Sensitivity of the Functional Reading Independence Index to Change in Size of Geographic Atrophy

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INTRODUCTION

- The advanced stage of age-related macular degeneration (AMD) is defined by the Age- Related Eye Disease Study (AREDS) as geographic atrophy (GA), an irreversible and blinding condition characterized by atrophy in the central retina that causes severe vision loss, including choroidal neovascularization (2001) and geogaphic atrophy (GA) of the macula (2005). GA is estimated to affect more than 5 million people worldwide, which can impact a patient’s central visual function for reading, driving, or recognizing faces. (1)

- The Mahalo study was a Phase 2 clinical trial evaluating temilastipant, a microtubule target for myeloid progenitor expansion as an immunomodulatory treatment in patients with GA and vision or extraretinal progression of the disease.

- Patients with GA are randomized to receive either monthly or every other month for 18 months (Figure 1).

METHODS

- Post hoc analyses were conducted with data from the randomized, Phase 2 Mahalo study. The FRI Index, a 7-item patient-reported measure of independence in performing daily activities that require reading (Figure 2), was administered in Mahalo at baseline and every 6 months.

- The FRI Index yields continuous mean scores (range 1 to 4), and the mean changes in FRI Index were calculated from baseline in Month 18 in the following groups:

- Lower growth GA lesions: Change in lesion area ≤0.04 mm2/year

- Higher growth GA lesions: Change in lesion area ≥0.04 mm2/year

RESULTS

- Figure 3 displays the FRI Levels of patients at baseline and 18 months for a 7 tasks.

- At 18 months, the mean change in FRI Index score (SD) from baseline for patients with lower growth GA lesion size change (≤0.04 mm2/year) was 0.4 (0.32) (P = 0.12) (Figure 4).

- Finding might be consistent with expectations based on changes in GA lesion size.

- For patients with more growth, 36% declined in FRI Levels, 7% (0.10) (P = 0.7) for patients with lower growth (≤0.04 mm2/year) (Figure 4).

- Improvement was observed in FRI Levels of patients with more growth (n = 56), declined in FRI Levels (n = 56), and patients with lower growth (n = 17). At Month 18, 11% (P = 0.04) (56) (22)

- Patients with higher growth GA lesions had 0.2 greater mean in lower GA growth rate (≤0.04 mm2/year) at Month 18 compared with those with lower growth GA lesions.

LIMITATION

- Finding from this study may be limited by the small sample sizes, particularly for the group of patients with lower growth GA lesion.

CONCLUSIONS

- These results provide evidence that patient-reported functional reading independence as measured by the FRI Index is linked to GA lesion growth, an objective clinical anatomical measure of disease progression.

- Data from Mahalo suggest that a change in mean FRI Index score of 0.2 or higher, compared with baseline, is associated with more severe visual acuity (BCVA). BCVA is a well-accepted outcome in ophthalmic trials but may not fully capture the impact of GA lesion growth on daily daily activities that are critical to quality of life.

- The Functional Reading Independence (FRI) Index can measure the effect of visual function on daily life, and therefore, may be a valuable endpoint for trials evaluating the benefits of GA treatments on patients’ quality of life.

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REFERENCES


DISCLOSURES

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