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Real Life Use of Intravitreal Aflibercept In FraNce: oBservatiOnal study in Wet AMD: the RAINBOW study

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BACKGROUND

- Obtaining real-life evidence is important in order to determine how outcomes achieved with strict protocols in randomized studies of anti-vascular endothelial growth factor (VEGF) translate into routine practices.

METHODS

Design and Objectives

- RAINBOW is an ongoing study to collect efficacy and safety data from patients with wet age-related macular degeneration (AMD) who are being treated with intravitreal aflibercept injections (IAI) in real-life clinical practices in France (**Figure 1**).
- The study includes 600 patients who received their first IAI between January 2014 and March 2015, and patients will be followed over 4 years. We report 12-month interim results.

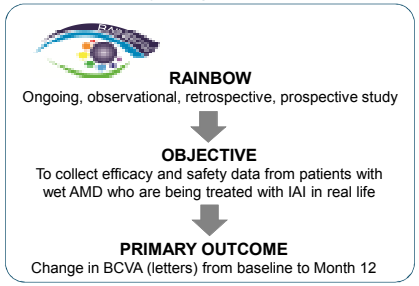
Participants

- Patients with wet AMD who are naïve to any anti-VEGF agent or macular laser.

Outcomes

- The primary outcome is the change in best-corrected visual acuity (BCVA) (ETDRS letters) from baseline to Month 12.
- Other outcomes include patients who gained ≥15 or lost >15 letters, change in central retinal thickness (CRT), and adverse events (AEs).

FIGURE 1: Study design.



RESULTS

Participants

- A preliminary analysis was performed using data from 122 patients who completed 12 months of follow-up and received at least 1 injection.
- Baseline characteristics for these patients are summarized in **Table 1**.
- Mean and median delay between the diagnosis of wet AMD and first IAI was 18 and 3 days, respectively.
- Mean number of IAI over 12 months was 6.1.
- 91.0% of patients received the first 3 IAI within the first 120 days (loading phase).

TABLE 1: Baseline Characteristics

Variable	Patients (n=122)
Age, years	79.1 (7.7)
Female, n (%)	77 (63.1)
Duration of wet AMD, months	0.6 (3.0)
BCVA, ETDRS letters	57.9 (16.8)
CRT, µm [n=111]	394.0 (119.4)
Subretinal fluid, n (%) [n=119]	97 (82.2)
Intraretinal fluid, n (%) [n=119]	71 (60.2)
CNV subtype on FA, n (%) [n=96]	
Predominantly classic	23 (24.0)
Occult	23 (24.0)
Retinal choroidal anastomosis	19 (19.8)
Minimally classic	9 (9.4)
RPE detachment	9 (9.4)
PCV	4 (4.2)
Other	9 (9.4)
IOP, mm Hg [n=51]	15.6 (3.0)

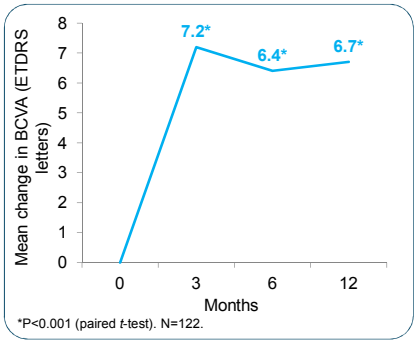
Mean (SD) unless stated.

CNV, choroidal neovascularization; FA, fluorescein angiography; IOP, intraocular pressure; PCV, polypoidal choroidal vasculopathy; RPE, retinal pigment epithelium.

IAI Effective in Real Life

- Mean improvement in BCVA at Month 12 was 6.7 letters in all patients, and 7.2 letters in patients who received a loading phase (**Figure 2**).
- 23.8% of all patients gained ≥15 letters and 1.6% of all patients lost >15 letters at Month 12 (**Figure 3**).
- Mean reduction in CRT at Month 12 was –121.5 µm in all patients (**Figure 4**).

FIGURE 2: Change in BCVA (letters) in all patients treated with IAI.



*P<0.001 (paired *t*-test). N=122.

FIGURE 3: Gain or loss of letters in all patients treated with IAI.

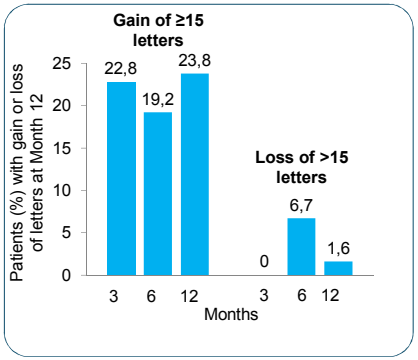
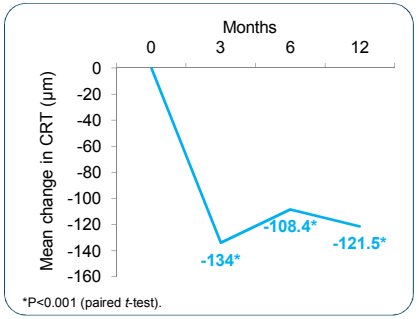


FIGURE 4: Change in CRT (µm) in all patients treated with IAI.



*P<0.001 (paired *t*-test).

Proven Safety Profile with IAI in Real Life

- The safety profile of IAI is shown in **Table 2**.
- Two patients experienced treatment-related treatment-emergent adverse events (TEAEs) (pain and transient ischemia), but they did not discontinue treatment.
- The most common serious TEAEs were hospitalization due to pneumonia/cancer (n=3), and hospitalization due to disorientation (n=2), (none were treatment-related).

TABLE 2: Safety Profile of IAI

AE, n (%)	Patients (n=122)
Any AE	29 (23.8)
TEAE	17 (13.9)
TEAE (treatment-related)	2 (1.6)
Pain	1 (0.8)
Transient ischemic attack	1 (0.8)
Discontinuations due to TEAE	4 (3.3)
Discontinuations due to TEAE (treatment-related)	0
Serious TEAE	11 (9.0)
Hospitalization due to pneumonia/cancer	3 (2.5)
Hospitalization due to disorientation	2 (1.6)
Sudden death (not treatment-related)	1 (0.8)

CONCLUSIONS

- RAINBOW showed that sustained visual and anatomical improvements at 12 months were evident in previously naïve wet AMD patients treated with IAI in routine practice.
- AEs were consistent with the known safety profile of IAI.
- RAINBOW illustrates the benefits associated with a mean number of 6.1 IAI in the first year.
- These findings support the outcomes from the VIEW[1] clinical studies.
- RAINBOW also highlights that the situation may have improved in real life (earlier observational studies with other anti-VEGF agents reported low resource use and poor outcomes[2]).
- Ophthalmologists should be confident prescribing IAI bi-monthly (after a loading phase) based on these outcomes.

PLEASE LEAVE COMMENTS HERE.

References

1. Heier JS *et al. Ophthalmology.* 2012;119:2537–2548.
2. Holz FG *et al. Br J Ophthalmol.* 2015;99:220–226.

Disclosures

H O-M: Allergan, Bayer, Novartis
CF: Alcon, Novartis, Bayer
FC: Bayer: Novartis, Allergan, Roche
TT: Bayer, Bausch&Lombs
B B-J: No Commercial Relationship
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MW: Alcon, Bayer, Allergan, Novartis, Thea, Alimera
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