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Comparative Efficacy and Safety of Epoetin Alfa Vs Desidustat In Chronic Kidney Disease Patients On Maintenance Hemodialysis

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ABSTRACT

This study was carried out to compare the efficacy and safety of epoetin alfa vs desidustat (propyl hydroxylase inhibitor) for treatment of anemia in chronic kidney disease (CKD) patients on maintenance hemodialysis. Sixty patients of CKD stage 5 were included in the study undergoing maintenance hemodialysis. These patients were divided randomly into two groups. Group A consists of 30 patients who received epoetin alfa during each dialysis (3 times/week). Group B consisting of 30 patients received desidustat tablet 3 times/week. The change in the haemoglobin level was taken as the main evaluation parameter between epoetin alfa and desidustat groups and measured after three months. The change in haemoglobin level from baseline to 3 months was 1.37 g/dl in epoetin alfa group and 1.53 g/dl in desidustat group. The safety profile of both the drugs was comparable. There were no increased risks seen with desidustat as compared to epoetin alfa. In this study desidustat is found to be more efficacious with equal side effects as compared to epoetin alfa in ckd patients on maintenance hemodialysis.

Keywords: Epoetin alfa, desidustat, ckd, hemodialysis.

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INTRODUCTION

Chronic kidney disease is a non-communicable, chronic disease that affects thousands of peoples around the world. A normocytic normochromic anemia develops in almost 90% of individuals with ckd stage 5. Anemia decreases the quality of life of patients and is associated with various kinds of co morbidity and mortality including cardiovascular diseases. Anemia can occur due to several reasons such as decreased RBC life span, iron deficiency, reduced erythropoietin formation, resistance to erythropoietin, decreased receptors etc. Repeated dialysis also further decreases RBC. We have to give the erythrocyte stimulating agents (esa) to reduce the anemia and increase the level of haemoglobin in these patients. We will compare the efficacy and safety of 2 esa – epoetin alfa and desidustat in treating anemia of these ckd patients on maintenance hemodialysis.

MATERIALS AND METHOD

Table 1: Baseline Parameters

Parameters	Group A	Group B
Haemoglobin	9.45 ± 1.37 gm%	9.51 ±0.99 gm%
Hematocrait	21.45 ±1.13%	$22.01\pm2.3\%$
Serum urea	105±2.1 mg%	106±2.3 mg%
Serum creatinine	8.6 ±1.1 mg%	$8.2 \pm 1.3 \text{ mg}\%$
Serum sodium	$140 \pm 1.2 \text{ meq/l}$	$141 \pm 1.3 \text{ meq/l}$
Serum potassium	$4.6 \pm 0.9 \text{ meq/l}$	$4.7 \pm 0.8 \text{ meq/l}$
Serum ferritin	$571 \pm 105 \text{ ng/ml}$	$585 \pm 110 \text{ ng/ml}$

Sixty adult patients of ckd stage 5 undergoing maintenance hemodialysis were included in the study. Ckd stage 5 Patients were considered who were anemic (hb <10 gm%). These patients were randomly divided into 2 groups – group A and group B (30 individuals each group). Group A patients received subcutaneous epoetin alfa injection (4000 i.u) during each dialysis (3 times/week). Group B patients received oral desidustat tablet (100mg) 3 times a week. Iron infusion was given to every patient (100mg\week). Serum ferritin was measured of every patient every month using serum immunoassay technique. SPSS software was used for statistical analysis. For comparison of means in two groups we used unpaired student t test and for comparison of means in a single group we used paired student t test. Repeated measures analysis of variance (ANOVA) test was used for comparison of means of different parameters. P- value was obtained to determine the statistical significance.

RESULTS AND DISCUSSION

In total 81 patients were choosen for the study but only 60 patients were able to complete the study. Out of 21 patients, 8 patients in group A and 5 patients in group B left the study for unknown reason. 3 patients in each group had their kidney transplant and 2 patients died in group B.

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The mean rise in hemoglobin level at the end of 3 months was 1.37gm% in group A and 1.53gm% in group B. The mean hemoglobin level after 3 months was 10.82gm % in group A and 11.04gm% in group B. The rise in haemoglobin level was more in desidustat group as compared to epoetin alfa group. The number of haemoglobin responders were also more in desidustat group (25) as compared to epoetin group (21). Overall, both the drugs was comparable in terms of safety profile. There was no major difference in both the drugs in occurrence of adverse events. No serious or life threatening adverse event was noted, all the adverse events was mild and resolved on their own. All vitals (blood pressure, pulse, spo2, temperature) were stable during treatment.

Anemia is a characteristic morbidity of CKD stage 5 patients. Anemia develops in almost 90% of patients in varying degree. Anemia is directly proportional to the renal dysfunction. Anemia can occur due to variety of reasons such as decreased erythropoietin production, erythropoietin hyporesponsivenes, decreased iron stores etc. Anemia reduces the quality of life and predisposes to various kinds of diseases including cardiovascular diseases. By giving erythrocyte stimulating agents such as epoetin alfa and desidustat we can improve the quality of life and reduces the co morbidity and mortality with CKD. These drugs increase the oxygen supply to heart and other tissues thereby enhancing physical capability, cognitive function and reduces fatique, incidence of blood transfusion. These drugs helps to maintain the hemoglobin level between 10-12 gm%.

CONCLUSION

It can be concluded that both epoetin alfa and desidustat increases the haemoglobin from baseline in ckd stage 5 patients undergoing maintenance hemodialysis but desidustat increases haemoglobin slightly more than the epoetin alfa. Both the drugs are comparable in terms of safety profile and causes no major adverse event during their treatment. "Desidustat in Anemia due to Dialysis-Dependent Chronic Kidney Disease.

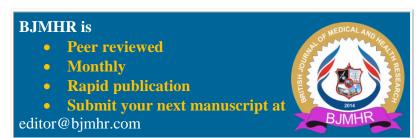
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