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Retinal Vasculitis With or Without Retinal Vascular Occlusion Among Eyes With nAMD or DME Treated With IVT Agents as Recorded in the Vestrum Database

Shriji Patel, MD, MBA[1]; Gloria C. Chi, PhD[1]; Vaibhavi Patel, BPharm, MSc[2]; Nick Boucher, BSc[3]; Nitika Aggarwal, BTech[4]; Shih-Chen Chang, PhD[1]; Sumit Sharma, MD, FASRS[5]; Manuel Amador, MD[1]; and Marco Zarbin, MD, PhD, FACS[6]

[1] Genentech, Inc., South San Francisco, CA; [2] Roche Products Ltd., Welwyn Garden City, UK; [3] Vestrum Health, Waltham, MA; [4] Vestrum Health, Ottawa, ON, Canada; [5] Cleveland Clinic, Cleveland, OH; [6] Rutgers New Jersey Medical School, Newark, NJ

Contact Email: patel.shriji@gene.com

Objective

To assess incident cases of retinal vasculitis with retinal vascular occlusion among eyes with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME) treated with anti–vascular endothelial growth factor (VEGF) agents as recorded by individual clinicians in routine clinical practice in the US

Conclusions

The percentages of eyes with incident events of retinal vasculitis, retinal vasculitis with retinal vascular occlusion, and intraocular inflammation (including retinal vasculitis) with retinal vascular occlusion were low and similar among eyes treated with faricimab, aflibercept 2 mg, or ranibizumab

A higher percentage of eyes treated with brolucizumab had events compared with other approved anti-VEGF agents

Financial Disclosures

- SP, GCC, S-CC, MA: E) Genentech, Inc.
- VP: E) Roche Products Ltd.
- NB, NA: N)
- SS: C) AbbVie, Bausch, Clearside Biomedical, EyePoint, Genentech/Roche, Regenxbio; F) Allergan, Genentech/Roche, Gilead, Ionis, Santen
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Study Disclosures

- Faricimab is approved for the treatment of neovascular age-related macular degeneration, diabetic macular edema, and retinal vein occlusion in multiple countries worldwide. Faricimab is not currently approved for use outside these indications
- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Trishan Gajanand, PhD, of Envision Pharma Group

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Background

- Anti-VEGF agents are the standard of care for patients with nAMD or DME[1,2]
- Retinal vasculitis, with or without occlusion, is a serious adverse event (AE) that can lead to vision loss[3] and has previously been reported in patients treated with anti-VEGF agents[4,5]
- The US labels for faricimab, ranibizumab, and aflibercept (2 mg and 8 mg) have been amended to include information related to retinal vasculitis, with or without occlusion
- We conducted this analysis of the Vestrum database to improve the understanding of anti-VEGF safety with respect to retinal vasculitis, with or without occlusion, in a real-world setting

Methods

Study Design and Data Source

- Retrospective observational study
- Data sourced from Vestrum Health, which is a database of longitudinal electronic health record data from private retina specialists in the US

Inclusion Criteria

- Eyes diagnosed with nAMD or DME, among patients aged ≥ 18 years, who had received ≥ 1 intravitreal (IVT) anti-VEGF treatment from January 1, 2014, to March 31, 2023, following initial diagnosis

Exclusion Criteria

- Eyes with no visits following the index injection date
- Eyes that had a diagnosis of intraocular inflammation, retinal vasculitis, or retinal vascular occlusion on or prior to index injection

Incident Case Ascertainment and Statistical Analysis

- Three AE types of interest: 1) retinal vasculitis, 2) retinal vasculitis with retinal vascular occlusion, and 3) intraocular inflammation (including retinal vasculitis) with retinal vascular occlusion
- Incident cases for the 3 AE types were assessed separately and were identified using *International Classification of Diseases, 9th/10th Revision, Clinical Modification* diagnosis codes
- Case definitions for retinal vasculitis with retinal vascular occlusion and intraocular inflammation with retinal vascular occlusion required a combination of diagnosis codes, which may have occurred on different dates. The date of the event was considered the date that the complete case definition of both diagnosis codes were met
- Patient eyes were followed up to a maximum of 180 days after each anti-VEGF injection until the first event was ascertained
- Eyes were not followed for any more events after the first event
- AEs were assessed up to September 30, 2023
- The number of events were summarized by n (%) of exposed eyes with events by approved anti-VEGF agents (faricimab, aflibercept 2 mg, ranibizumab, and brolucizumab)
- Events were attributed to the anti-VEGF agent immediately before (but not on) the date of the event

References

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3. Rivera PA et al. *Ther Adv Ophthalmol*. 2023;15:1-12.
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Results

