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Humanistic Burden of Retinal Vein Occlusion and the Impact of Treatment: A Systematic Literature Review

Seenu M Hariprasad MD,[1] Steven Sherman MPH,[2] Fabiana Q Silva MD,[2] Gillian Sibbring PhD,[3] Anna McCormick PhD,[3] Quan Dong Nguyen MD, MSc[4]

[1]Department of Ophthalmology and Visual Science, The University of Chicago, Chicago, Illinois, USA; [2]Regeneron Pharmaceuticals, Inc., Tarrytown, New York, USA; [3]Prime Access, Knutsford, UK; [4]Byers Eye Institute, Stanford University, Palo Alto, California, USA

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Disclosures

- Seenu M Hariprasad reports being a consultant or a member of the Speakers Bureau for Abbvie, Alimera Sciences, Apellis, Bayer, Biogen, Coherus, EyePoint Pharmaceuticals, Iveric Bio, and Regeneron Pharmaceuticals, Inc.
- Fabiana Q Silva and Steven Sherman are employees of and stockholders in Regeneron Pharmaceuticals, Inc.
- Gillian Sibbring and Anna McCormick are employees of Prime Access (a division of Prime, Knutsford, UK). Their institution received funding from Regeneron Pharmaceuticals, Inc. to support this analysis
- Quan Dong Nguyen reports being a Scientific Advisory Board member for Bausch and Lomb, Genentech, and Regeneron Pharmaceuticals, Inc.
- This analysis was funded by Regeneron Pharmaceuticals, Inc. (Tarrytown, New York), who is the sponsor and participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
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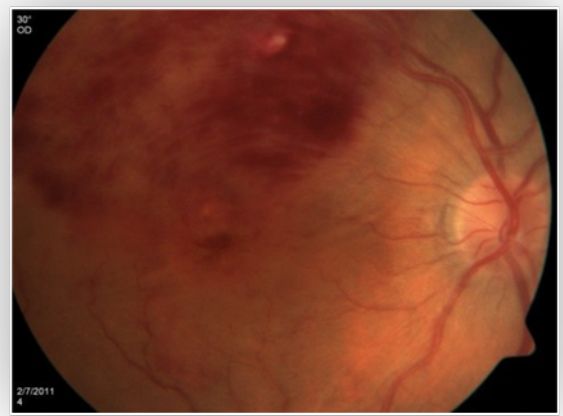
Background

- RVO is the second most common retinal vascular disorder affecting more than 28 million people worldwide[1,2]
- Although the clinical burden of RVO is well-characterized, the impact of this disease on patients' QoL has not been well-explored

We conducted a systematic literature review to better understand the burden of RVO and reported impact of treatment on humanistic outcomes



RVO, retinal vein occlusion; QoL, quality of life.
1. Jaulim A et al. *Retina*. 2013;33:901-910. 2. Song P et al. *J Glob Health*. 2019;9:010427.

Methods

- A systematic literature review was conducted to retrieve relevant clinical data from published literature in accordance with the PICOS framework[1]

Database search:

Medline and Embase databases were searched via the Ovid search engine to identify relevant RCTs/ observational studies published from January 1, 1990, to March 16, 2022, and literature reviews/ meta-analyses published from January 1, 2017, until March 16, 2022

Grey literature search:

Abstracts presented at congresses within the last 2 years were searched using focused browsing and keyword searching of specific websites

Backwards citation searches:

Reference lists of published SLRs and meta-analyses meeting the eligibility criteria were reviewed to identify any relevant RCTs/observational studies that were not identified in the literature searches

Overall, 3455 records were screened, of which 25 manuscripts covering 19 unique studies were eligible for data extraction describing humanistic outcomes among treated and untreated adult patients with BRVO, CRVO, or HRVO

BRVO, branch retinal vein occlusion; CRVO, central retinal vein occlusion; HRVO, hemiretinal vein occlusion; PICOS, Population, Intervention, Comparison, Outcomes, and Study; RCT, randomized clinical trial; SLR, systematic literature review.

1. CRD's guidance for undertaking reviews in health care. Systematic Reviews. Centre for Reviews and Dissemination; 2009. Accessed October 17, 2023. https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf.

Outcomes Identified

NEI VFQ-25 scores

- General burden: Impact of RVO on NEI VFQ-25 composite and subscale scores in *untreated patients*
- Effect of *treatment*:
  - Change from baseline to post-treatment in NEI VFQ-25 composite scores in patients with RVO
  - Comparison of post-treatment NEI VFQ-25 composite scores in patients with RVO
  - NEI VFQ-25 subscale scores in patients with RVO

Utility measures

- VFQ-UI
- EQ-5D Index Score

Patient-reported pain

- Pain associated with intravitreal injection, as measured by VAS score
- Eye pain as an ocular complication

Ocular complications[a]

- Incidence of ocular complications

[a]Only if reported in studies also reporting QoL outcomes.
EQ-5D, EuroQol-5 dimensions; NEI VFQ-25, National Eye Institute Visual Function Questionnaire-25; VA, visual acuity; VAS, Visual Analog Scale; VFQ-UI, Visual Function Questionnaire-Utility Index.

