

Efficacy of Faricimab versus Aflibercept-8 mg in patients with treatment naïve diabetic macular oedema. Real-World Outcomes.

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BACKGROUND

- Diabetic Macular Oedema (DMO) remains a leading cause of vision loss in the working-age population globally, and represents a significant financial burden to the NHS
- While high-dose Aflibercept-8mg (Anti-VEGF-A/B, PIGF) and Faricimab (Anti-Ang-2, VEGF-A) have shown success in pivotal trials [1,2], real-world comparative head-to-head studies remain limited
- The reduced vascular leakage observed with Aflibercept-8 mg or Faricimab, as compared to Aflibercept-2 mg, appears to correlate with improved structural outcomes

AIM

To compare real-world functional (best corrected visual acuity, BCVA) and structural (central subfoveal thickness, CST; macular volume, MV) outcomes between the two agents one month after the initial loading phase according to local treatment protocol.

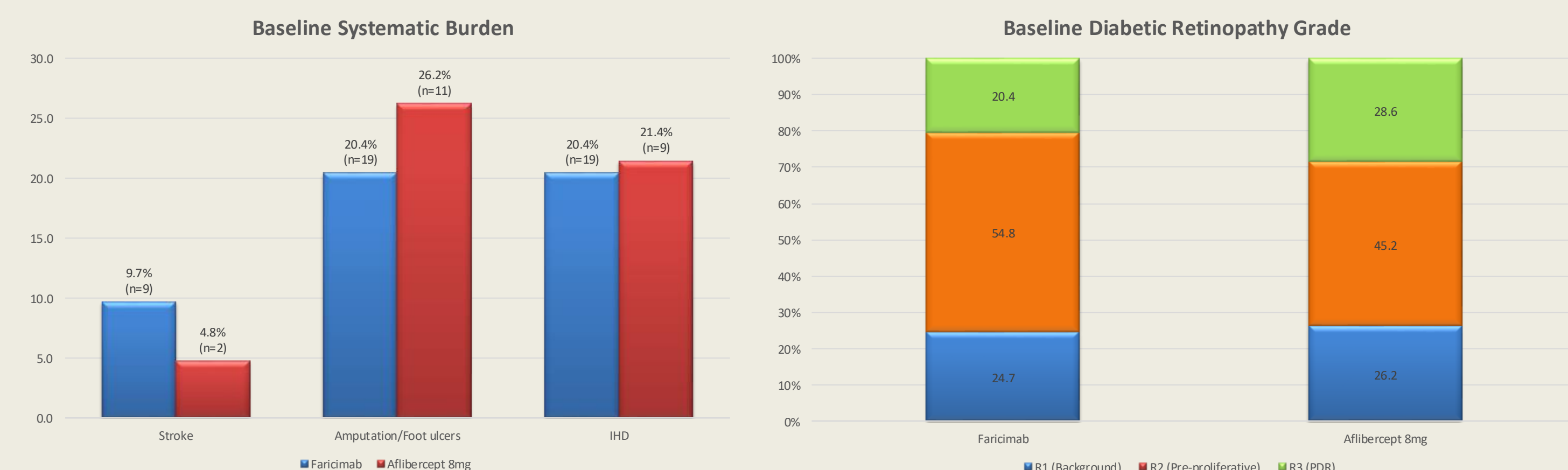
METHODS

- Retrospective study of 135 eyes (108 patients); 93 Faricimab vs 42 Aflibercept-8 mg
- Predetermined** structural outcomes: Dry macula (absence of IRF/SRF and restored foveal profile), > 20% CST reduction from baseline, and post-loading CST < or > 325 µm
- Protocol: Loading phase (3 consecutive monthly injections) with 1-month post-loading review (local protocol)
- Statistics: Linear Regression (BCVA/CST/MV) and Modified Poisson Regression Model (binary outcomes, IRR)

