Impact of Baseline Vision on Visual Outcomes and Vision-Related Function in Eyes With Diabetic Macular Edema: A Post Hoc Analysis of VISTA and VIVID Trials

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BACKGROUND & PURPOSE

- Several clinical trials in diabetic macular edema (DME) have shown that eyes with better baseline vision have smaller visual gains from treatment compared with eyes with worse baseline vision[1-3]
  - In randomized-controlled trials, treatment success is typically evaluated based on improvements in visual acuity, as measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters
- However, other factors are important to patients in the real world, such as their ability to read, drive, and lead an independent life
- This post hoc analysis of VISTA and VIVID examined the relationship between baseline vision and vision-related functions in patients with DME

METHODS

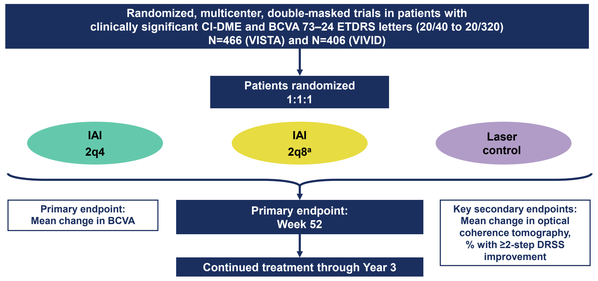
- This was an integrated analysis of the VISTA and VIVID trials in patients who received laser, intravitreal aflibercept injection (IAI) 2 mg every 4 weeks (2q4), or IAI 2 mg every 8 weeks (2q8) (**Figure 1**)
- Eyes were categorized by baseline best-corrected visual acuity (BCVA):

	BCVA		
ETDRS letters	≥25 to ≤54	≥55 to ≤69	≥70 to ≤74
Snellen equivalent	20/320 to <20/80	20/80 to <20/40	20/40 to <20/32

The full analysis set comprised observed cases; for patients who received rescue treatment (laser or 5 initial monthly doses of IAI followed by 2q8 in IAI- or laser-treated patients, respectively), data were censored from the time of rescue

- Change in BCVA, percentage of patients with BCVA ≥70 letters, change in central subfield thickness (CST), and Visual Function Questionnaire (VFQ-25) scores were analyzed by baseline BCVA category in each of the 3 treatment groups
- To compare the difference between groups, the Cochran-Mantel-Haenszel test was used for binary outcomes and analysis of covariance was used for continuous outcomes

Figure 1. VISTA and VIVID study design[4]



[a]After 5 initial monthly doses.
2q4, 2mg every 4 weeks; 2q8, 2 mg every 8 weeks; CI-DME, center-involved diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale.

RESULTS

- At baseline, patients with better vision had lower CST values and higher VFQ-25 composite scores in each treatment group (**Table 1**)

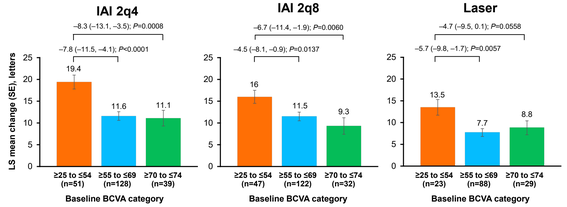
Table 1. Demographics and Baseline Characteristics by Baseline BCVA Category

	IAI 2q4 (n=289[a])			IAI 2q8 (n=283[b])			Laser (n=285[c])		
	≥25 to ≤54 (n=77)	≥55 to ≤69 (n=161)	≥70 to ≤74 (n=51)	≥25 to ≤54 (n=74)	≥55 to ≤69 (n=168)	≥70 to ≤74 (n=41)	≥25 to ≤54 (n=68)	≥55 to ≤69 (n=160)	≥70 to ≤74 (n=57)
Male, n (%)	43 (55.8)	91 (56.5)	35 (68.6)	42 (56.8)	100 (59.5)	22 (53.7)	32 (47.1)	2 (57.5)	39 (68.4)
White, n (%)	61 (79.2)	136 (84.5)	39 (76.5)	62 (83.8)	130 (77.4)	37 (90.2)	54 (79.4)	132 (82.5)	51 (89.5)
Hispanic or Latino, n (%)	9 (11.7)	23 (14.3)	4 (7.8)	5 (6.8)	21 (12.5)	3 (7.3)	4 (5.9)	17 (10.6)	1 (1.8)
BCVA, letters	45.5 (8.8)	62.8 (4.6)	71.3 (1.1)	44.2 (8.2)	62.7 (4.2)	71.5 (1.1)	44.4 (8.2)	62.9 (4.4)	71.4 (1.1)
CST, µm	567.6 (205.0)	480.6 (115.4)	**423.5 (101.0)**	579.9 (165.7)	476.3 (132.2)	**422.5 (97.0)**	599.5 (188.9)	492.4 (131.2)	**446.3 (121.3)**
VFQ-25 composite	60.5 (20.2)	72.2 (18.1)	**77.9 (19.3)**	66.0 (17.3)	70.9 (17.2)	**76.1 (15.3)**	62.2 (18.0)	69.6 (17.9)	**75.0 (16.3)**

[a]One patient in the IAI 2q4 group had baseline BCVA of 75 letters and was excluded from this analysis.
[b]Three patients in the IAI 2q8 group had baseline BCVA of 24, 76, and 80 letters, respectively, and were excluded from this analysis.
[c]One patient in the laser group had baseline BCVA of 76 letters and was excluded from this analysis.
Data are mean (SD) unless specified otherwise.

