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The hematopoietic effect of Epotin (recombinant human erythropoietin-alpha) on maintenance hemodialysis end-stage kidney disease patients.

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Source

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Abstract

Recombinant human erythropoietin (rHuEpo) has revolutionized the management of renal anemia, significantly improving patient quality of life. Great attention has been paid lately on how to optimally use this potent anti-anemic agent. Aiming to overview anemic patient management with Epotin (Julphar's rHuEpo) according to the new guidelines, we included in the study anemic (hemoglobin [Hb]<or=11 g/dL) end-stage kidney disease (ESKD) patients (n=35) of ages>or=18 years who were of iron replete (transeferene saturation (TSAT)>or=20% and serum ferritin>or=100 microg/L) with no evidence of serious inflammation (creactive protein (CRP)<30 mg/L) on thrice-weekly hemodialysis. The mean age and dialysis duration of 50.8+/-17 and 3.8+/-2.8 years, respectively, included 88.6% (n=31) de novo patients in the corrective phase with no previous exposure to erythropoietin. Safety-efficacy parameters showed insignificant changes throughout the 4-month study period, including iron profile that was maintained according to Kidney Disease Outcome Quality Initiative guidelines. Efficacy parameters revealed a significant increase (P<.0001) of Hb levels from a baseline of 8.5+/-1.0 to 11.1+/-1.1. Targeting an absolute increase of 2.5 g/dL in Hb throughout 3 months of the study period resulted in a 90.3% success rate. There were no dropouts due to intolerance, whereas all the recorded adverse events were classified as unrelated to the test product. In conclusion, Epotin was clinically effective to correct and maintain Hb levels in ESKD anemic patients on maintenance hemodialysis within the current recommended range and with a satisfactory safety profile consistent with previous international reports