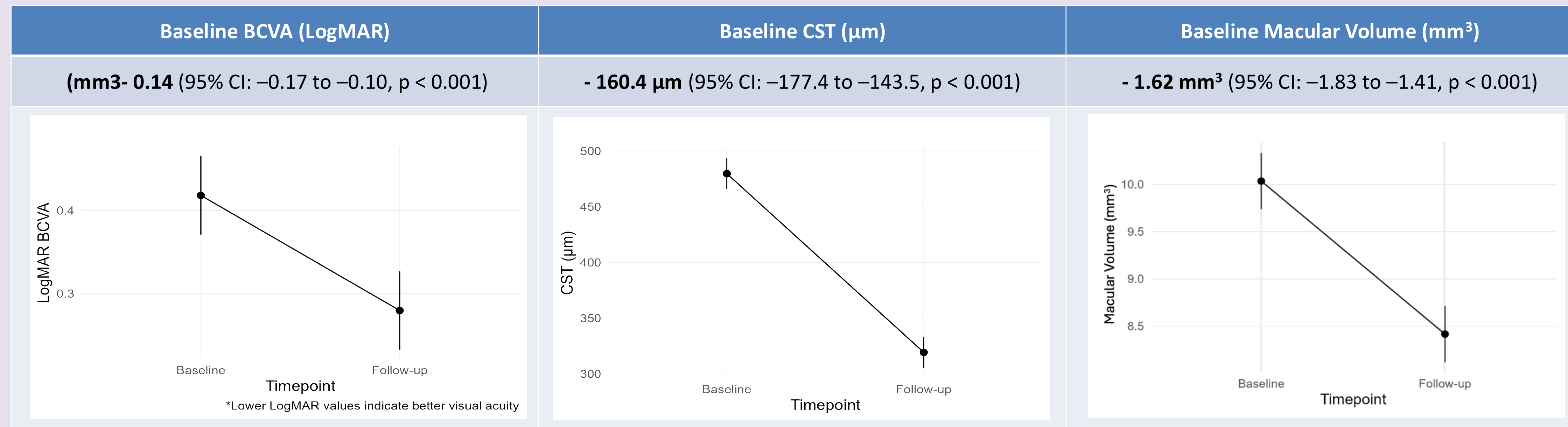
BASELINE CHARACTERISTICS

High-risk real-world cohort with significant systemic and ocular morbidity at baseline

- Cardiovascular Burden:
 - 20.7% had ischaemic heart disease (IHD)
 - 8.1% with history of stroke
- Diabetes Complications: 22.2% with history of amputation or foot ulcers
- Advanced Retinopathy: 75.9% of eyes had pre-proliferative (R2) or proliferative (R3) disease at baseline