Impact of RVO on NEI VFQ-25 Composite Scores at Baseline

Five publications of 4 studies[1-5] reported the impact of different types of RVO on composite NEI VFQ-25 scores

Two studies showed that patients with BRVO and overall RVO (ME not specified) had significantly lower NEI VFQ-25 composite scores when compared with a control population[4-5]

NEI VFQ-25 composite scores were significantly lower in patients with MEfCRVO or MEfHRVO when compared with 2 different normal vision reference populations[1]

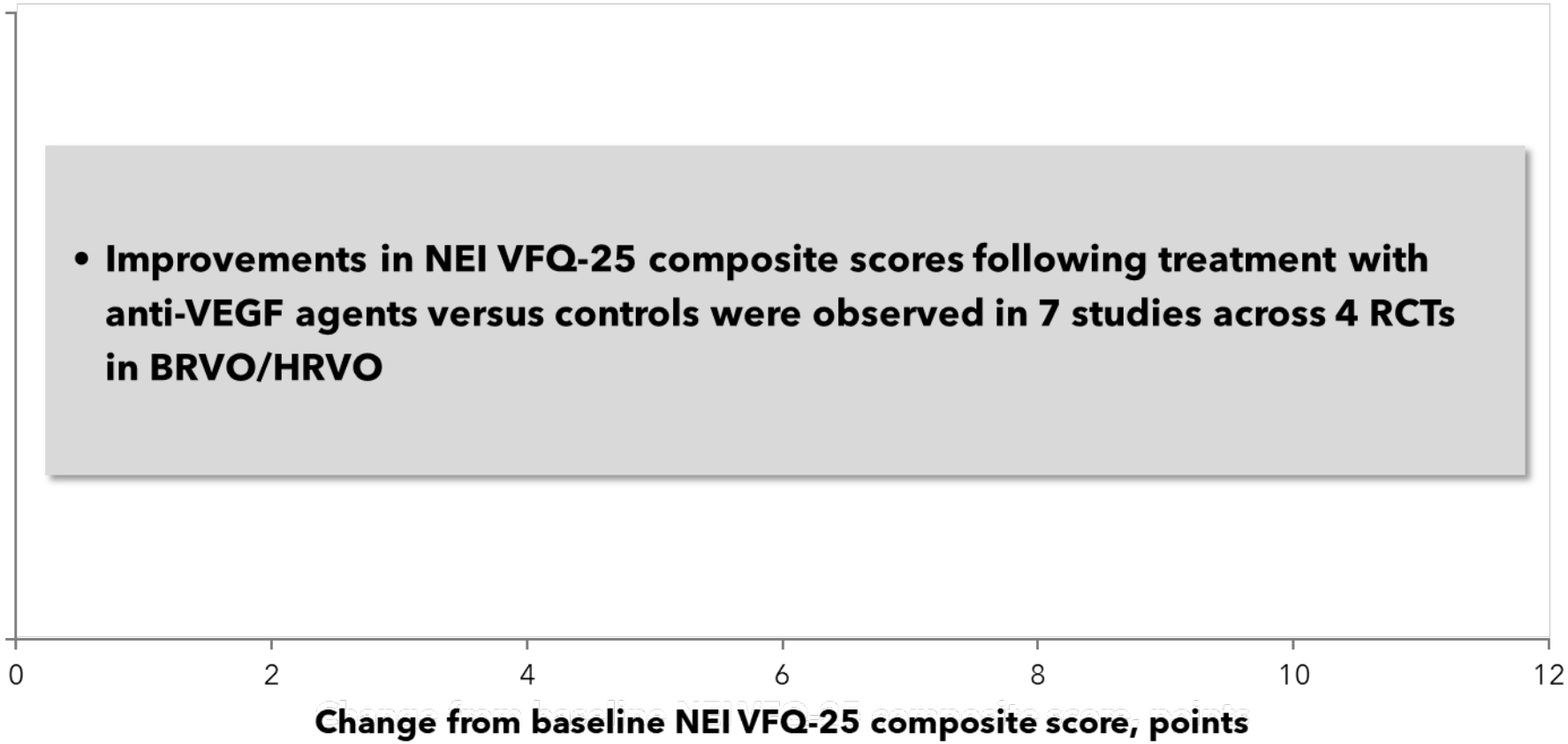
MEfCRVO, macular edema following central retinal vein occlusion; MEfHRVO, macular edema following hemiretinal vein occlusion.

1. Scott IU et al. *Am J Ophthalmol*. 2017;184:147-156. 2. Scott IU et al. *JAMA Ophthalmol*. 2022;24:458-464. 3. Bertelmann T et al. *Health Qual Life Outcomes*. 2016;14:132. 4. Chatzirallis A et al. *Semin Ophthalmol*. 2021;36:658-664. 5. Awdeh RM et al. *Br J Ophthalmol*. 2010;94:319-323.

Post-Treatment Change in NEI VFQ-25 Composite Scores Across Treatment Strategies (BRVO/HRVO)

Study	Study type	Patients
VIBRANT[1,2]	RCT	MEfBRVO/ MEfHRVO
BRAVO[3,4]	RCT	MEfBRVO/ MEfHRVO
COMO[5]	RCT	BRVO
BRIGHTER[6,7]	RCT	BRVO

- **Improvements in NEI VFQ-25 composite scores following treatment with anti-VEGF agents versus controls were observed in 7 studies across 4 RCTs in BRVO/HRVO**



[a]Eligible eyes received sham laser rescue at Week 12, 16, or 20; [b]Eligible eyes received 1 laser rescue from Week 12 to 20; [c]Eligible eyes received sham laser rescue at Week 12, 16, or 20; no treatment at Weeks 24, 28, 32, 40, 44, and 48; or active laser at Week 36; [d]Eligible eyes received 1 laser rescue from Week 12 to 20. From Week 24 to 48, eligible eyes received IAI 2 mg every 8 weeks after 3 initial monthly doses. At Week 36, eyes received sham laser in addition to IAI 2 mg; [e]$P<0.05$. Dex IV, dexamethasone intravitreal implant 0.7 mg at Day 1 and Month 5, with optional retreatment at Month 10 or 11; IAI, intravitreal aflibercept injection; IRI, intravitreal ranibizumab injection; M, month; MEfBRVO, macular edema following branch retinal vein occlusion; PRN, when required; Q4W, every 4 weeks; Q8W, every 8 weeks; VEGF, vascular endothelial growth factor; W, week.

