TREAT-AND-EXTEND VERSUS PRO-RE-NATA REGIMENS OF RANIBIZUMAB 0.5MG IN VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR EDEMA: 2-YEAR EFFICACY AND SAFETY RESULTS OF RETAIN STUDY

J. Figueira
Department of Ophthalmology, Centro Hospitalar e Universitário de Coimbra, Portugal
Department of Ophthalmology, Association for Innovation and Biomedical Research on Light and Image, Portugal

Purpose: To explore the non-inferiority/superiority of a ranibizumab treat-and-extend (T&E) regimen, with/without laser, versus a pro-re-nata (PRN) regimen in patients with visual impairment due to diabetic macular edema (DME).

Methods: A phase IIIb, single-masked, multicenter study with patients randomized 1:1:1 to T&E-ranibizumab+laser (G1; n=121), T&E-ranibizumab (G2; n=128), or PRN-ranibizumab (G3; n=123). In all groups, patients received monthly ranibizumab 0.5 mg until visual acuity stability (G1 received laser on Day1 and according to ETDRS guidelines thereafter). Key objectives: non-inferiority (4-letter margin)/superiority testing of G1 and G2 versus G3 based on mean average change in best-corrected visual acuity (BCVA) from baseline to Month(M)1 through M12 (primary endpoint), mean BCVA change from baseline-M24; treatment exposure and safety profile over 2-years.

Results: At baseline patients had mild/moderate vision loss (mean BCVA: 63.4 letters). Both G1 and G2 were non-inferior to G3 based on mean average BCVA change from baseline to M1 through M12 (+5.9 and +6.1 versus +6.2 letters; both P<0.0001; primary endpoint met; superiority not shown). Mean BCVA change from baseline at year 2 was similar across groups (+8.3/+6.5/+8.1 letters). Median injection number administered over 2-years was 12 in both G1 and G2, and 10 in G3. The T&E regimen led to a 40% reduction in patient treatment visits; around 70% of patients had a monitoring interval of ≥2M. No new safety findings observed over 2 years.

Conclusions: Ranibizumab T&E regimens were non-inferior to PRN in DME patients with mild/moderate vision loss, and have the potential to reduce patient visits based on individual responses.