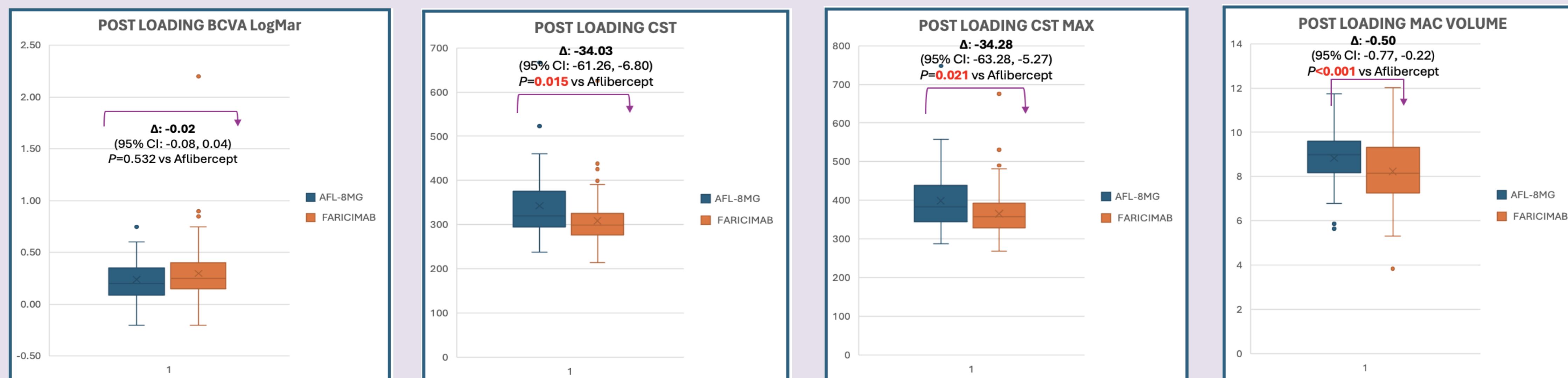


OVERALL COHORT RESULTS



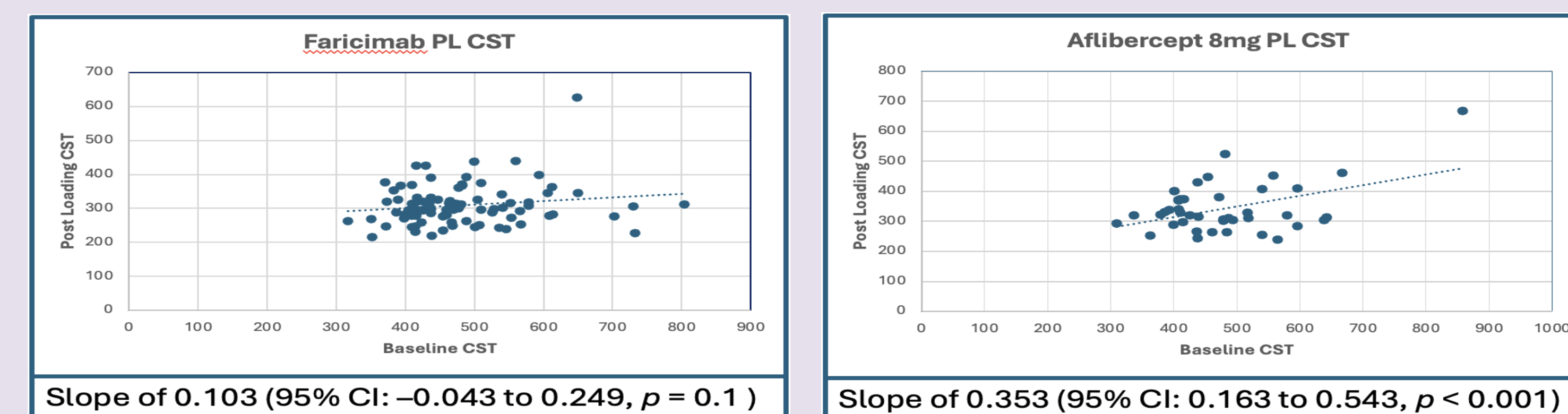
- Improvements were seen across vision, baseline thickness and macular volume outcomes in the overall cohort – all of which are statistically significant

