Background: The French Health Technology Assessment agency requested information on the ranibizumab (RBZ) usage and impact in real-world setting.

Objectives: To assess the effectiveness and patterns of use of RBZ intravitreal injections (IVI) for patients with visual impairment due to macular edema secondary to branch (B) or central (C) retinal vein occlusion (ME-RVO) for up to 24-month follow-up.

Methods: This is a real-world, post-authorization, observational cohort study in adult patients with RBZ intravitreal injections initiation for best-corrected visual acuity (BCVA) loss due to ME-RVO, followed-up for up to 24 months by their ophthalmologist.

Results: Between December 2013 and April 2015, for B/C cohorts, 223 / 196 patients were enrolled, and 207 / 180 (92.8% of included patients) patients with at least one previous systemic treatment initiated RBZ and 3.6 (±1.2) for studied eye in CRVO Cohort.

Ranibizumab (Lucentis®) is an anti-VEGF administered by intravitreal injections (IVI). Ranibizumab had an extent of market authorization for the treatment of visual impairment due to ME secondary to RVO in France in January 2012. At that time, the French Health Technology Assessment agency requested a complementary data on the impact of ranibizumab on the change in visual activity.

The BOREAL ME-BRVO (BRVO) and ME-CRVO (CRVO) cohorts answer to this request.

The study was performed at the request of the HAS, the French Health Technology Assessment agency and funded by Novartis.

Objectives

Main objective: To assess the change in visual activity at Month 6.

Secondary objectives: during the follow-up,

- To assess the change in visual activity,
- To assess the change in central subfield thickness,
- To describe patterns of ranibizumab use.

Methods

- Design: This is a 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 ophthalmologist.
- Data sources: data collection from patient medical files at inclusion (general characteristics, history of ME-RVO, previous treatments, ophthalmological workup) and at 3, 6, 9, 12, 18 and 24 months (ophthalmological workup, ME-RVO treatments and follow-up modalities).
- Endpoints: Primary endpoint: BVCA evolution from baseline to Month 6 (320 patients expected for each pathology, in order to have a precision of a 2 letters), Secondary endpoint: central subfield thickness evolution, description of ME-RVO treatments modalities, and ophthalmological workup during the follow-up.

This presentation describes results of BRVO cohort and CRVO cohort with 6 months of follow-up. Patients with OVRH were included in BRVO cohort.

Overall improvement in BVCA was observed over time with high variability in patients (Figure 2).

In BRVO cohort, the mean BCVA change from baseline was:

- +14.7 (±14.0) letters (95% CI [12.4; 17.1]) at 3-month follow-up (±0.5),
- +13.9 (±16.4) letters (95% CI [11.5; 16.3]) at 6-month follow-up (±4.5).

In CRVO cohort, the mean BCVA change from baseline was:

- +16.0 (±21.4) letters (95% CI [12.1; 19.8]) at 3-month follow-up (±0.5),
- +9.5 (±20.3) letters (95% CI [5.5; 3.5]) at 6-month follow-up (±1.5).

At 6-month follow-up, 43.5% of BRVO Cohort patients and 30.6% of CRVO Cohort patients had BVCA above 70 letters (Figure 3).

Central subfield thickness evolution

During the first 3 months of follow-up, nearly 80% of patients (BRVO: 80.7%, CRVO: 76.1%) received the initial three recommended ranibizumab injections (induction IVI). At the end of 6-month follow-up, the mean number of IVI was 3.8 (±4.2) in BRVO Cohort and 3.6 (±1.2) for studied eye in CRVO.

More than half of patients (BRVO: 59.4%, CRVO: 56.1%) had at least one interruption of ranibizumab IVI:

- For pathology improvement (BRVO: 52.7%, CRVO: 38.3%),
- For lack of efficiency (BRVO: 7.2%, CRVO: 16.5%).