Intravitreal anti-VEGF injections: real-world data on the pattern of use using multiple administrative healthcare databases from Southern Italy

1)Marcianò I. 2)Giorgianni F. 3)Aliquò G. 4)Scondotto G. 5)Pollina addario SW. 6)Scondotto S. 7)Cananzi P. 8)Puzo MR. 9)De sarro G. 10)De francesco A. 11)Trifirò G.

A.O.U. Policlinico "G. Martino" U.O.S.D. Farmacologia Clinica

Background

Anti-vascular endothelial growth factor (anti-VEGF) agents, including aflibercept, pegaptanib, ranibizumab and bevacizumab, as well as dexamethasone are approved as intravitreal injections for the treatment of neovascular age-related macular degeneration or visual impairments due to retinal vein occlusions, diabetic macular edema and myopic choroidal neovascularisation. Limited data on the use of these drugs from Italian real world setting are currently available.

Objectives

To explore the pattern of use of intravitreal anti-VEGF agents and dexamethasone to treat retinal disease, using healthcare databases from three Italian Regions in the years ranging from 2012 to 2016.

Methods

This population-based, retrospective, drug-utilization study was conducted using administrative healthcare databases of Sicily, Calabria and Basilicata Regions during study period ranging from 2012 to 2016. Incident users of aflibercept, pegaptanib, ranibizumab and dexamethasone were identified and characterized; prevalence of use of the study drugs as well as frequency of sporadic users, switching pattern, and timing of administration were assessed over time. The study was conducted in the context of the project “Monitoraggio a breve e lungo termine del profilo beneficio-rischio dell’uso intravitreale dei farmaci anti-VEGF tramite network di dati clinici ed amministrativi”, funded by the Italian Medicines Agency.

Results

In the study years, 4,297 (0.1% of the total residents in the catchment areas) patients received at least one dispensing of the study drugs. Of these, 4,286 (99.7%) were naïve users (i.e. no dispensing of the study drugs within one year prior to first study drug dispensing that is the Index Date [ID]). The most frequently dispensed drug was ranibizumab (N= 3,448; 80.4%), followed by aflibercept (N= 438; 10.2%) and dexamethasone (N= 374; 8.7%). Naïve users had a median age of 71 years (interquartile range: 63-79) and equally distributed by sex (M/F= 1.1). Among naïve users, 587 (23.3%) had only one dispensing within one year after the treatment start, especially among pegaptanib and dexamethasone users (respectively, 89.5% and 50.3%). In line with the Summaries of Product Characteristics, ≥3 dispensing were received by 81.2% of aflibercept and 59.4% of ranibizumab naïve users. Considering naïve dexamethasone users, 59.8% received a second

dispensing within 6 months after the ID (the overall median interval between ID and the following dispensing was 156.5 days [interquartile range: 125.5-244.0]).

During a mean follow-up of 1.2 years, number of dispensing ranged from 1 to 12 for aflibercept, 1 to 6 for dexamethasone, 1 to 2 for pegaptanib and 1 to 21 for ranibizumab.

The mean interval between two consecutive dispensings was higher for dexamethasone users (167.9 days ± 68.8) than for ranibizumab and aflibercept (respectively: 72.8 days ± 53.7; 50.0 days ± 16.6). During the first year of treatment, switch was frequent (10.5%), especially from dexamethasone to ranibizumab (40.0%) and, to much lower extent, from ranibizumab to aflibercept (6.1%).

Conclusions

In a large general population from three Southern Italian Regions, intravitreal use of anti-VEGF agents and dexamethasone for retinal diseases is frequently not in line with the recommendations reported in the Summary of Product Characteristics. Switching between different drugs occurs occasionally within one year after the beginning of therapy. Availability of longer follow-up data from real-world setting than those available in pre-marketing randomized clinical trials of the study drugs will allow better evaluation of comparative effectiveness and safety of different anti-VEGF agents and dexamethasone in the treatment of retinal diseases.