ANCOVA LINEAR MODEL ESTIMATION OF BETWEEN-AGENT OUTCOMES



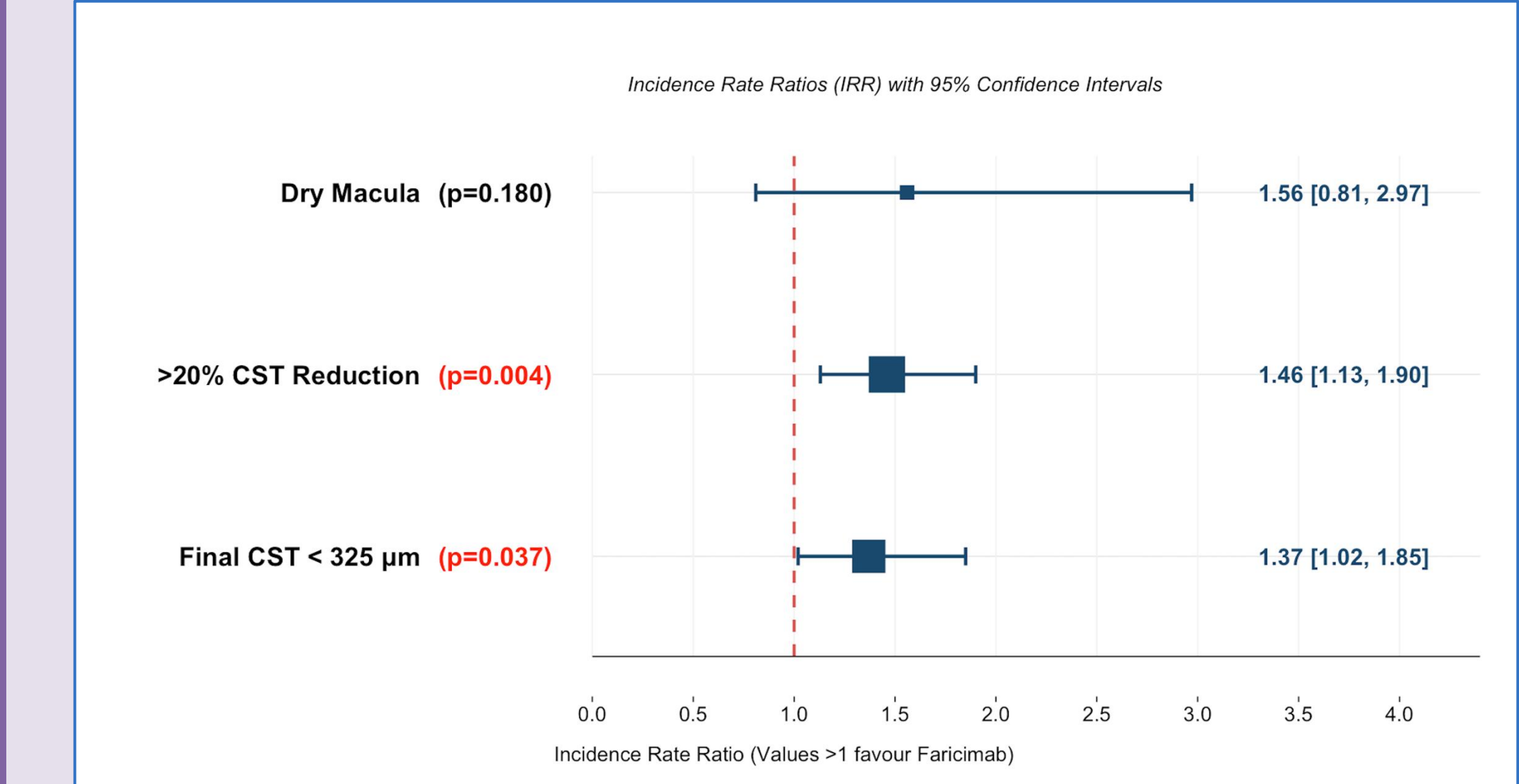
- Faricimab achieved statistically significant reductions in CST, CST max, and MV, while for BCVA results there was no difference between the two agents

RELATIONSHIP BETWEEN BASELINE AND POST-LOADING CST



- Statistically significant difference between Faricimab and Aflibercept-8 mg, slopes: $p = 0.04$
- Faricimab achieved baseline-independent anatomical outcomes (consistent post-loading CST regardless of initial thickness, $p = 0.1$), whereas Aflibercept-8 mg showed a significant positive correlation ($p < 0.001$), suggesting Faricimab may be more effective for patients starting with higher macular thickness

BINARY STRUTURAL OUTCOMES (IRR)



Both agents demonstrated drying efficacy:

- A favourable trend towards a dry macula was observed in both agents
- Faricimab showed a higher likelihood of achieving significant anatomical targets, specifically a > 20% CST reduction and a final CST < 325 µm, with 95% CI >1.0

CONCLUSION

- Faricimab and Aflibercept-8 mg both demonstrated favourable functional and structural outcomes
- Unlike Aflibercept-8mg, Faricimab post-loading CST is unrelated to its baseline CST values
- Data results favour Faricimab for achieving pre-determined better structural outcomes (CST < 325 µm, > 20% reduction in baseline CST, and marginally dry macula)

LIMITATIONS

- Given the small sample size and short-term, post-loading nature of this assessment, these results reflect an early clinical window and warrant cautious interpretation
- Longitudinal studies and larger-scale analyses, including the pooling of real-world data and meta-analyses, are essential to validate the long-term clinical relevance and durability of these findings

REFERENCES

- Wong TY, et al. Faricimab Treat-and-Extend for Diabetic Macular Edema: Two-Year Results from the YOSEMITE and RHINE Trials. *Ophthalmology*. 2024;131(6):708-723.
- Brown DM, et al. Intravitreal aflibercept 8 mg in diabetic macular oedema (PHOTON): 48-week results. *Lancet*. 2024;403(10432):1153-1163.