CO-ORGANIZED EVENT
International Conference on
Toxicology and Clinical Pharmacology
&
2nd International Conference on
Generic Drugs and Biosimilars
December 14-16, 2017 Rome, Italy

Roberto Castelli, Clin Exp Pharmacol 2017, 7:6(Suppl)
DOI: 10.4172/2161-1459-C1-025

Biosimilar epoetin in elderly patients with low-risk myelodysplastic syndromes improves anemia, quality of life, and brain function

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The myelodysplastic syndromes (MDS) are a group of clonal hematopoietic disorders characterized by bone marrow failure and a risk of progression to acute myeloid leukemia (AML). Anemia affects the course of disease, quality of life (QOL), and cognitive function of MDS patients. Erythroid-stimulating agents (ESAs) are effective; however, not all patients respond to ESAs. To evaluate the effectiveness of a biosimilar epoetin α (Binocrit) for the treatment of anemia in low-/intermediate-1 risk MDS patients and to evaluate the impact of ESAs on QOL and on cognitive function, 24 consecutive patients aged over 65 years were treated with Binocrit at 40,000 IU once a week for 12 weeks and were followed for at least three months. Responsive patients continued with 40,000 IU once a week for a further 12 weeks. Changes in QOL were assessed by the Functional Assessment of Cancer Therapy-Anemia (FACT-An), while cognitive assessment was carried out by mini-mental state examination (MMSE). All patients completed 12 weeks of therapy. Sixteen patients (66.67 %) achieved an erythroid response (ER), 15 patients (62.5 %) became transfusion independent and remained free from transfusion requirement for at least 3 months, while two patients had reduction in transfusion requirement of at least four RBC transfusions/8 weeks compared with the pretreatment transfusion requirement. Seven patients were non responders (29.1 %), of whom four patients were low risk and three intermediate-I risk. Seven transfusion-independent patients were low risk, and eight were intermediate-1 risk. Median hemoglobin (Hb) values were significantly higher after treatment in responders ($p<0.001$). ER was maintained after 24 weeks. Statistically significant positive correlations between improvement in Hb and variations in patients' mini-mental (Spearman's Rho=0.54, $p<0.01$) and FACT-An scores (Spearman's Rho = 0.59, $p<0.003$) were demonstrated. This preliminary study shows that Binocrit is promising for the treatment of anemia of MDS patients. ER positively correlates with improvements in patients' cognitive status and positive changes in QOL.

Recent Publications

1. A Tefferi, J W Vardiman (2009) Myelodysplastic syndromes. N. Engl. J. Med. 361(19): 1872–85.
2. L Malcovati et al., (2011) Impact of the degree of anemia on the outcome of patients with myelodysplastic syndrome and its integration into the WHO classification-based Prognostic Scoring System (WPSS). Haematologica 96 (10): 1433–40.
3. L Malcovati (2007) Impact of transfusion dependency and secondary iron overload on the survival of patients with myelodysplastic syndromes. Leuk. Res., 31(3): S2-6.
4. M. Jädersten et al. (2008) Erythropoietin and granulocyte-colony stimulating factor treatment associated with improved survival in myelodysplastic syndrome. J. Clin. Oncol. 26(21): 3607–13.
5. V Santini (2011) Clinical use of erythropoietic stimulating agents in myelodysplastic syndromes. Oncologist 16 (3): 35–42.

Biography

Roberto Castelli obtained degree in Medicine at University of Milan, and then specialization in Internal Medicine and Hematology at university of Milan. In addition, he obtained PhD in Clinical Methodology at University of Milan. He worked as Hematologist at Ospedale Maggiore di Milano University of Milan until 2015 at University Hospital Ospedale Luigi Sacco. He is involved in malignant and non-malignant hematological disease focusing on myelodisplastic syndromes, acute and chronic leukemias and myeloprolipherative neoplasms. He is responsible of Leukemia Section at Ospedale Luigi Sacco University of Milan

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