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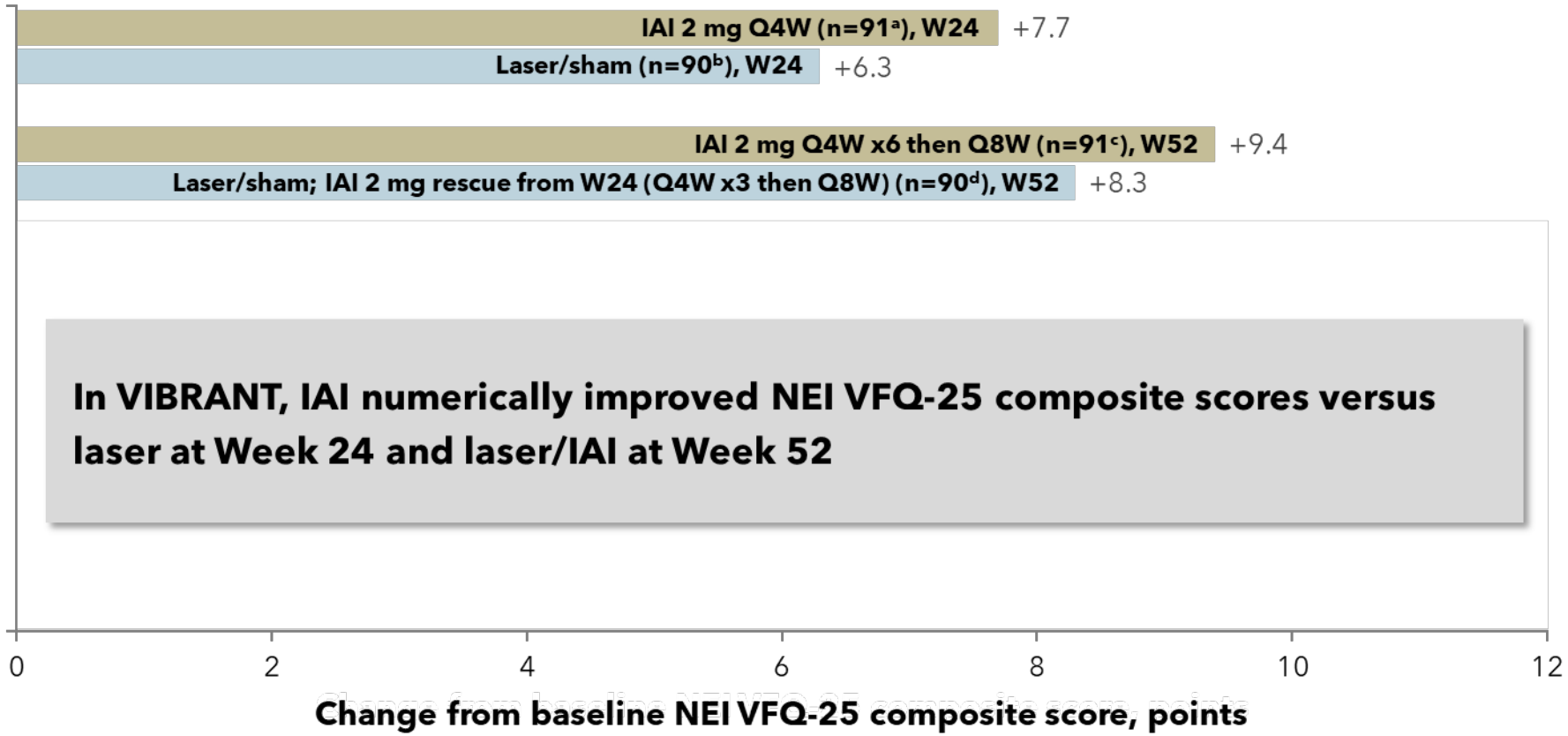

