

Impact of Baseline Vision on Visual Outcomes and Vision-Related Quality of Life Functions in Eyes With Diabetic Macular Edema

Dilraj S Grewal MD

*on behalf of the VISTA and VIVID study investigators
Duke University School of Medicine, Durham, North Carolina*

Presented at the Retina Society Annual Meeting, October 11-14, 2023

Disclosures

- Dilraj S Grewal reports being a consultant for EyePoint, Priovant, Iveric Bio, Regeneron Pharmaceuticals, Inc., and Unity
- This analysis was funded by Regeneron Pharmaceuticals, Inc. (Tarrytown, New York). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
- Medical writing support was provided by Linda Brown, BSc (Hons), of Core Medica, London, UK, in accordance with Good Publication Practice guidelines, and funded by Regeneron Pharmaceuticals, Inc.

Background

Several clinical trials in DME showed that eyes with better baseline vision have smaller visual gains from treatment compared with eyes with worse baseline vision¹⁻³

However, other factors are important to patients in the real world



ETDRS CHART



DRIVING



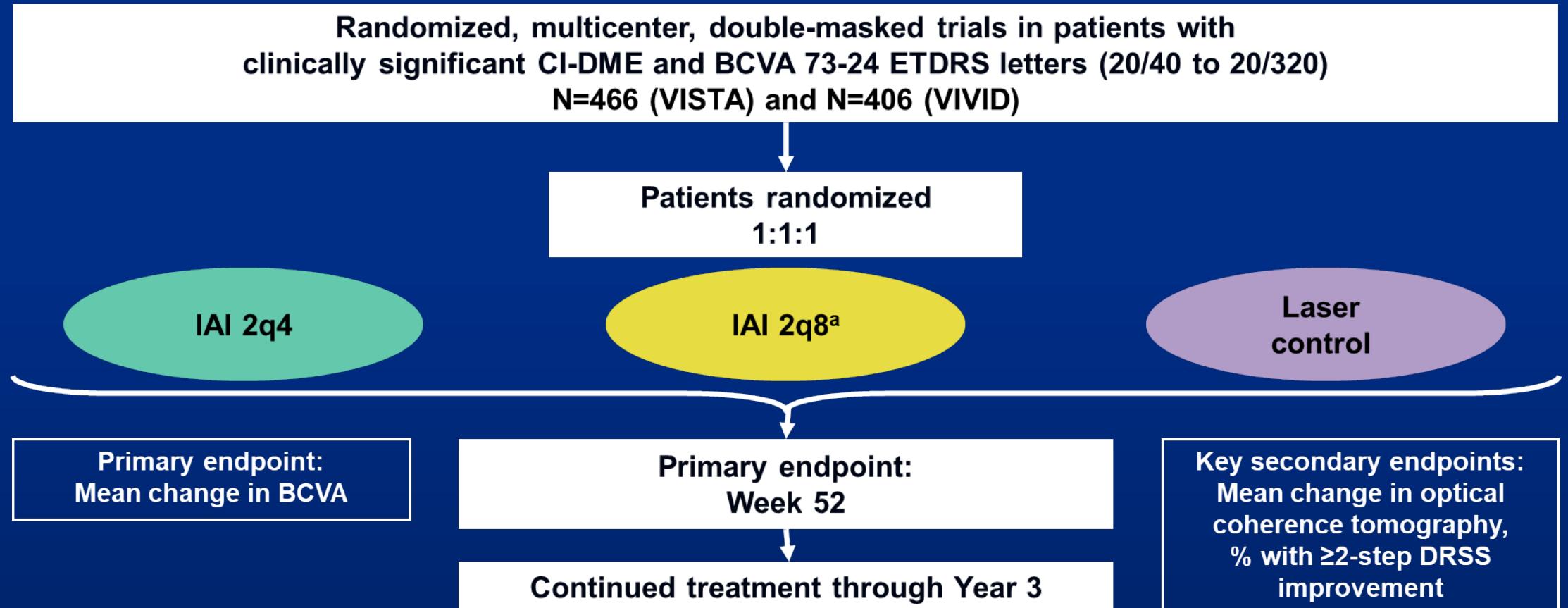
DEPENDENCY



READING

This post hoc analysis of VISTA and VIVID examined the relationship between baseline BCVA and visual outcomes and vision-related functions in patients with DME treated with aflibercept 2 mg

VISTA and VIVID: Study Design



^aAfter 5 initial monthly doses.

Brown DM et al. *Ophthalmology*. 2015;122:2044-2052.

2q4, 2 mg every 4 weeks; 2q8, 2 mg every 8 weeks; CI-DME, center-involved diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale; IAI, intravitreal aflibercept injection.

