Effects of Time Since Diagnosis to Intravitreal Aflibercept Injection and Baseline BCVA on Outcomes in CRVO: Post Hoc Analysis of the COPERNICUS and GALILEO Trials

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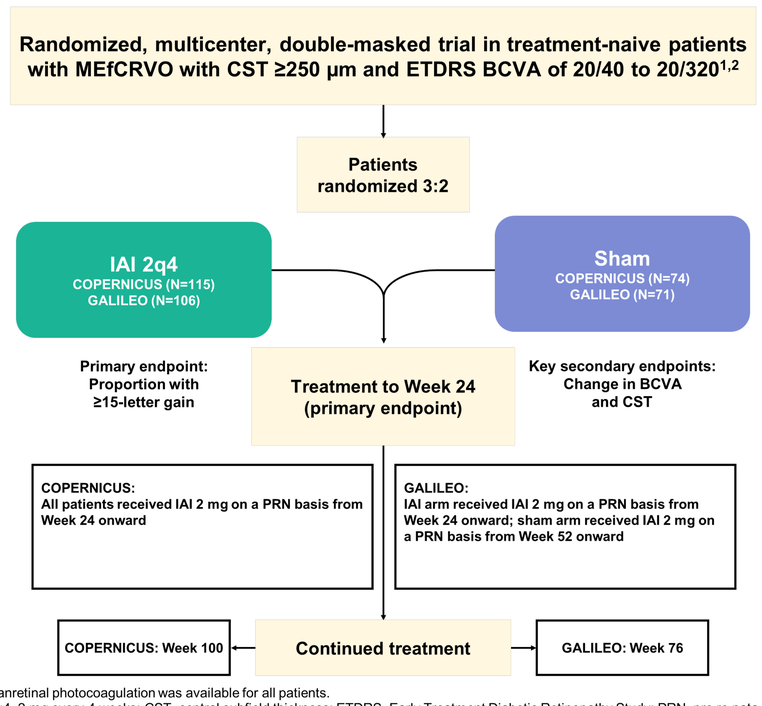
INTRODUCTION

- COPERNICUS and GALILEO demonstrated improved visual and anatomical outcomes with intravitreal aflibercept injection (IAI) in patients with macular edema secondary to central retinal vein occlusion (MEfCRVO)[1,2]
- Understanding factors that may affect visual and anatomic outcomes can inform treatment decisions and manage physician and patient expectations
- The purpose of this analysis was to examine the impact of time since diagnosis of MEfCRVO to first IAI and baseline best-corrected visual acuity (BCVA) on visual and anatomic outcomes

METHODS

- This post hoc analysis included patients from COPERNICUS and GALILEO with MEfCRVO treated with IAI 2 mg every 4 weeks followed by dosing as needed from Week 24 to Week 100 (COPERNICUS) or Week 76 (GALILEO) (**Figure 1**)

Figure 1. Study Design



Panretinal photocoagulation was available for all patients.
2q4, 2 mg every 4 weeks; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; PRN, pro re nata.

- **Impact of time since diagnosis to first IAI treatment** on visual and anatomic outcomes at Week 24 was assessed according to 3 groups:

<1 month	1-3 months	>3 months

- **Impact of baseline BCVA** on visual and anatomic outcomes at Week 24 was evaluated in BCVA tertiles:

COPERNICUS

T1: ≤44 letters	T2: >44 to ≤58 letters	T3: >58 letters

GALILEO

T1: ≤47 letters	T2: >47 to ≤65 letters	T3: >65 letters

- Outcomes were evaluated by the above categories and were analyzed using mixed-effect model repeat measurement (MMRM)
- Baseline values were observed, all other values were generated from an MMRM
- *P*-values were considered nominal

RESULTS

Impact of Time Since Diagnosis to IAI Treatment

- In COPERNICUS and GALILEO, baseline BCVA was similar across all time since diagnosis groups, while mean CST was lowest for the >3 months group (**Table 1**)