- Overall, 300,940 eyes received 4.27 million injections across all 4 agents

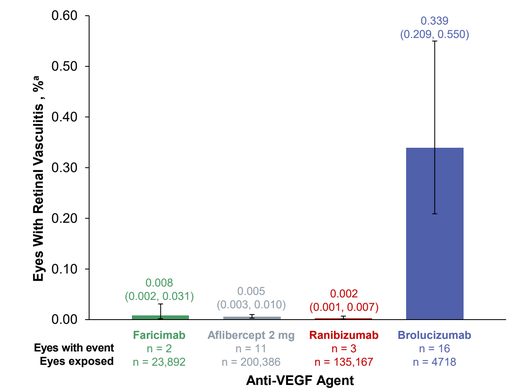
Overview of Events by Anti-VEGF Agent in Eyes With nAMD or DME

Eyes	Faricimab	Aflibercept 2 mg	Ranibizumab	Brolucizumab
Retinal Vasculitis				
Exposed, N	23,892	200,386	135,167	4718
Eyes with event, n	2	11	3	16
Eyes with event, % (95% CI)[a]	0.008 (0.002, 0.031)	0.005 (0.003, 0.010)	0.002 (0.001, 0.007)	0.339 (0.209, 0.550)
Retinal Vasculitis With Retinal Vascular Occlusion				
Exposed, N	23,897	200,389	135,169	4718
Eyes with event, n	0	3	1	3
Eyes with event, % (95% CI)[a]	0.000 (0.000, 0.016)	0.001 (0.001, 0.004)	0.001 (0.000, 0.004)	0.064 (0.022, 0.187)
Intraocular Inflammation (Including Retinal Vasculitis) With Retinal Vascular Occlusion				
Exposed, N	23,889	200,384	135,162	4718
Eyes with event, n	3	50	15	7
Eyes with event, % (95% CI)[a]	0.013 (0.004, 0.037)	0.025 (0.019, 0.033)	0.011 (0.007, 0.018)	0.148 (0.072, 0.306)

[a] 95% CIs calculated using the Wilson score interval for binomial confidence limits.
CI, confidence interval; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

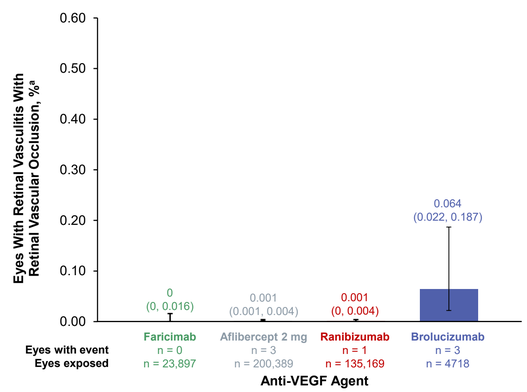
Percentage of eyes with events for faricimab, aflibercept, and ranibizumab were comparable, whereas brolucizumab exhibited a higher percentage

Percentage of Eyes With Retinal Vasculitis by Anti-VEGF Agent in Eyes With nAMD or DME



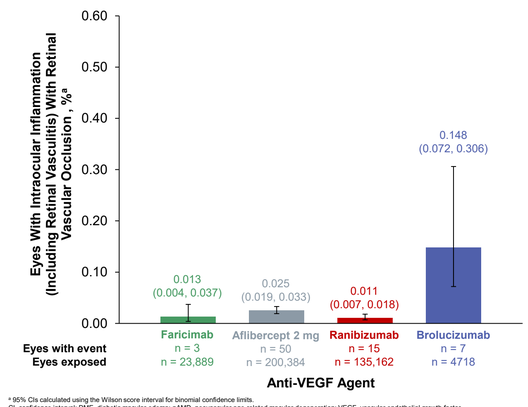
[a] 95% CIs calculated using the Wilson score interval for binomial confidence limits.
CI, confidence interval; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

Percentage of Eyes With Retinal Vasculitis With Retinal Vascular Occlusion by Anti-VEGF Agent in Eyes With nAMD or DME



[a] 95% CIs calculated using the Wilson score interval for binomial confidence limits.
CI, confidence interval; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

Percentage of Eyes With Intraocular Inflammation (Including Retinal Vasculitis) With Retinal Vascular Occlusion by Anti-VEGF Agent in Eyes With nAMD or DME



[a] 95% CIs calculated using the Wilson score interval for binomial confidence limits.
CI, confidence interval; DME, diabetic macular edema; nAMD, neovascular age-related macular degeneration; VEGF, vascular endothelial growth factor.

Discussion

- Faricimab is approved in > 90 countries with > 2 years of postmarketing experience in the US
- As of March 2024, > 3 million vials of faricimab have been distributed globally, and the faricimab benefit/risk profile remains favorable
- Patient safety is a top priority for Roche
- Roche evaluates all postmarket cases, consistent with the safety reporting processes, and will continue to monitor for and report AEs to health authorities and the medical community

Limitations

- Sample sizes differ between agents, with smaller sample sizes leading to wider 95% confidence intervals
- Estimates may have been affected by surveillance bias
- Identified AEs were not validated through individual case review
- Analyses did not account for varying duration of exposure for eyes
- Analyses did not account for correlation between eyes if they were from the same patient
- Misclassification of events to agents could occur if eyes received multiple agents
- Events may be underreported or misclassified in electronic health records
- Limited generalizability to eyes seen at practices outside of the US or in nonprivate settings