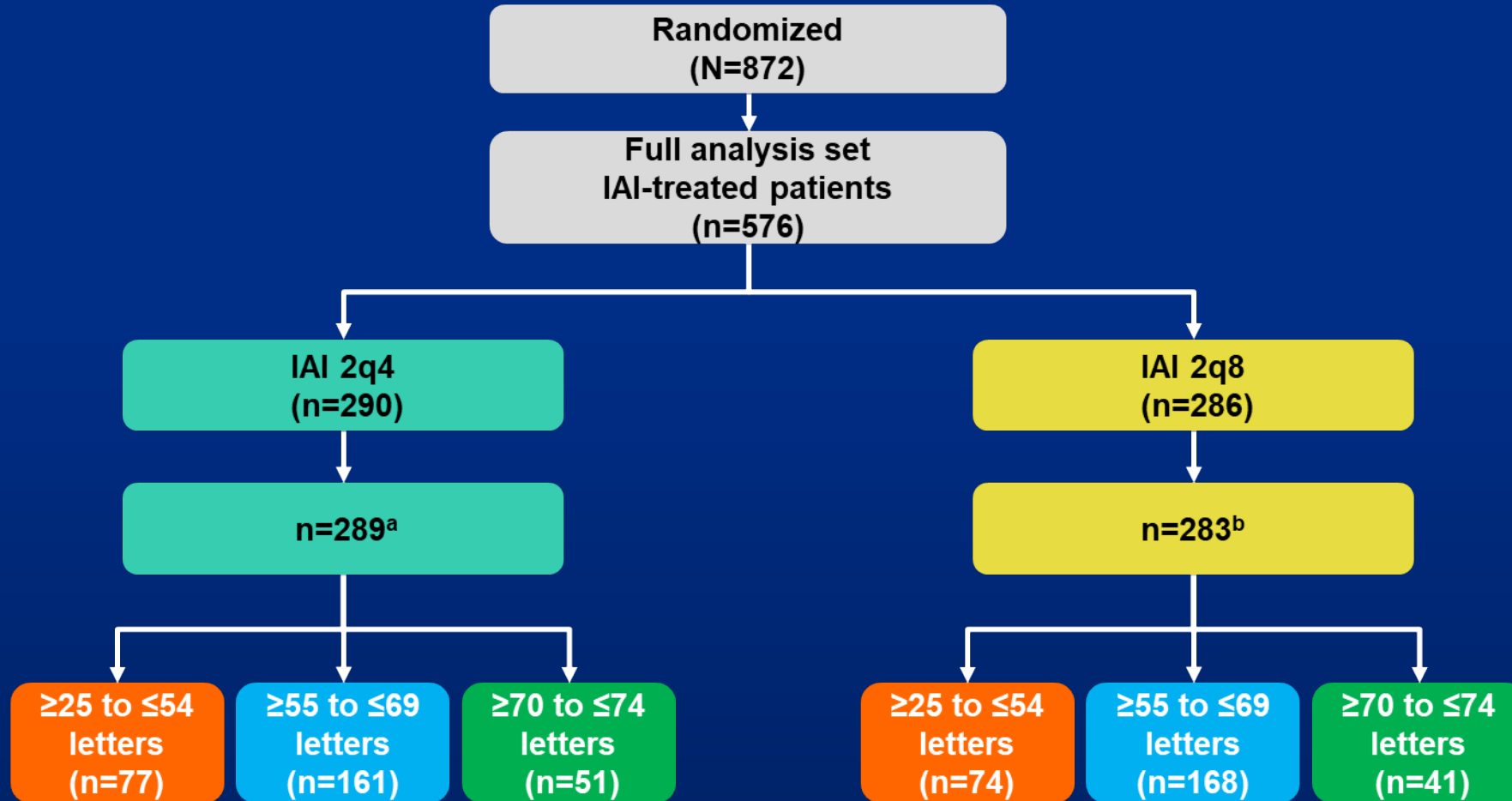
Methods

- This was an integrated analysis of VISTA and VIVID trials in patients who received IAI 2q4 or 2q8
- Eyes were categorized by **baseline BCVA**:

	BCVA		
ETDRS letters	≥25 to ≤54 letters	≥55 to ≤69 letters	≥70 to ≤74 letters
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 for IAI-treated patients), data were censored from the time of rescue
- Change in BCVA, percentage of patients with BCVA ≥70 letters, change in CST, and VFQ-25 scores were analyzed by baseline BCVA category in each IAI treatment group
- 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

Patient Disposition at Baseline



^aOne patient in the IAI 2q4 group had baseline BCVA of 75 letters and was excluded from this analysis.