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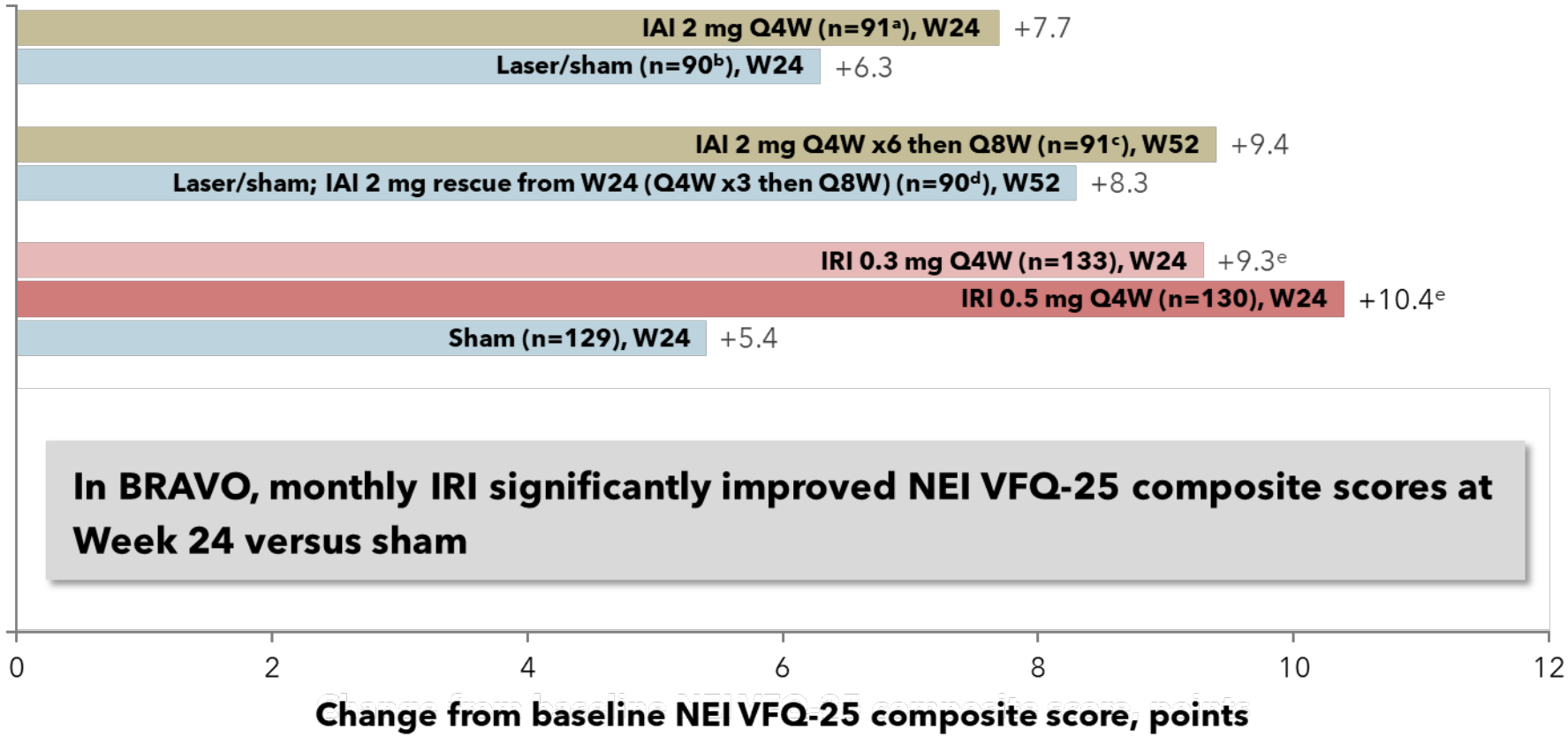

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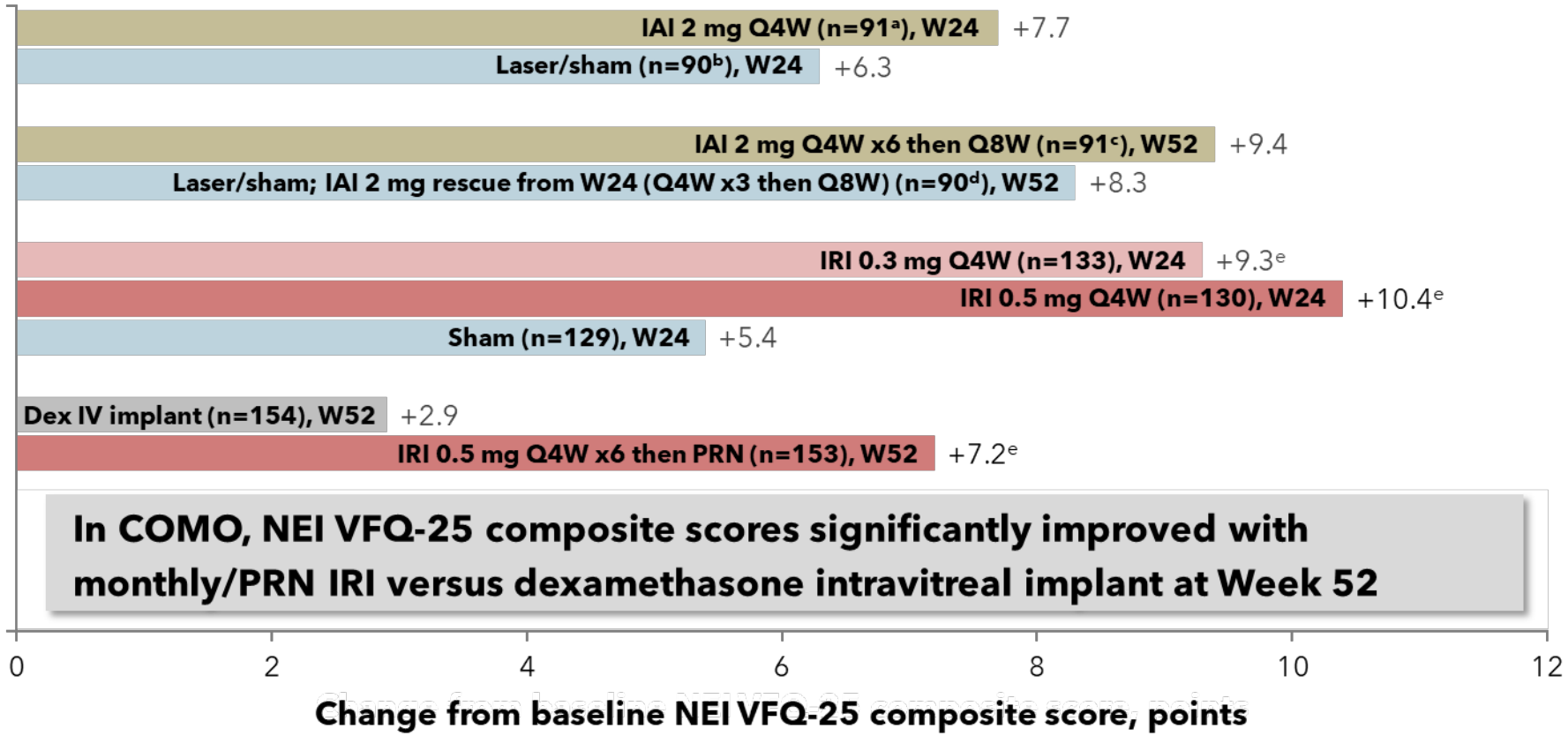