- At Week 100:
  - Mean BCVA letter gains were higher in the lowest versus higher baseline BCVA categories across treatment groups (**Figure 2**)
  - All differences in letter gains between the lowest and higher baseline BCVA categories were significant within treatment groups except for the difference between lowest and highest baseline BCVA category in the laser group (**Figure 2**)

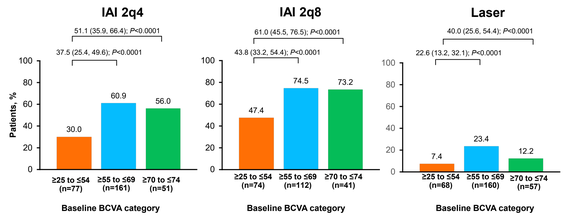
Figure 2. Change in BCVA at Week 100 by Baseline BCVA



Values above the error bars represent the difference between LS mean change (95% CI).
CI, confidence interval; LS, least squares; SE, standard error.

- At Week 100, significantly greater proportions of patients in the higher versus lowest baseline BCVA categories had BCVA ≥70 letters in all treatment groups (**Figure 3**)

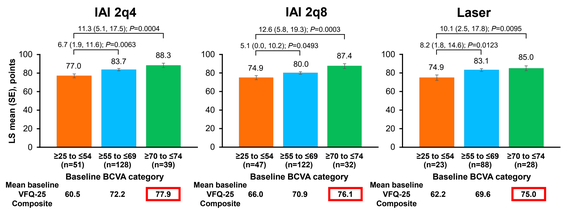
Figure 3. Proportion of Patients With BCVA ≥70 Letters (≥20/40) at Week 100 by Baseline BCVA Category



Values above the error bars represent the difference between LS mean change (95% CI).
Patients with missing values were considered non-responders.
Full analysis set, observed cases.

- At Week 100, patients with higher baseline BCVA had significantly higher VFQ-25 composite scores in all treatment groups (**Figure 4**)

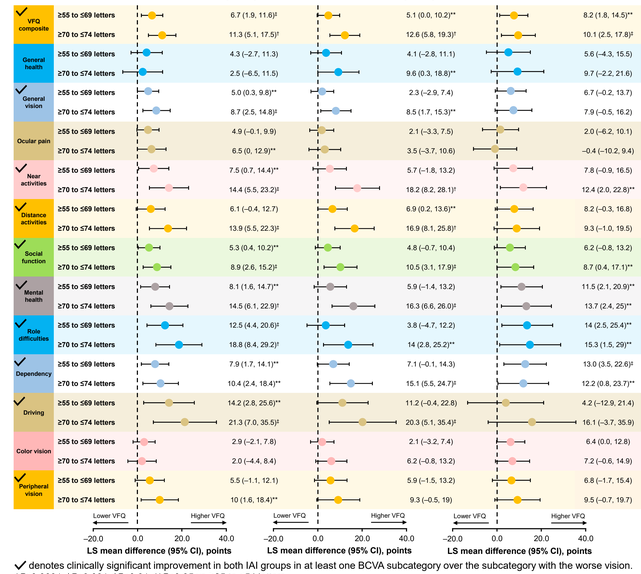
Figure 4. VFQ-25 Composite Score at Week 100 by Baseline BCVA Category



Values above the error bars represent the difference between LS mean value (95% CI).
Full analysis set, observed cases.

- At Week 100, VFQ-25 composite and 9 of 12 subscale scores were higher in patients with baseline BCVA ≥70 to ≤74 letters versus ≥25 to ≤54 letters. Similar trends were observed for those with baseline BCVA ≥55 to ≤69 letters
  - In both IAI groups at Week 100, patients with higher baseline BCVA had higher subscale scores for General Vision, Near Activities, Distance Activities, Social Functioning, Mental Health, Role Difficulties, Dependency, and Driving, with the largest difference observed for the Driving subscale (**Figure 5**)

Figure 5. Difference in VFQ-25 Composite and Subscale Scores at Week 100 from Patients With Worse Baseline Vision



✓ denotes clinically significant improvement in both IAI groups in at least one BCVA subcategory over the subcategory with the worse vision.
*P≤0.0001, †P<0.001, ‡P<0.01, **P<0.05 vs ≥25 to ≤54 letters.

CONCLUSIONS

- Patients with CI-DME and worse baseline BCVA gained more letters at Week 100 than patients with better baseline BCVA; a higher proportion of patients with better baseline BCVA had BCVA ≥70 letters (≥20/40) at Week 100
- Patients with better baseline BCVA had higher VFQ-25 scores at Week 100
- Patients with better baseline BCVA may achieve improved visual outcomes and vision-related function through optimal treatment

REFERENCES

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DISCLOSURES

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