^bThree patients in the IAI 2q8 group had baseline BCVA of 24, 76, and 80 letters, respectively, and were excluded from this analysis.

Demographics and Baseline Characteristics by Baseline BCVA Category

	IAI 2q4 (n=289 ^a)			IAI 2q8 (n=283 ^b)		
	≥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)
Male, n (%)	43 (55.8)	91 (56.5)	35 (68.6)	42 (56.8)	100 (59.5)	22 (53.7)
White, n (%)	61 (79.2)	136 (84.5)	39 (76.5)	62 (83.8)	130 (77.4)	37 (90.2)
Hispanic or Latino, n (%)	9 (11.7)	23 (14.3)	4 (7.8)	5 (6.8)	21 (12.5)	3 (7.3)
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)
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)
VFQ-25 composite	52.6 (24.7)	65.2 (22.1)	76.0 (20.2)	66.2 (18.3)	70.9 (17.2)	78.8 (13.7)

At baseline, patients with better vision had lower CST values and higher VFQ-25 composite scores

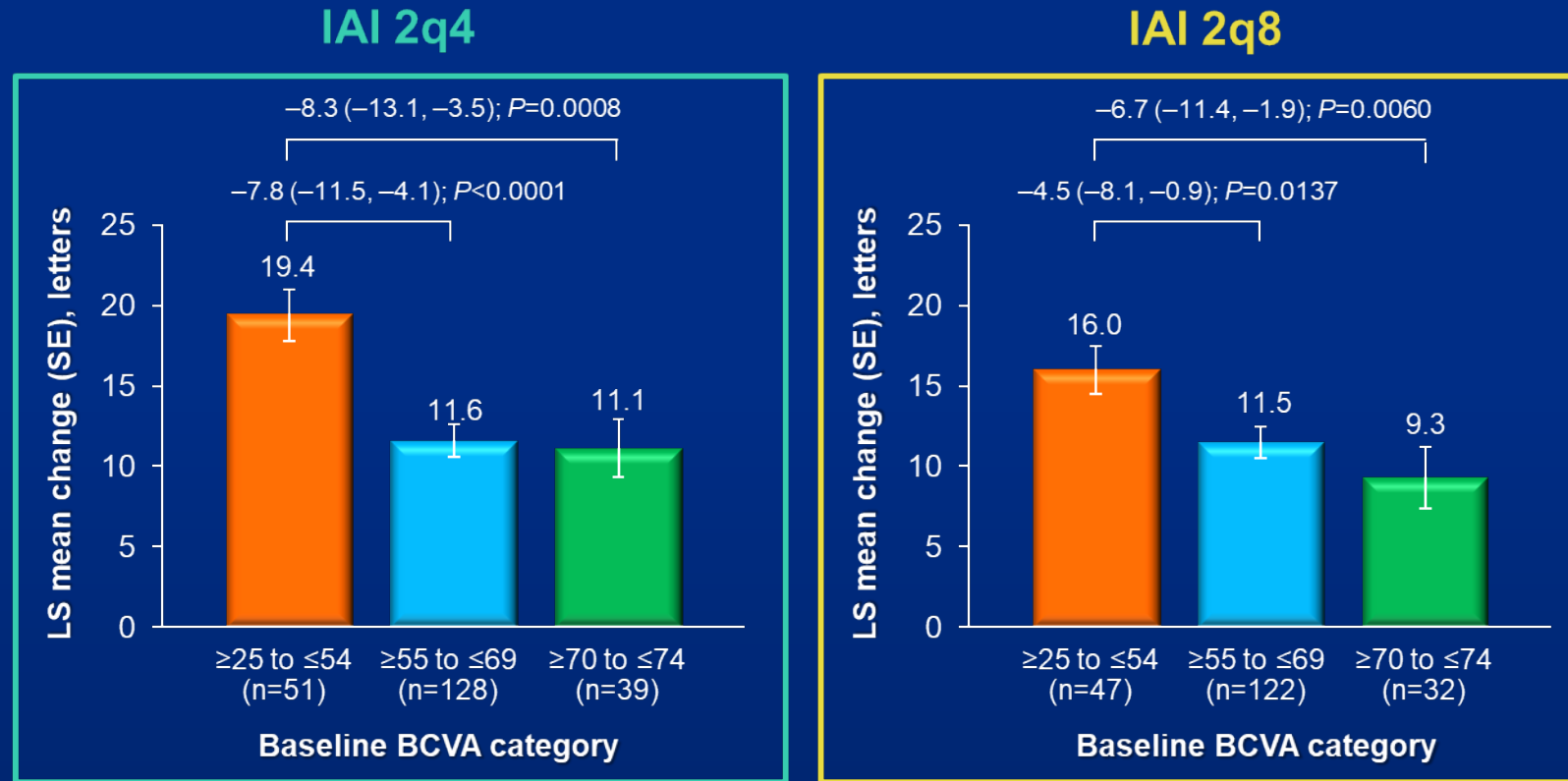
Data are mean (SD) unless specified otherwise.

