Author(s)
Principal: Ananth Viswanathan
Presenting: David Garway-Heath, M.D.
Contributing: Ananth Viswanathan, M.D.
Stefano Gandolfi, M.D.
David Garway-Heath, M.D.
Roger Hitchings, M.D.

- - -

Abstract Information

Abstract Title:
The suitability of rate-based methods of visual field progression analysis for outcome measurement in randomized controlled trials

Purpose:
To examine the performance of different types of regression analysis in the setting of an interventional trial

Design:
Prospective, investigator- masked, randomized controlled clinical trial

Participants:
Clinically “unstable” (on perimetric criteria) glaucoma patients

Main Outcome Measures:
1. Visual field progression on analysis of GHT clusters (Katz 1997)
2. Change in mean slope, PROGRESSOR software (Bhandari 1997)

Methods:
1. 18 months observational phase to ascertain eyes showing progression
2. Randomization to treatment (Group 1 to brimonidine tartrate 0.2% b.i.d. or Group 2 to argon laser trabeculoplasty) stratified by MD and IOP
3. 18 months intervention phase to assess progression using the outcome measures stated

Results:
108 patients (178 eyes) initially screened for progression. 52 eyes (35 pts) satisfied inclusion criteria and were randomized to treatment. Results for the 2 outcome measures were:
1. GHT Clusters: Group 1, 15 of 27 eyes showed no further progression; Group 2, 2 of 23 eyes showed no further progression ($p = 0.0003$)

2. Mean slope: Pre-intervention Group 1, - 1.37 dB / yr; Group 2, - 0.99 dB / yr (p = 0.488). Post-intervention Group 1, 0.85 dB / yr; Group 2, - 0.77 dB / yr (p = 0.0009)

Conclusion:
Methods of longitudinal visual field analysis based on the rate of sensitivity change over time are potentially suitable for use as outcome measures in randomized clinical trials in glaucoma. Further work is necessary to elucidate which combination of summary, cluster-based or pointwise approach would be most appropriate under different trial conditions.