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TREATMENT-NAÏVE DIABETIC MACULAR EDEMA: PRELIMINARY RESULTS FROM THE CLINICAL STUDY “FOVEA”.

Oral

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Purpose:

To assess retinal changes in treatment-naïve diabetic macular edema (DME) under Aflibercept therapy for 12 months follow-up.

Methods:

Sixty-six eyes with treatment-naïve DME were included in the FOVEA study and evaluated using both traditional multimodal retinal imaging and optical coherence tomography angiography (OCTA). Best corrected visual acuity (BCVA) was also measured, at baseline and last follow-up. Specifically, the presence of intra- and sub-retinal fluid, and central macular thickness (CMT) were assessed on spectral domain optical coherence tomography (SD-OCT), whereas diabetic retinopathy (DR) features, including microaneurysms, intraretinal microvascular abnormalities and retinal neovascular lesions, were investigated by fluorescein angiography.

Fractal analysis of OCTA slabs of both superficial and deep capillary plexus was carried-out to estimate vascular perfusion density (VPD) and lacunarity (LAC).

Results:

At the last follow-up, BCVA significantly improved in all patients (from 64.77 ± 12.73 to 73.01 ± 10.72 ETDRS letters; $p=0.004$). There was also a substantial anatomic improvement in terms of intra- and sub-retinal fluid, CMT and DR features, on traditional multimodal imaging. However, no statistically significant differences were found in terms of quantitative OCTA parameters, such as VPD and LAC, between baseline and last follow-up examinations.

Conclusions:

Aflibercept is an effective first-line treatment for DME, allowing for significant anatomical improvements and visual gain, after 12 months of follow-up.