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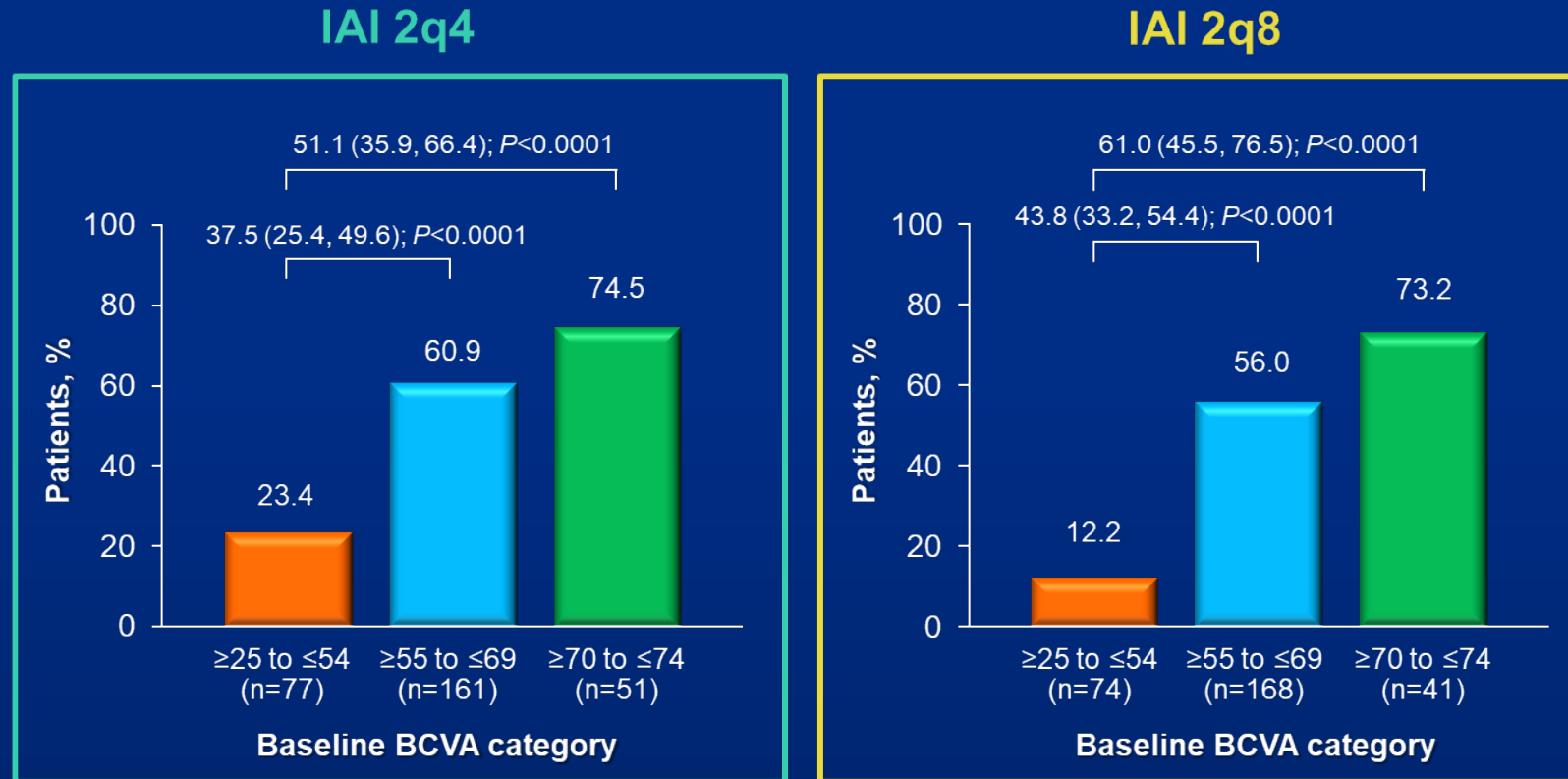
SD, standard deviation.

