

# Visual outcomes of age-related macular degeneration patients undergoing intravitreal ranibizumab monotherapy in an urban population: letter to the editor

Michael W Stewart

Department of Ophthalmology, Mayo Clinic Florida, Jacksonville, FL, USA

## Dear editor

In their recently published manuscript entitled “Visual outcomes of age-related macular degeneration patients undergoing intravitreal ranibizumab monotherapy in an urban population” Basheer et al<sup>1</sup> reported on the prospectively acquired results of 123 eyes (106 patients) treated for 2 years with ranibizumab as needed. Visual acuity (VA) outcomes from this series were summarized by the following statement: “Although our results, and those from other clinical settings, do not quite match the degree of vision preservation and gain as the large clinical trials, they are not dramatically dissimilar”.<sup>1</sup> Unfortunately, the authors provide no statistical analysis to support this statement.

The important visual outcomes – loss of <15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters and gain of ≥15 ETDRS letters – at both 1 and 2 years were summarized by the authors in their Table 2. To directly compare the VA changes from CATT,<sup>2</sup> MARINA,<sup>3</sup> and ANCHOR<sup>4</sup> with the present study, I have recreated the table (Table 1) and added the probability results ( $\chi^2$  test of each trial versus the present study).

Contrary to the concluding statement by the authors, significant differences exist between the present study and the pivotal trials. Maintenance of VA (loss of <15 letters)

**Table 1** The major visual acuity outcomes of the Basheer et al<sup>1</sup> study compared with those from three pivotal ranibizumab trials

Visual outcomes	Present study	CATT trial <sup>2</sup>	ANCHOR trial <sup>4</sup>	MARINA trial <sup>3</sup>
12 months				
Maintained vision: loss of <15 ETDRS letters (% of eyes)	91.8	96.0 (P=0.03)	96.4 (P=0.03)	94.6 (P=0.24)
Improved vision: gain of ≥15 ETDRS letters (% of eyes)	20.3	25.0 (P=0.25)	40.3 (P=0.00004)	33.8 (P=0.003)
24 months				
Maintained vision: loss of <15 ETDRS letters (% of eyes)	88.6	93.0 (P=0.08)	89.9 (P=0.64)	90.0 (P=0.65)
Improved vision: gain of ≥15 ETDRS letters (% of eyes)	19.7	33.0 (P=0.002)	41.0 (P=0.00001)	35.0 (P=0.0007)

**Abbreviation:** ETDRS, Early Treatment Diabetic Retinopathy Study.

Correspondence: Michael W Stewart  
4500 San Pablo Rd, Department of  
Ophthalmology, Mayo Clinic Florida,  
Jacksonville, FL 32224, USA  
Tel +904 953 2232  
Fax +904 953 7040  
Email [stewart.michael@mayo.edu](mailto:stewart.michael@mayo.edu)

was significantly better in CATT<sup>2</sup> and ANCHOR<sup>4</sup> trials at 12 months, but the results tended to equilibrate among all the studies by 24 months. Patients were significantly more likely to improve by at least 15 letters at both 1 and 2 years in all the three pivotal trials (except for CATT<sup>2</sup> at 12 months).

The pro re nata regimen described by the authors effectively maintains VA for over 2 years, but compared to monthly therapy it reduces the patient's likelihood of achieving a meaningful (15 letters) improvement in VA. These findings resemble CATT<sup>2</sup> and IVAN<sup>5</sup> where discontinuous therapy produced significantly inferior VA gains at 2 years compared to continuous therapy. Physicians should carefully weigh these important VA differences against the needs of the patient when deciding between continuous and discontinuous therapy for neovascular age-related macular degeneration.

## Disclosure

Michael W Stewart has received institutional research support from Allergan and Regeneron; is a consultant for Boehringer-Ingelheim; and is on the advisory board for Allergan and Regeneron.

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## Author's reply

Khadijah Basheer

Ophthalmology Department, Central Middlesex Hospital,  
London, UK

Correspondence: Khadijah Basheer  
Central Middlesex Hospital, Ophthalmology Department,  
Acton Lane, London NW10 7NS, UK  
Tel +44 77 9503 0069  
Email khadijahbasheer@nhs.net

## Dear editor

We would like to thank you for your interest in our paper and we recognize that we did not undertake any statistical analysis of our results. Our population demographic differed significantly to the populations selected for the pivotal studies, and in addition, we were not analyzing a study population. Instead, we analyzed our true clinic population facing the issues of inner city life, and this is why we compared our result percentages rather than conducting a statistical analysis.

We were unsure of the rationale behind your  $\chi^2$  analysis, as from our understanding a  $\chi^2$  test uses categorical data

such as absolute numbers, rather than continuous data such as percentages. Furthermore, a number of your results gave a *P*-value that was greater than 0.05 rendering them insignificant.

Finally, we would like to clarify that our conclusion states that our results simply “follow the same trends as the pivotal trials”, particularly the CATT trial which conducted discontinuous ranibizumab therapy, as you also have mentioned in your response. However, we also stated that we recognize “our results do not match the degree of vision preservation and gain as the large clinical trials”. The possible reasons for these differences and limitations to our study were discussed. Through your analysis, you confirm that our results are similar to the trials at 2 years and resemble the results of the CATT and IVAN trials, and hence, we are pleased to show that we can achieve this similarity in a real life population of patients.

## Disclosure

The author reports no conflicts of interest in this correspondence.

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