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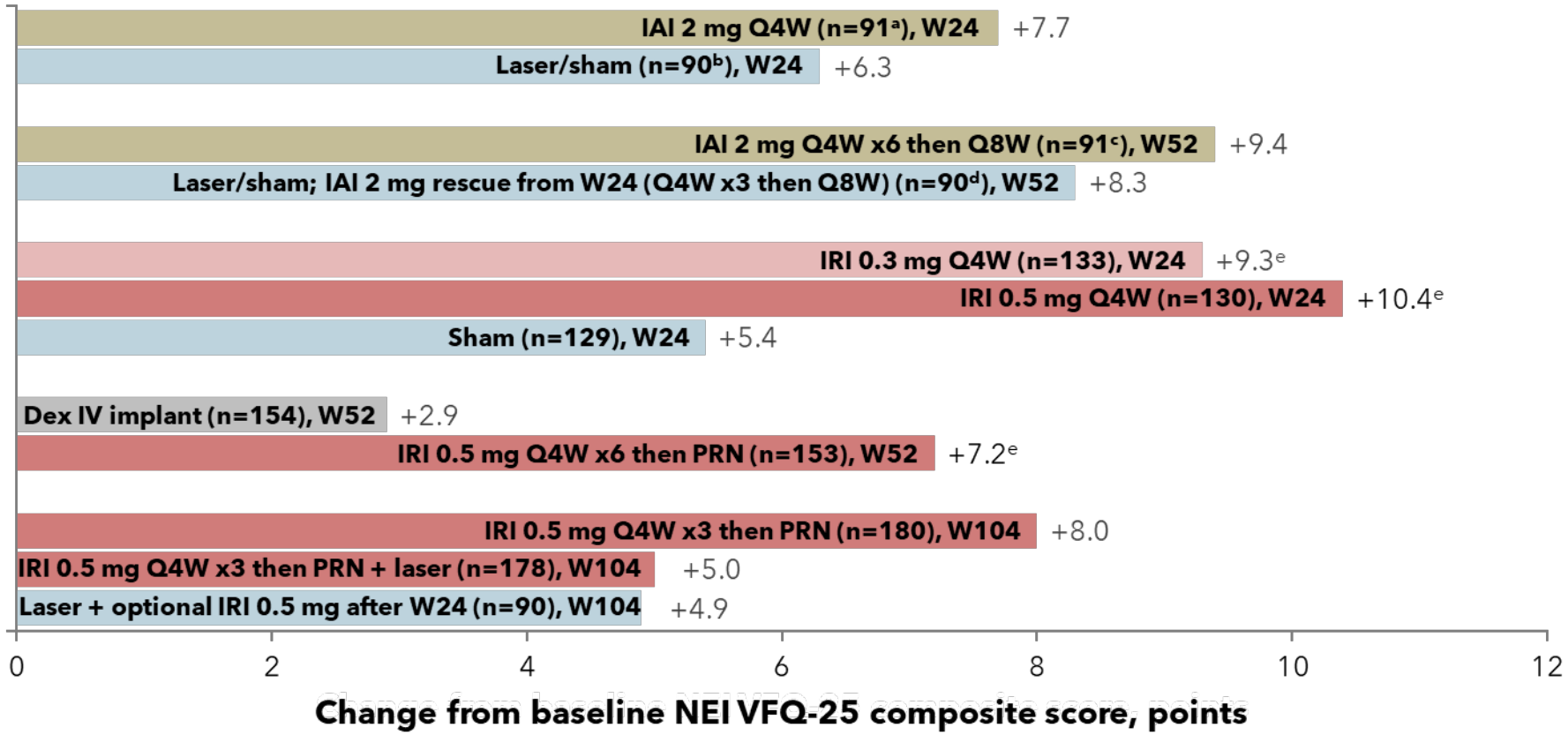

In BRIGHTER, IRI PRN numerically improved NEI VFQ-25 composite scores versus IRI/laser combination at Week 104

