3.77 and 3.52, respectively. Both groups' mean improvements in PCV levels were substantially the same (Table 4). In addition to evaluating the two medications' effectiveness, their side effects were examined. Patients in groups A and B experienced increased episodes of hypertension (38.89% and 35.19%, respectively), which was determined to be significantly the same for both medications. Headache, joint discomfort, and vomiting were additional side effects (Table 5 and 6).

Discussion

The goal of the current study was to evaluate and compare the safety and effectiveness of darbepoetin

40 mcg and erythropoietin 4000 units in treating anemia in individuals with chronic kidney disease. Age, gender, and CKD stages were among the demographic factors that were assessed and found to be similar in both groups. Taking the lab results, the improvement in hemoglobin, red blood cells, and PCV was assessed both before and after taking erythropoietin and darbepoetin. Erythropoiesis-stimulating agents (ESAs) include darbepoetin and erythropoietin.[11] By attaching to EPO receptors on colony forming units (CFU), proerythroblast, and basophilic erythroblast and stimulating them to transform into polychromatophilic erythroblast, erythropoietin directly acts on the kidney to create erythrocytes (RBCs).[4,12]

When darbepoetin binds to erythropoietin receptor monomers, the receptor dimerizes and the Janus kinase-2 (JAK-2) intracellular signal transduction pathway is activated, causing RBCs to proliferate, differentiate, mature, and block apoptosis.[4,6] They raise the concentrations of PCV, hemoglobin, and red blood cells.

Both medications were shown to be equally effective since they considerably raised the concentrations of hemoglobin, red blood cells, and PCV. The mean improvement in all concentrations was the same in both groups.

The patients on erythropoietin and darbepoetin in the Sinha et al. research had mean changes in hemoglobin of 1.85 and 1.84, respectively. The two groups' mean changes in hemoglobin levels differed by 0.01g/dl. There was no statistically significant difference. Thus, the study's findings showed that darbepoetin and erythropoietin are equally effective in treating patients with anemia brought on by chronic kidney disease.[5]

A total of 216 patients were enrolled in the current study (108 on EPO and 108 on DPO). Of these, 42 (38.89%) patients from the EPO group and 38 (35.19%) patients from the DPO group reported an increase in blood pressure (HTN), 2 (1.85%)

reported headache, 2 (1.85%) reported joint pain, and 2 (1.85%) reported vomiting. Erythropoietin and darbepoetin were judged to be equally safe because the number of side effects reported by both patient groups was comparable.

In the study by Sinha et al., at least one treatment-emergent adverse event (TEAE) occurred in 25 (39.7%) of the 63 patients in the Darbepoetin group and 32 (50.8%) of the 63 patients in the erythropoietin group.

With the exception of one patient (1.58%) from the EPO group who had a severe TEAE, the majority of patients reported mild to moderately severe TEAEs. Four patients from the EPO group had five adverse events (AEs) associated with the study medication, while none from the DPO group reported any TEAE. Four individuals in the EPO group reported five adverse events (AEs) associated with the study medication.[5]

Pyrexia (DPO vs. EPO 9.5% vs. 7.9%), joint pain (9.5% vs. 15.9%), and vomiting (4.8% vs. 6.3%) were the most frequently reported events in both treatment groups. There was no statistically significant difference in TEAEs between the two groups. Overall, DPO's safety profile was comparable to EPO's, and no antibody development was found.[5]

Conclusion

Both medications were shown to be equally beneficial for individuals with anemia caused by chronic kidney disease (CKD) since there was little difference in the mean change in hemoglobin, red blood cells, and haematocrit levels between groups of patients on erythropoietin and darbepoetin.

Patients on erythropoietin reported more adverse events than those on darbepoetin, but both groups experienced statistically significant adverse effects, indicating that both medications were similarly safe for patients with anemia brought on by chronic kidney disease.

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