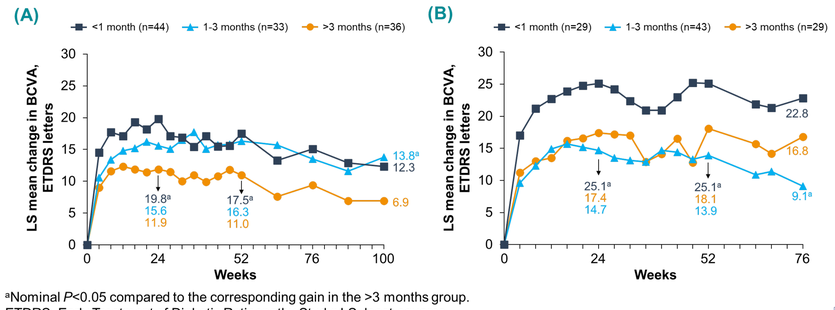
Table 1. Baseline Demographics and Ocular Characteristics

	COPERNICUS			GALILEO		
	<1 month (n=44)	1-3 months (n=33)	>3 months (n=36)	<1 month (n=29)	1-3 months (n=43)	>3 months (n=29)
Male, n (%)	29 (65.9)	24 (72.7)	16 (44.4)	16 (55.2)	25 (58.1)	17 (58.6)
White, n (%)	40 (90.9)	28 (84.8)	19 (52.8)	18 (62.1)	32 (74.4)	22 (75.9)
Hispanic or Latino, n (%)	6 (13.6)	2 (6.1)	9 (25.0)	1 (3.4)	2 (4.7)	1 (3.4)
BCVA, mean (SD), ETDRS letters	48.5 (14.9)	50.2 (13.2)	53.9 (13.3)	54.9 (15.5)	52.7 (16.8)	52.6 (15.0)
CST, mean (SD), µm	741 (242)	658 (220)	564 (220)	704 (192)	746 (255)	580 (216)
Perfused retina, n (%)	34 (77.3)	21 (63.6)	22 (61.1)	27 (93.1)	35 (81.4)	25 (86.2)

SD, standard deviation.

- In both studies, a delay of >3 months to treatment initiation was associated with less vision gain at Week 24 compared with a <1-month delay (**Figure 2**)

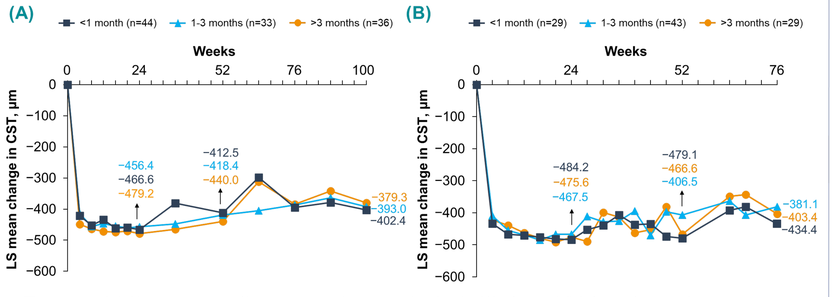
Figure 2. Mean BCVA Gains by Time Since Diagnosis to First IAI Treatment in (A) COPERNICUS and (B) GALILEO



[a]Nominal *P*<0.05 compared to the corresponding gain in the >3 months group.
ETDRS, Early Treatment of Diabetic Retinopathy Study; LS, least-squares.