Change in BCVA at Week 100 by Baseline BCVA



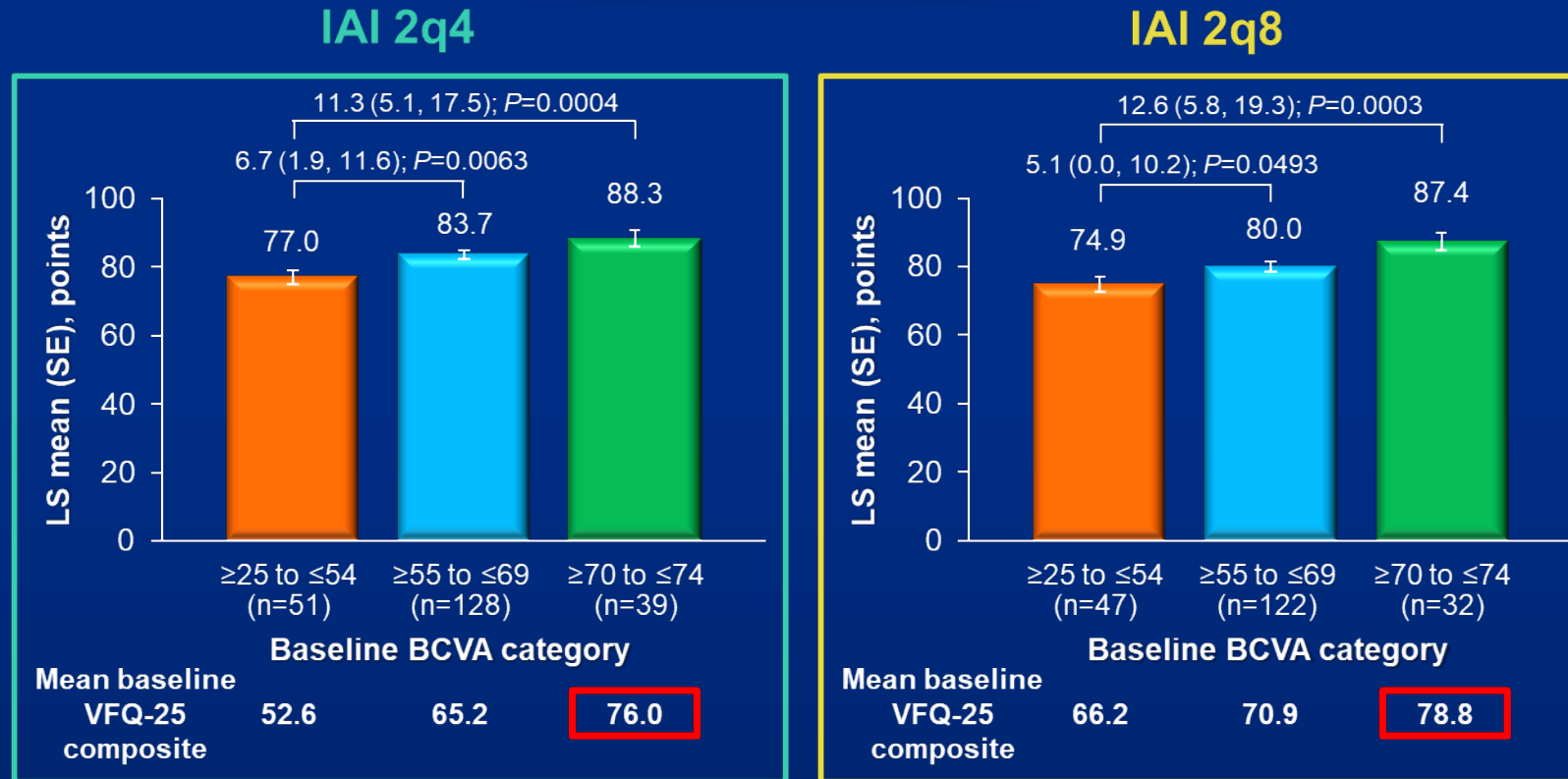
Patients with worse vision at baseline gained more letters at Week 100

Proportion of Patients With BCVA ≥ 70 Letters ($\geq 20/40$) at Week 100 by Baseline BCVA Category