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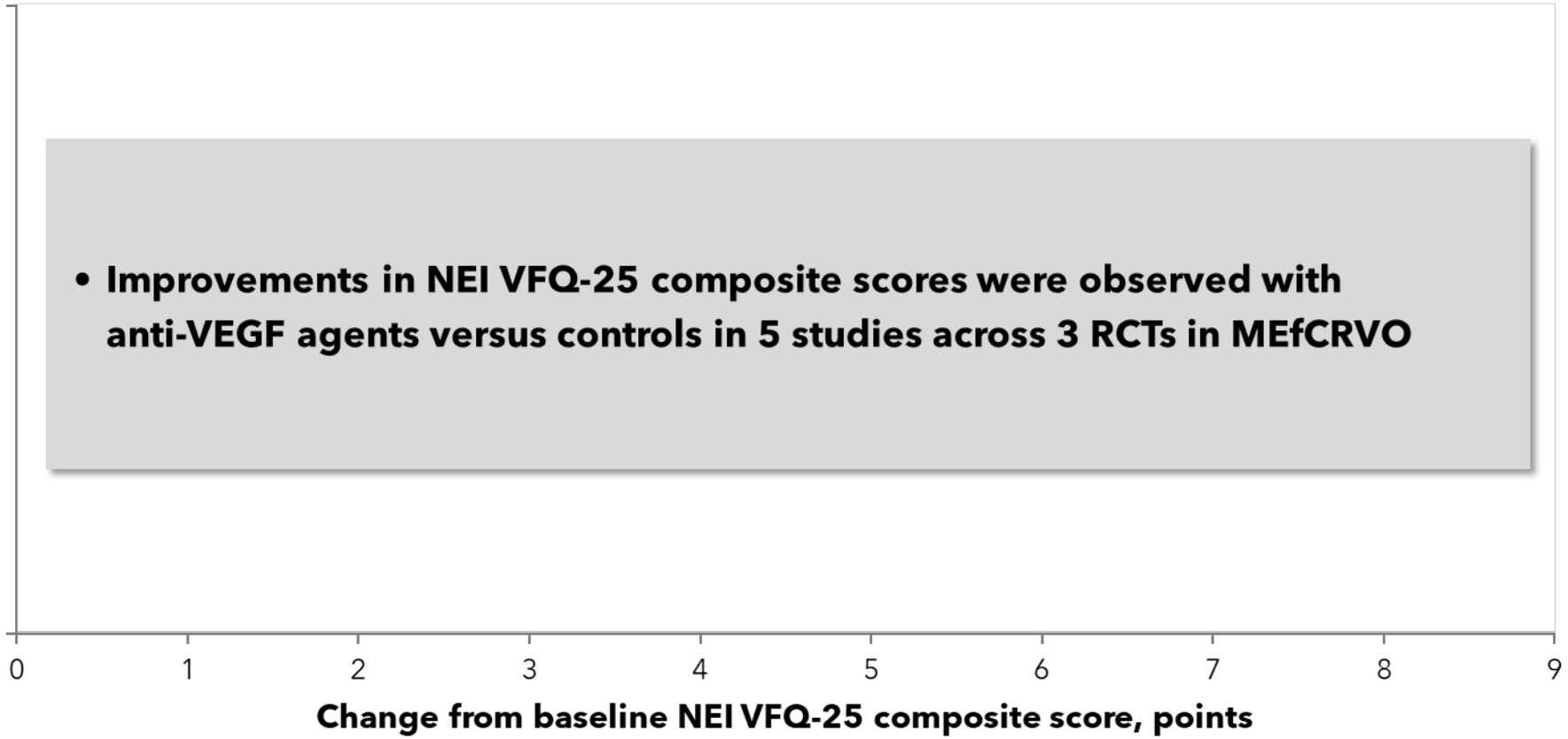
Post-Treatment Change in NEI VFQ-25 Composite Scores Across Treatment Strategies (CRVO)

Study	Study type	Patients
CRUISE[1,2]	RCT	MEfCRVO
GALILEO[3,4]	RCT	MEfCRVO
COPERNICUS[5]	RCT	MEfCRVO

- **Improvements in NEI VFQ-25 composite scores were observed with anti-VEGF agents versus controls in 5 studies across 3 RCTs in MEfCRVO**



[a]*P*<0.01; [b]*P*<0.05 versus sham.

1. Varma R et al. *Ophthalmology*. 2012;119(10):2108-2118. 2. Campochiaro PA et al. *Ophthalmology*. 2011;118(10):2041-2049. 3. Holz FG et al. *Br J Ophthalmol*. 2013;97(3):278-284. 4. Korobelnik JF et al. *Ophthalmology*. 2014;121(1):202-208. 5. Heier JS et al. *Ophthalmology*. 2014;121:1414-1420.

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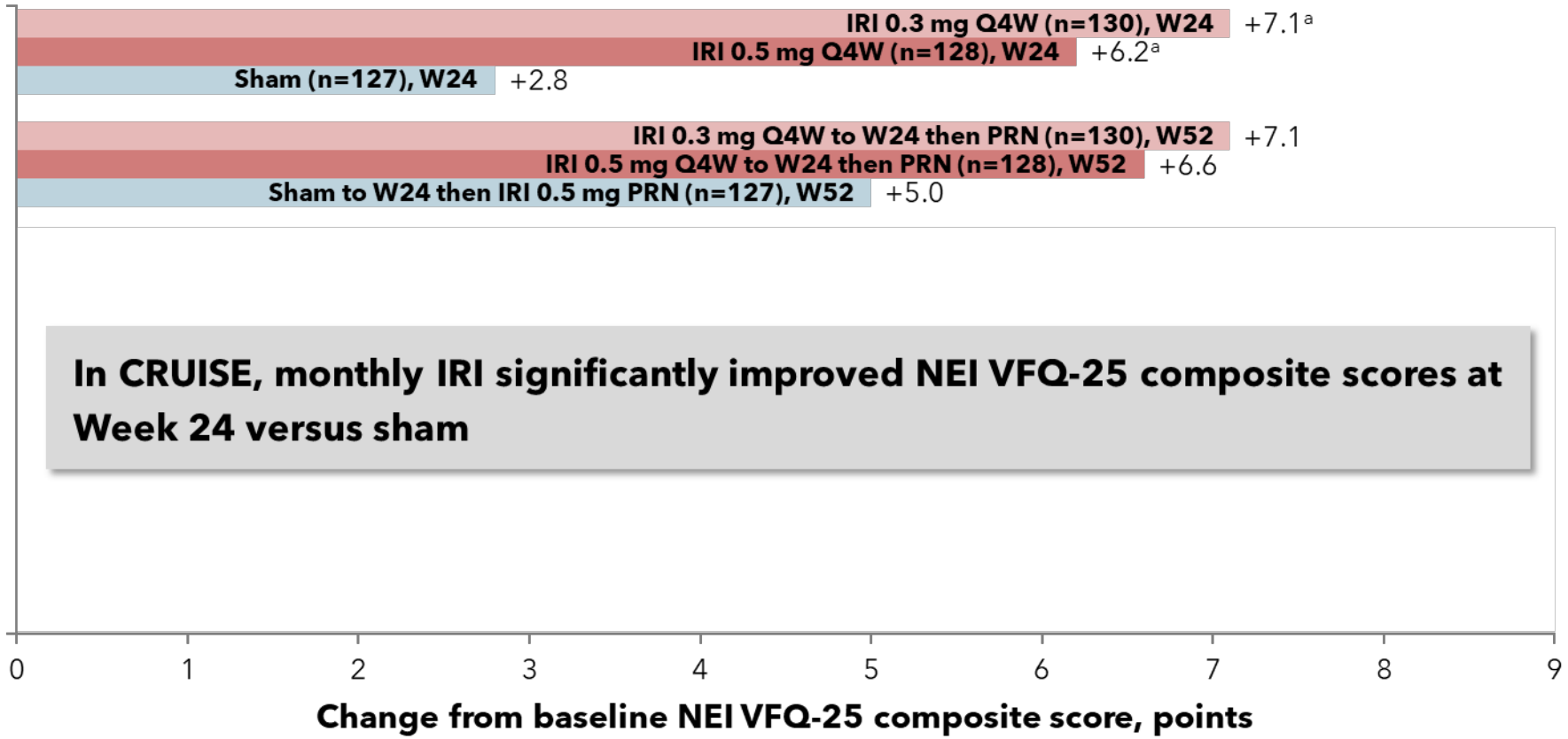