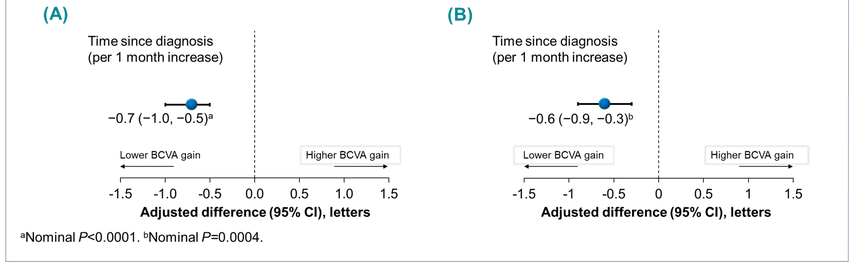
- Mean CST decreased substantially and to a similar extent from baseline to Week 24 in both studies across all time since diagnosis groups (**Figure 3**)

Figure 3. Mean Change in CST by Time Since Diagnosis to First IAI Treatment in (A) COPERNICUS and (B) GALILEO



- Each additional month since diagnosis to initiating IAI treatment was associated with a significant reduction in BCVA gain through Week 24 in both studies (**Figure 4**)

Figure 4. Effect of Time Since Diagnosis on Vision Gain Through Week 24 in (A) COPERNICUS and (B) GALILEO

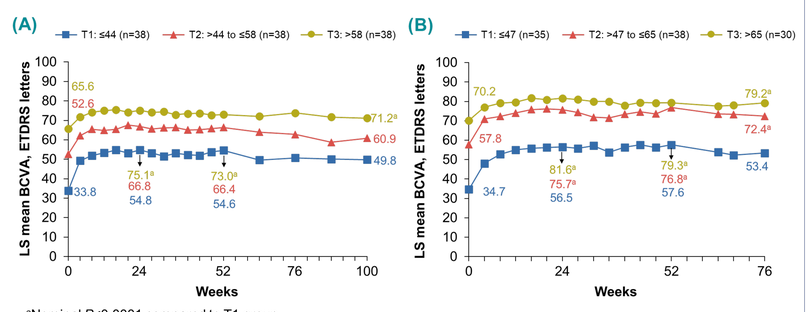


[a]Nominal *P*<0.0001. [b]Nominal *P*=0.0004.

Impact of Baseline BCVA

- In COPERNICUS and GALILEO, patients with worse BCVA at baseline achieved larger increases in BCVA by Week 24, but had worse BCVA by Week 100 and Week 76, respectively, compared with patients in T3 (**Figure 5**)

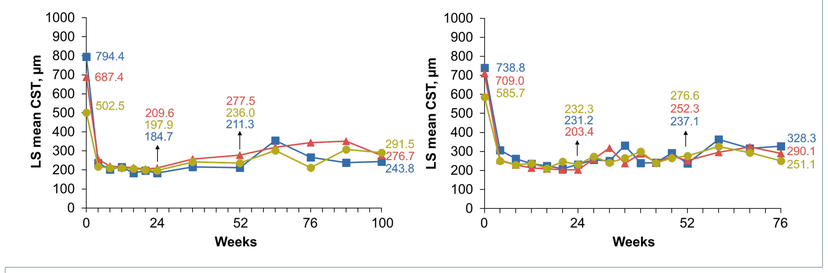
Figure 5. Absolute BCVA Over Time by Baseline BCVA Tertiles in (A) COPERNICUS and (B) GALILEO



[a]Nominal *P*<0.0001 compared to T1 group.

- In both studies, CST values were similar over time for all three baseline BCVA tertiles (**Figure 6**)

Figure 6. Absolute CST Over Time by Baseline BCVA Tertiles in (A) COPERNICUS and (B) GALILEO



CONCLUSIONS

- In patients with MEfCRVO, a delay of >3 months to initiate treatment was associated with less vision gain at Week 52 despite similar improvements in CST
- Patients with worse baseline BCVA showed greater visual improvement, but mean final BCVA was lower versus patients with better baseline BCVA
- These findings can help inform treatment decisions for MEfCRVO and manage physician and patient expectations

REFERENCES

1. Boyer D et al. *Ophthalmology*. 2012;119:1024–1032.
2. Holz FG et al. *Br J Ophthalmol*. 2013;97:278–284.

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