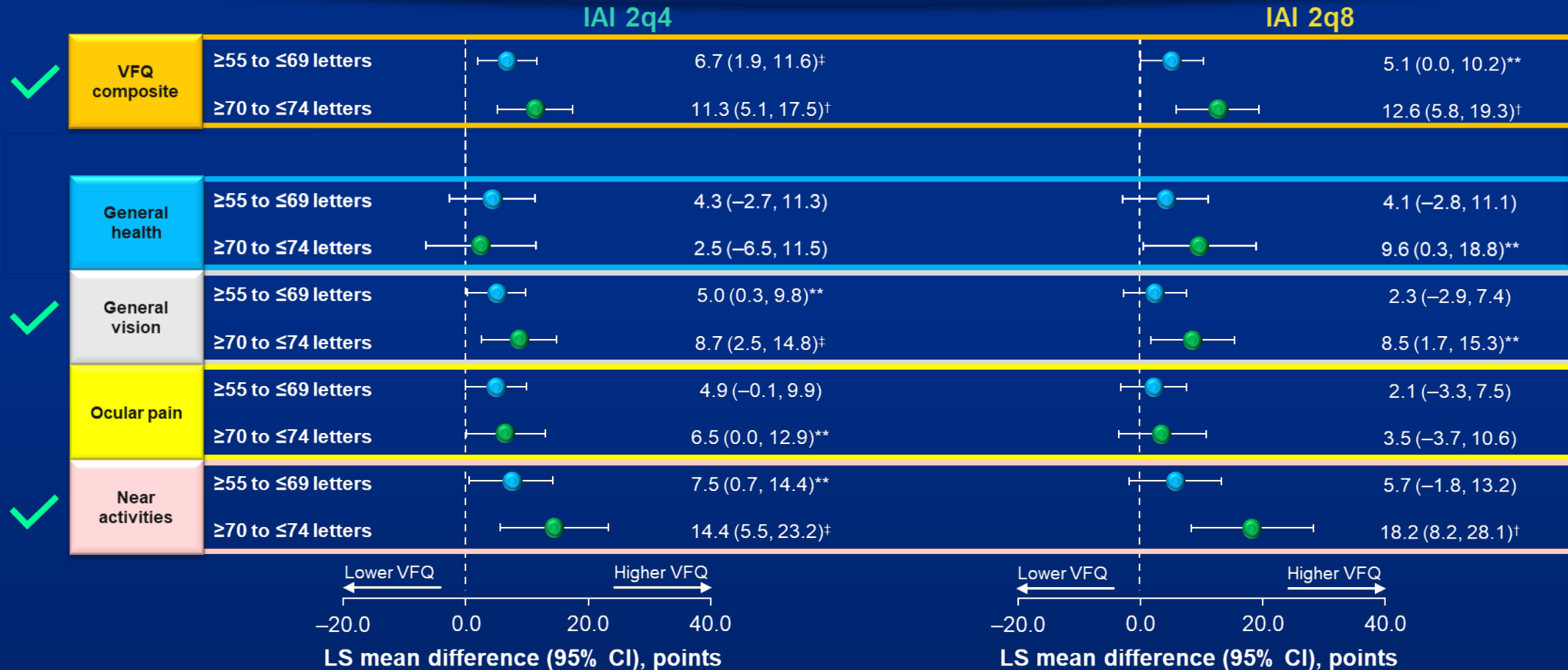
A greater proportion of patients with better vision at baseline achieved BCVA ≥ 70 letters at Week 100 compared with those with worse vision at baseline

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



At Week 100, patients with higher baseline BCVA achieved higher VFQ-25 composite scores

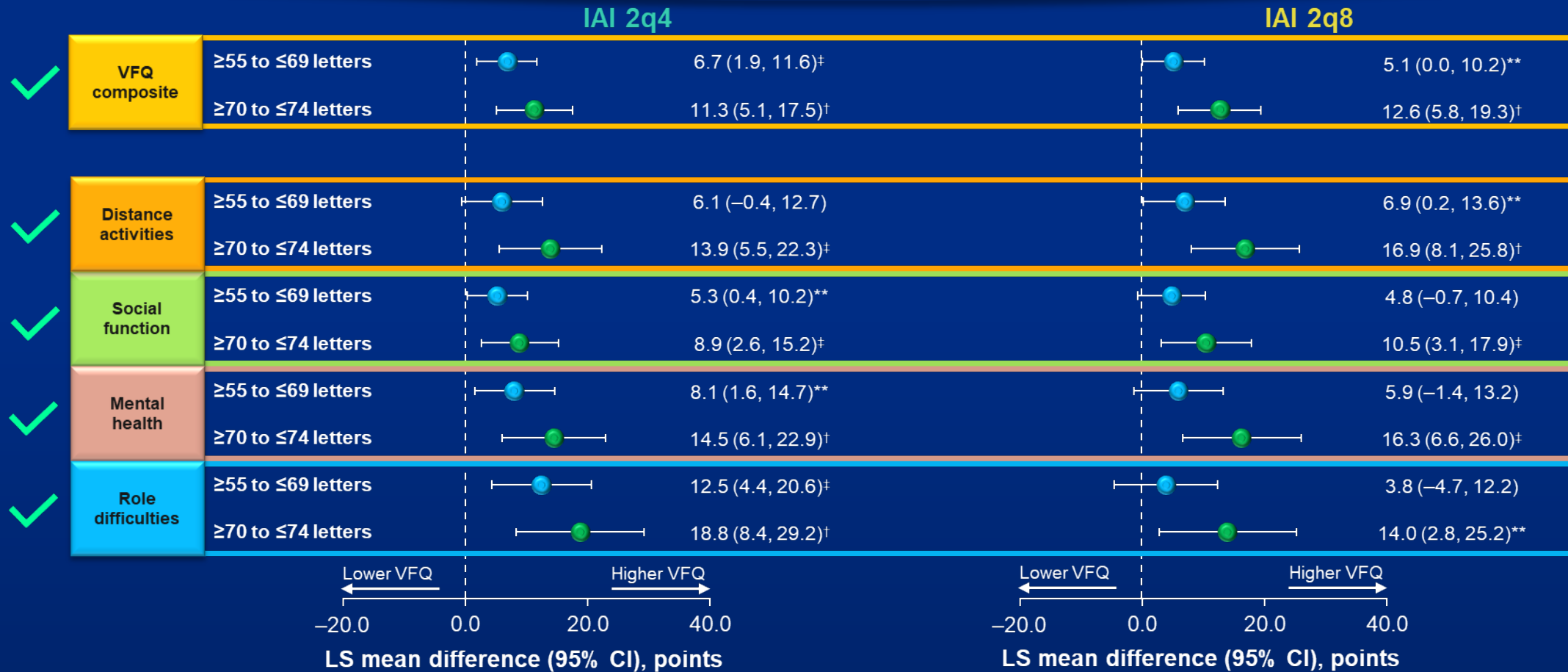
Difference in VFQ-25 Composite and Subscale Scores at Week 100 From Patients With Worse Baseline Vision



