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SPECTRAL-DOMAIN OCT PREDICTORS OF VISUAL OUTCOMES AFTER RANIBIZUMAB TREATMENT FOR MACULAR EDEMA RESULTING FROM RETINAL VEIN OCCLUSION

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ABSTRACT

The authors are commenting on the study entitled "Spectral-domain OCT predictors of visual outcomes after ranibizumab treatment for macular edema resulting from retinal vein occlusion" published by Yiu et al. in Ophthalmology Retina 2020;4(1):67-76. Published online August 28, 2019.The conclusion of this study was that none of the imaging biomarkers showed an independent association with visual outcomes after 7 monthly ranibizumab injections in both central and branch retinal vein occlusions. However, the validation, extrapolation, and generalizability of the authors' finding can be made only by statistical analyses including all the missing baseline potential predictive factors mentioned by us in addition to the baseline characteristics already evaluated in this study, serving to identify all the key metrics (including the SD-OCT putative biomarkers) of visual outcomes after ranibizumab treatment for macular edema resulting from retinal vein occlusions.

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INTRODUCTION

We read with interest the study by Yiu *et al*. (2019) which assessed the spectral-domain optical coherence tomography (SD-OCT) predictors associated with baseline best-corrected visual acuity (BCVA) and changes in BCVA after 7 monthly ranibizumab (Lucentis; Genentech, Inc., South San Francisco, CA) injections in 202 participants with retinal vein occlusion (RVO) – emergent macular edema. The authors concluded that the only factors independently associated with BCVA gain after 7 monthly ranibizumab treatments were younger age and worse presenting BCVA whereas only older age and better baseline BCVA limited improvements. We would like to address several challenges that have arisen from the study by (Yiu *et al.,* 2020) which can be specifically summarized below.

First, there was a selection bias attributable to inclusion in the study and pooled analysis of patients with 2 forms of RVOs (ischemic and nonischemic occlusions) having totally different pathogeneses, clinical features and evolutions, prognoses, and management (Călugăru *et al*., 2018). Although the presence of a relative afferent pupillary defect was an exclusion criteria, the ischemia was still present among the RVO patients included. Actually, the authors of this study themselves explained the fact that SD-OCT features were associated more strongly with vision in branch retinal vein occlusion (BRVO) than central retinal vein occlusion (CRVO) by the greater likelihood of ischemia and poorer vision in eyes with CRVO. Of note, the fluorescein angiography images in this study were not of sufficient quality to conclude the exact area of ischemia in at least one third of them. Likewise, 2 completely different etiological subgroups of patients with definitely different prognoses were lumped together, namely, patients older than 50 years who usually have common systemic vascular conditions such as hypertension and diabetes, and patients less than 50 years, in whom other mechanisms, such as the hyperviscosity syndrome or inflammatory condition should be specifically considered. Taken together, these findings may have confounded the results.

Second, the following relevant data, which should have been included in the statistical analyses, were missing from the study: the forms of RVO included (ischemic/nonischemic occlusions); the stratification of the patient age (≤ 50 years/> 50 years); the stratification of the mean duration of the symptoms after RVO onset (< 1 month/1-3 months/4-12

months); the SD-OCT patterns of the 3 vitreoretinal interface abnormalities (full-thickness macular hole/lamellar macular hole/combined vitreomacular traction and epiretinal membrane); the stratification of the disorganization of retinal inner layers (DRIL) severity e.g., the mild DRIL (the boundary between the ganglion cell complex and inner nuclear layer [INL] cannot be distinguished separately and is irregular), the severe DRIL (both the boundaries between the ganglion cell complex and INL and between the INL and outer plexiform layer cannot be delineated and are irregular), and the severe DRIL with damaged ellipsoid zone; the changes of the retinal pigment epithelial band-Bruch's membrane complex and grading of the retinal pigment epithelium (RPE) changes (pigment migration within the neurosensory retina, RPE porosity, microrips or blowouts in the RPE, focal RPE atrophy, RPE thickening); the proportions of the patients with ocular hypertension, cardiovascular and cerebrovascular diseases, obesity, hyperviscosity syndromes, and inflammatory conditions; the stratification of the BCVA letter score improvements according to the RVO type (BRVO/CRVO) and the treatment regimen administered (monthly/pro re nata); and the prevalence of the subretinal hyperreflective material and its composition (blood/ fibrin/ fluid/ scar/ choroidal neovascularization) (Călugăru *et al*. 2017).

Third, we published in 2015 a prospective clinical study on the 3-year results of bevacizumab (Avastin; Genentech, Inc.,) treatment in patients with acute (≤ 1 month after the occlusion was diagnosed) central/hemicentral RVOs) (Călugăru *et al.* 2015). Of these patients, 50% had ischemic forms. The results of this study showed, for the first time, evidence suggesting that early treatment applied immediately after the clinical onset of venous occlusion provided significant and sustained improvements in BCVA and central subfoveal thickness with inactive disease (dry retina and stable visual acuity for at least 6 months after the last injections) in most phakic patients, making this treatment option a rational and viable therapeutic strategy.

Altogether, the authors of this study found that at baseline, although external limiting membrane disruption was significantly independently associated with worse baseline BCVA in eyes with BRVO, none of the imaging biomarkers were associated independently with presenting BCVA in eyes with CRVO. Likewise, none of the imaging biomarkers showed an independent association with visual outcomes after 7 monthly ranibizumab injections in both CRVO and BRVO patients. However, the validation, extrapolation, and generalizability of the authors' conclusions can be made only by statistical analyses including all the missing baseline potential predictive factors referred to above by us in addition to the baseline characteristics already evaluated in this study, serving to identify all the key metrics (including the SD-OCT putative biomarkers) of visual outcomes after ranibizumab treatment for macular edema resulting from RVOs.

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