In CRUISE, monthly IRI significantly improved NEI VFQ-25 composite scores at Week 24 versus sham

[a]*P*<0.01; [b]*P*<0.05 versus sham.

1. Varma R et al. *Ophthalmology*. 2012;119(10):2108-2118. 2. Campochiaro PA et al. *Ophthalmology*. 2011;118(10):2041-2049. 3. Holz FG et al. *Br J Ophthalmol*. 2013;97(3):278-284. 4. Korobelnik JF et al. *Ophthalmology*. 2014;121(1):202-208. 5. Heier JS et al. *Ophthalmology*. 2014;121:1414-1420.

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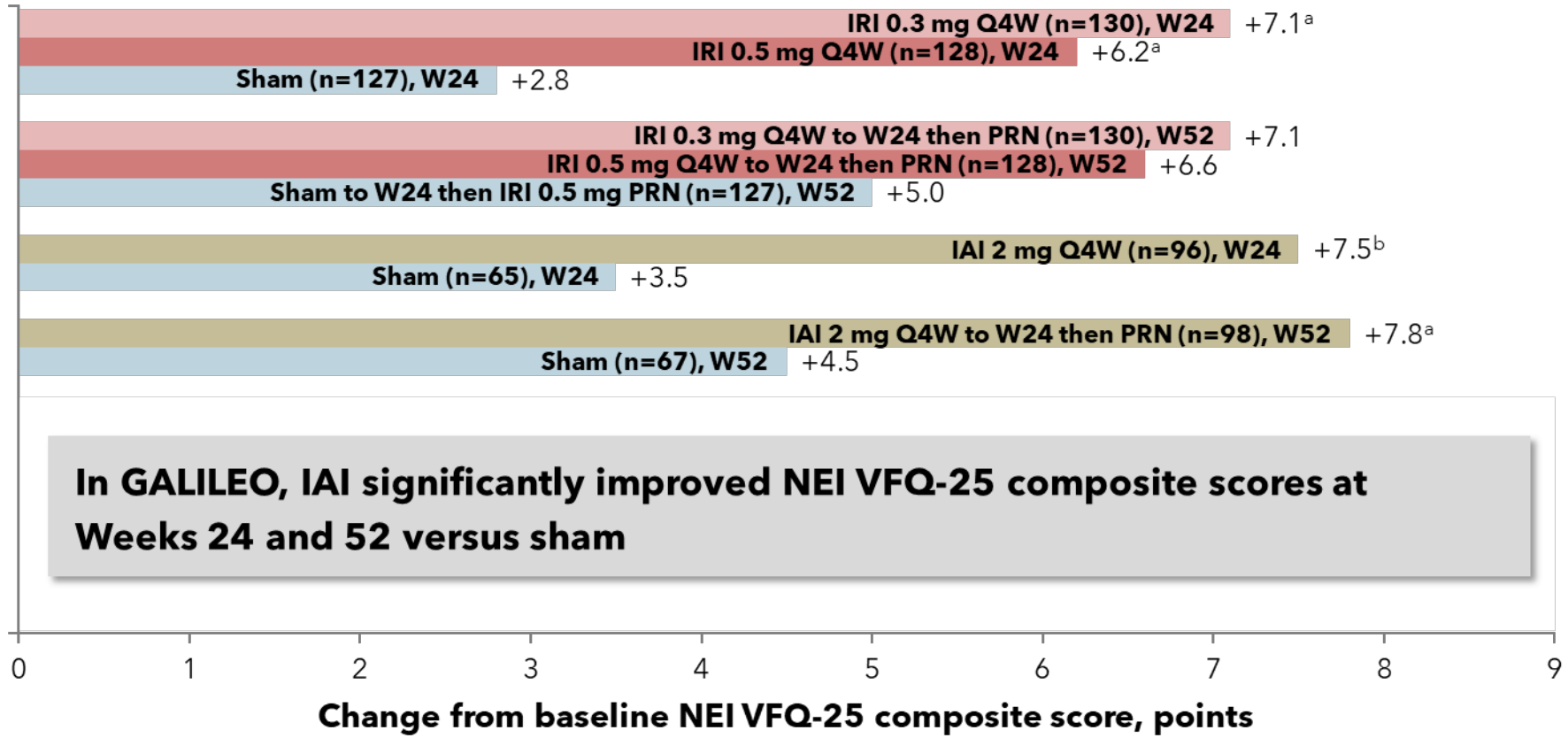

[a]$P<0.01$; [b]$P<0.05$ versus sham.