VFQ-25 composite and 9 of 12 subscale scores showed clinically meaningful improvements in patients with baseline BCVA ≥70 to ≤74 letters versus those with baseline BCVA ≥25 to ≤54 letters

✓ denotes clinically significant improvement in both IAI groups in ≥1 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.

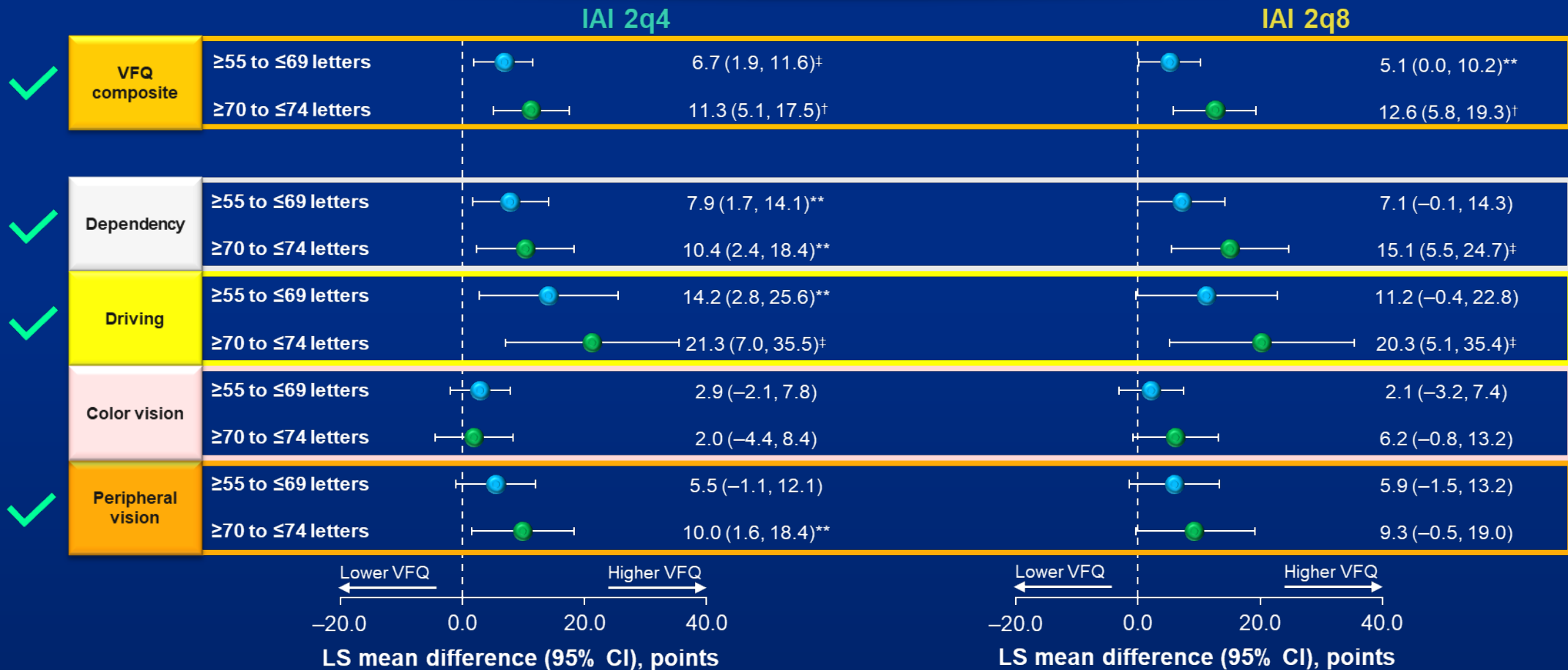
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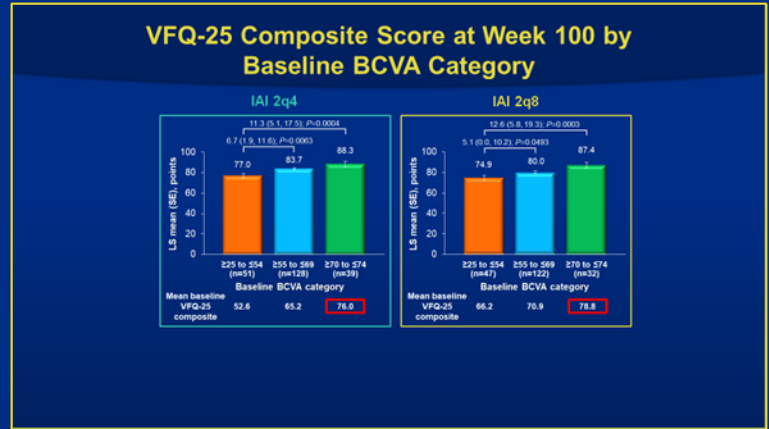
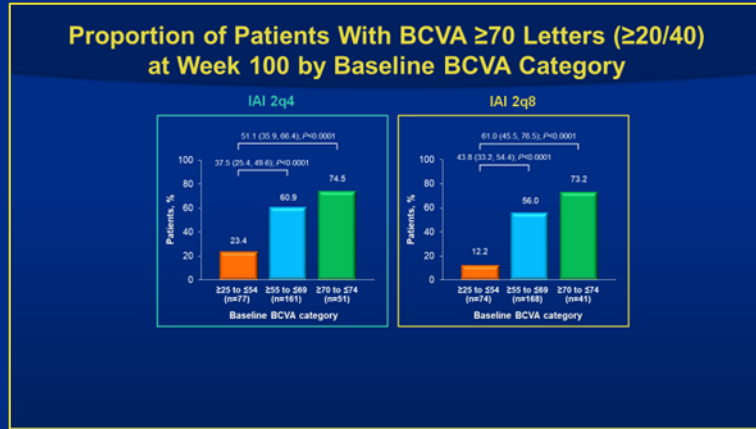
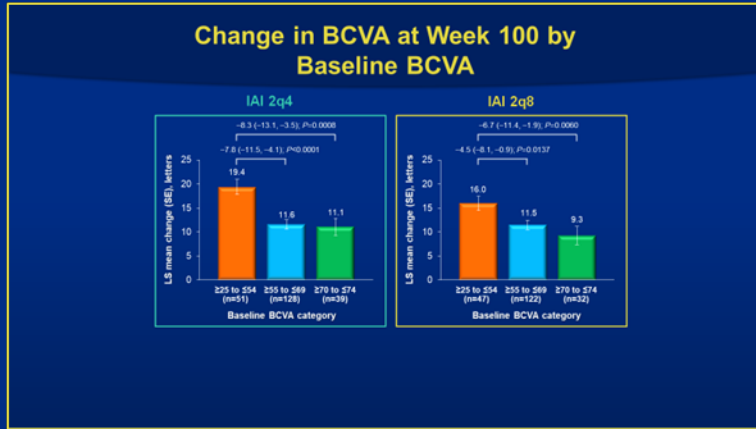
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Difference in VFQ-25 Composite and Subscale Scores at Week 100 From Patients With Worse Baseline Vision



VFQ-25 composite and 9 of 12 subscale scores showed clinically meaningful improvements in patients with baseline BCVA ≥70 to ≤74 letters versus those with baseline BCVA ≥25 to ≤54 letters

Conclusions



- Although 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 achieved BCVA ≥70 letters (≥20/40) at Week 100
- Patients with better baseline BCVA achieved higher VFQ-25 scores at Week 100
- Patients with better baseline BCVA may achieve improved visual outcomes and vision-related function with treatment