Improving the Power of Glaucoma Neuroprotection Trials Using Existing Visual Field Data

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PURPOSE: Selecting reliable visual field (VF) test takers could improve the power of randomized clinical trials in glaucoma. We test this hypothesis via simulations using a large real world data set.

DESIGN: Methodology analysis: assessment of how improving reliability affects sample size estimates.

METHODS: A variability index (VI) estimating intertest variability was calculated for each subject using the residuals of the regression of the mean deviation over time for the first 6 tests in a series of at least 10 examinations for 2,804 patients. Using data from the rest of the series, we simulate VFs at regular intervals for 2 years. To simulate the neuroprotective effect (NE) , we reduced the observed progression rate by 20%, 30%, or 50%. The main outcome measure was the sample size to detect a significant difference (P RESULTS: In the first experiment, we simulated a trial including one eye per subject, either selecting randomly from the database or prioritizing patients with low VI. We could not reach 80% power for the low NE with the available patients, but the sample size was reduced by 38% and 49% for the 30% and 50% NE, respectively. In the second experiment, we simulated 2 eyes per subject, one of which was the control eye. The sample size (smaller overall) was reduced by 26% and 38% for the 30% and 50% NE by prioritizing patients with low VI.

CONCLUSIONS: Selecting patients with low intertest variability can significantly improve the power and reduce the sample size needed in a trial.

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