

EVALUATION OF HEALTH DIRECT COSTS ASSOCIATED WITH THE USE OF BIOSIMILAR AND ORIGINATOR ERYTHROPOIESIS STIMULATING AGENTS (ESAS): AN ITALIAN, MULTI-REGIONAL, POPULATION BASED STUDY

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Background

Chronic kidney disease (CKD) is a growing public health issue worldwide. In Italy, the prevalence of CKD is 7.5% in men and 6.5% in women, even if prevalence of the most severe stages (IIIb-V) ranges from 0.5% to 0.1%. The more severe is the CKD stage, the higher is the clinical and economic impact of the disease on the National Health System. The annual direct costs of management of patient on dialysis were estimated to be around € 30,000 for peritoneal dialysis and € 44,000 for haemodialysis. Erythropoiesis stimulating agents (ESAs) have a significant economic burden in CDK as they are widely used to treat CKD-related anaemia. Since 2007, ESA biosimilars are available in the Italian market, allowing around 30.0% saving of ESA purchase costs in CKD patients.

Aim

To measure and compare the direct costs of biosimilar ESAs vs. reference products vs. other ESAs still covered by patents, in the context of the entire management of different CKD stages in five regional centres of Italy.

Methods

This 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, funded by the Italian Ministry of Health.

A population-based, retrospective, multicentre study was conducted during the years 2009–2014, using the administrative databases of Tuscany and Umbria Regions and Caserta, Treviso and Palermo Local Health Units (LHUs), covering a total population of around 8 million persons (13.2% of the total Italian Population). Incident ESA users (no drug dispensing within the year prior to the first ESA dispensing (Index date-ID)) affected by CKD and having an ESA treatment duration of almost one year were identified and characterized at the start of treatment. Moreover, all incident ESA users with a specific CKD stage were identified. Direct costs related to ESA drugs, other concomitant drugs, hospitalizations, diagnostic tests and dialysis were analysed from the NHS perspective. Annual mean direct costs per incident CKD patient stratified by severity of CKD, type of ESA and year of treatment were calculated.

Results

During the study years, 7,810 incident CKD ESA users (reference product: 14.6%; biosimilars: 15.4%; other ESAs still covered by patent: 70.0%) were treated for at least one year after ID. No age (mean \pm SD: 75.6 \pm 13.6) and sex differences across ESA types in different centres were observed. Among 2,921 CKD patients for whom information on stage was reported, 1,179 (40.4%) had a CKD stage between 1 and 3, 776 (26.6%) between 4 and 5 and 966 (33.0%) were on dialysis, with heterogeneity of CKD stage distribution across different centres (e.g. dialyzed patients from 6.8% to 25.5% of CKD patients).

The highest total costs were observed for dialysed patients, with crude estimates ranging from € 20,715 in ESA biosimilar users to € 35,176 in users of other ESAs still covered by patent. The cost for yearly ESA treatment represented 16.3% (€ 4,524) of total yearly direct costs of CKD management in stage 1-3. Such a proportion decreased to 11.9% (€ 3,842) in CKD 4-5 stage and to 6.7% (€ 5,913) of total costs in dialyzed patients.

As compared to ESA reference product and other ESAs still covered by patent, using biosimilar guaranteed yearly economic saving for ESA treatment specifically equal to € 906 and € 604 in CKD 1-3 stage, € 335 and € 755 in CKD 4-5 stage, and € 838 and € 616 in dialysed patients, respectively.

Conclusions

The management of CKD patients requires high costs especially in dialyzed patients. Using ESA biosimilars may save economic resources, which are proportionally more significant in the early stages of the diseases. Appropriate use of ESAs as well as of other therapeutic interventions aimed at slowing down the progressive renal impairment are essential for minimizing clinical and economic burden of CKD in general population.