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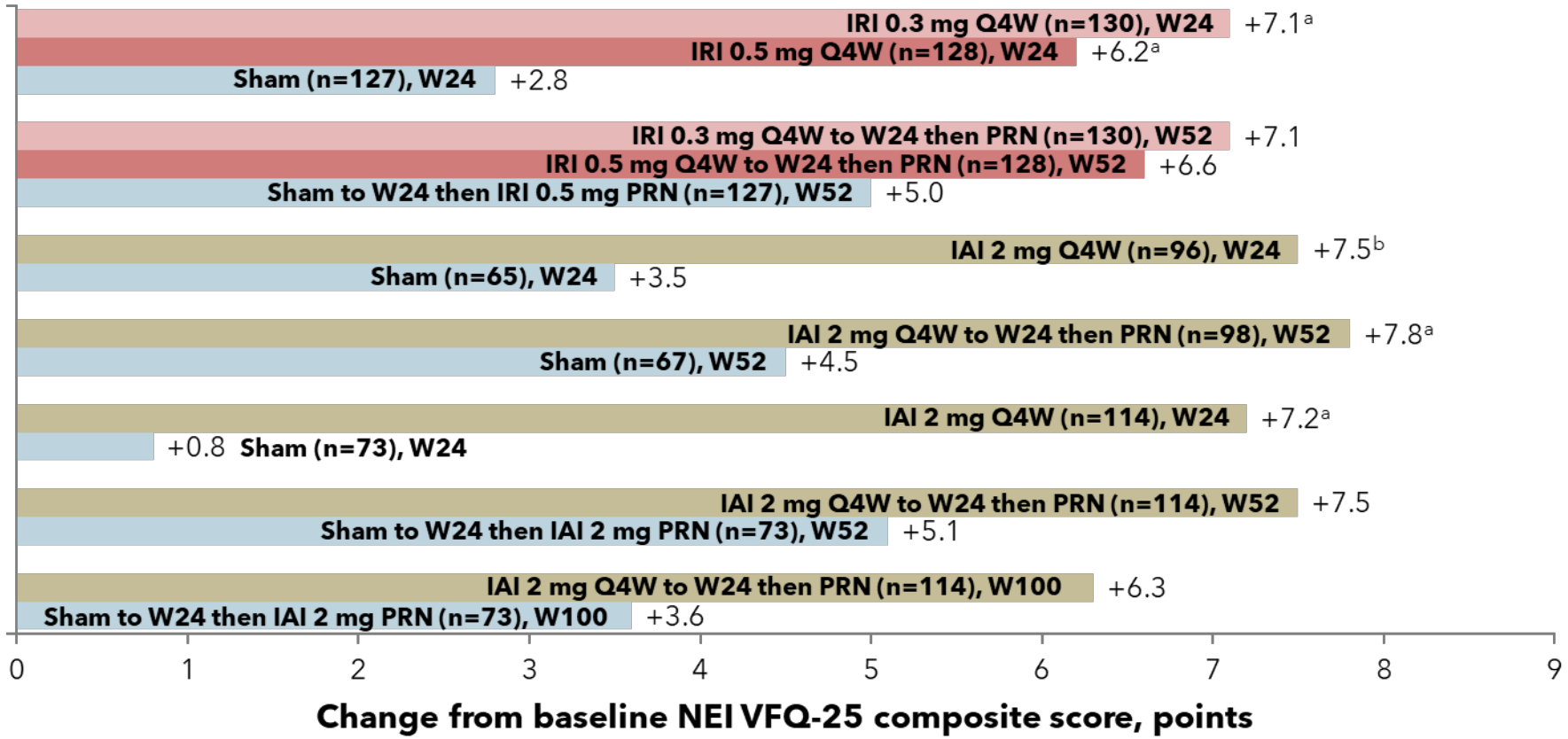

In COPERNICUS, monthly IAI significantly improved NEI VFQ-25 composite scores at Week 24 versus sham

[a]*P*<0.01; [b]*P*<0.05 versus sham.

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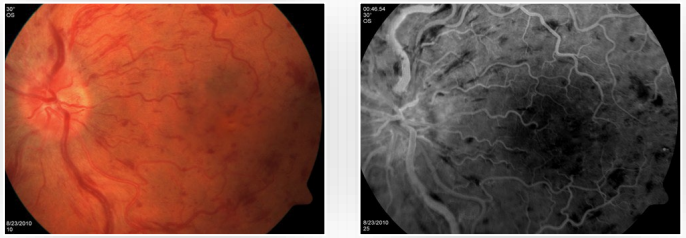
Conclusions



Only 25 articles published over a >30-year period were identified on the humanistic burden of RVO. There were a lack of data on the additional burden of ME on QoL in patients with RVO and the effect of treatment

QoL in patients with RVO was reduced compared with healthy individuals. QoL could be improved by IAI or IRI; dexamethasone intravitreal implant was inferior to anti-VEGF in improving QoL in a single study

Given the paucity of research on the humanistic burden of RVO or MEfRVO before and after treatment, we believe that further research is necessary to further elucidate the impact of modern-day therapies

THANK YOU