Effectiveness of ranibizumab intravitreal injections in visual impairment due to macular edema secondary to retinal vein occlusion: final results at 24 months from the French BOREAL Cohorts


Abstract

- **Background**: The French Health Technology Assessment agency requested information on the ranibizumab (RBZ) usage and impact of RBZ treatment in real-life settings. The objective was to assess the effectiveness of different patterns of use of RBZ intravitreal injections (IVI) for patients with visual impairment due to macular edema secondary to branch (BRVO) or central (CV) retinal vein occlusion (ME-RVO) for up to 24 months follow-up. This is a real-world, post-authorization, observational study in adult patients with RBZ initiation for best-corrected visual acuity (BCVA) loss due to ME-RVO, followed-up for up to 24 months by their ophthalmologists.

- **Methods**: The primary endpoint was BCVA evolution from baseline to Month 6. BCVA, central retinal vein occlusion (ME-RVO), followed-up for up to 24 months by their ophthalmologists.

- **Results**: The study was performed at the request of the HAS and funded by Novartis.

- **Objectives**
  - To assess the change in central subfield thickness
  - To describe patterns of ranibizumab use

- **Conclusions**: Effectiveness of RBZ in daily practice is close to the final results at 24 months from the French BOREAL Cohorts

Methods

- **Central subfield thickness evolution**
  - **Patients identified by 39 ophthalmologists between December 2013 and April 2014**
  - **Patients included in BRVO cohort**
  - **Patients included in CRVO cohort**

- **BCVA evolution**

- **Results**

- **Central subfield thickness evolution**

- **Conclusion**: This real-world study of patients with ranibizumab IVI initiation in ME-RVO showed an improvement of BCVA and CSFT 6 months after initiation followed by a relative stability until 24 months. Mean BCVA change at 24-month is lower in this study than in RCT but with less mean injections in real life: 11.4 letters and 7.2 IVI in BRVO cohort compared to 11.5 letters and 11.4 IVI in BOREAL RCT, and 7.1 IVI in CVR cohort compared to 12.1 letters and 13.1 IVI in CRVO cohort.

Declarations of interest

The study was performed at the request of the HAS and funded by Novartis.

Figure 4: Evolution of patients distribution according to central subfield thickness (CSFT) measure during the follow-up study for eyes followed patients in BRVO cohort and CRVO cohort

Figure 5: Intravitreal treatments modalities of ME-BRVO and ME-CRVO for studied eyes of followed patients in BRVO cohort and CRVO cohort at 24-month

Table 1: Intravitreal treatment and interruption details of ME-BRVO and ME-CRVO for studied eyes of followed patients in BRVO cohort and CRVO cohort at 24-month

Table 2: Intravitreal and injection details of ME-BRVO and ME-CRVO for studied eyes of followed patients in BRVO cohort and CRVO cohort at 24-month

- **Treatments modalities**
  - **BRVO patients**
  - **CRVO patients**

- **Baseline characteristics of patients at inclusion**

- **Study populations**

- **Design**: real-world, post-authorization; observational cohort study in adult patients with ranibizumab IVI initiation for best-corrected visual acuity (BCVA) loss due to ME-RVO, followed-up for up to 24 months by their ophthalmologists.

- **Data sources**: Data collection from patient medical files at:
  - Inclusion: general characteristics, history of ME-RVO, previous treatments, ophthalmological workup
  - 3, 6, 9, 12, 18, 24 months: ophthalmological workup, ME-RVO treatments, follow-up modalities

- **Endpoints**
  - **Primary endpoint**: BCVA evolution from baseline to Month 6
  - **Secondary endpoints**: BCVA evolution, central subfield thickness, and description of ME-RVO treatments modalities, ophthalmological workup and adverse events during the follow-up

- **This presentation details final results of BRVO and CRVO cohorts at 24 month of follow-up.

- **Patients with RBZ were included in BRVO cohort as in randomized controlled trial (RCT).**