Short term effect on hemoglobinemia of erythropoiesis-stimulating agents in clinical practice: no difference between biosimilar and originator

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Since 2007, biosimilars of erythropoiesis-stimulating agents (ESAs) are available on the Italian market. Very limited post-marketing data exist on the comparative effectiveness of originator and biosimilar ESAs. The aim of this population-based study was to evaluate and compare the short-term effects of biosimilars and originators on hemoglobinemia, in chronic kidney disease (CKD) or cancer patients in a Local Health Unit (LHU) from Northern Italy.
A retrospective cohort study was conducted during the years 2009–2013 using the Treviso LHU administrative database. Incident ESA users (no ESA dispensing within 6 months prior to the treatment start, that is the index date (ID)) with at least one hemoglobin (Hb) measurement within one month prior to ID, and another one between 2nd and 3rd month after ID were identified. The consumption (as median number of defined daily dose (DDD)) along with interquartile range (IQR), and the effect on Hb measurements after three months from the start of the ESA treatment were investigated. The difference between the last Hb measurement after ID and the one prior to ID, defined as delta Hb (ΔHb) was also evaluated. Based on Hb increase (or decrease) during the treatment, ESA users were classified as non-responders (ΔHb≤0 g/dl), responders (0<ΔHb≤2 g/dl) and highly responders (ΔHb>2 g/dl).
All analyses were stratified by indication for use (CKD and cancer) and type of dispensed ESA (biosimilar or reference product/ESAs whose patent has not expired, i.e. originators) at ID.
The study was conducted in the context of the 'Assessment of short and long term risk-benefit profile of biologics through healthcare database network in Italy' project, which was funded by Italian Ministry of Health.
Overall, 753 incident users of ESAs (CKD: 441, 58.6%; cancer: 312, 41.4%) were identified. Baseline demographic and clinical characteristics of originator and biosimilar ESA users were comparable. No statistically significant difference in DDD consumption between biosimilars and originators was found in either CKD patients (originator median= 89.0, IQR= 54.0-142.4; biosimilar median=80.0, IQR=48.0-120.0; p-value= 0.323) and cancer patients (originator median=270.0, IQR= 160.0-436.5; biosimilar median=320.0, IQR=160.0-480.0; p-value= 0.843). No statistically significant differences between biosimilars and originators in ΔHb after three months from the treatment start were observed in CKD (p-value=0.669) or cancer (p-value= 0.507) patients. No differences between originator and biosimilar ESAs were found in terms of distribution of non-responders, responders and highly responders, based on the effect on Hb in CKD (p-value= 0.734) or cancer (p-value= 0.496) patients.
No difference on the short-term effects on hemoglobinemia among users of either originator or biosimilar ESAs was observed in a general population from Northern Italy, despite a comparable consumption of the different ESAs during the first three months of treatment. These findings indicate that ESAs with lowest cost should be prescribed to CKD/cancer patients, irrespective of the fact that the ESA is biosimilar, reference product or drug still covered by patent.