Incidence of Intraocular Inflammation Following Intravitreal Aflibercept Prefilled Syringe and Vial Injections in US Clinical Practice

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Presented at the American Society of Retina Specialists (ASRS) Annual Meeting, July 28–August 1, 2023

Disclosures

- David M. Brown serves as a scientific advisor for Regeneron/Bayer and Genentech/Roche and as a member of the Regeneron Combination Products Steering Committee
- This study was sponsored by Regeneron Pharmaceuticals, Inc. (Tarrytown, NY). The sponsor participated in the design and conduct of the study, analysis of the data, and preparation of this presentation
- Study disclosures: Institutional review board approval was not required given that this study included anonymized patient data only
- Writing assistance by Stephanie Agbu, PhD, of Regeneron Pharmaceuticals, Inc., is acknowledged

Background and Purpose

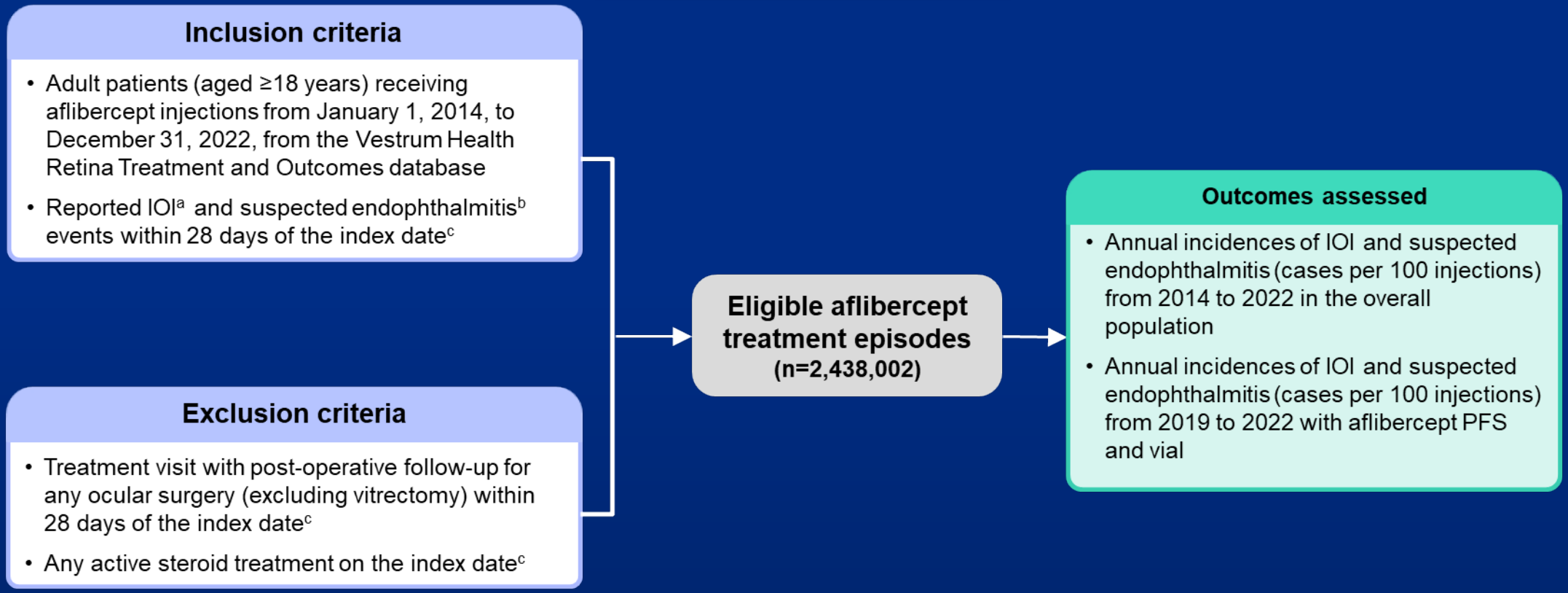
- IOI is an infrequent complication of intravitreal anti-VEGF injections that may be associated with substantial visual impairment[1,2]
- PFS provide ease of injection and require fewer preparation steps than vials,[3,4] potentially decreasing the risk of contamination and IOI following intravitreal anti-VEGF injection[5,6]
- A number of observational studies in ranibizumab-treated patients have suggested that the incidence of endophthalmitis may be lower with PFS compared with vials[5-8]
- Similarly, a post-marketing surveillance analysis showed that incidences of IOI and endophthalmitis outside the US may be lower with aflibercept PFS compared with vials[9]

This observational cohort study evaluated incidences of IOI and suspected endophthalmitis following intravitreal aflibercept injections administered from PFS and vials in US clinical practice

IOI, intraocular inflammation; PFS, prefilled syringes; VEGF, vascular endothelial growth factor.

1. Anderson WJ et al. *Int J Retina Vitreous*. 2021;7(1):37. 2. Fine HF et al. *Retina*. 2015;35(4):681-686. 3. Souied E et al. *Eur J Ophthalmol*. 2015;25(6):529-534. 4. Sassalos TM et al. *Clin Ophthalmol*. 2019;13:701-706. 5. Storey PP et al. *Am J Ophthalmol*. 2019;199:200-208. 6. Baudin F et al. *JAMA Ophthalmol*. 2018;136(12):1352-1358. 7. Pancholy M et al. *Curr Eye Res*. 2021;46(9):1370-1377. 8. Dhoot DS et al. *Ophthalmic Surg Lasers Imaging Retina*. 2021;52(6):312-318.; 9. Schmidt-Ott U et al. *Clin Ophthalmol*. 2023;17:385-390.

Study Design



[a]IOI events were identified using ICD-9 or ICD-10 diagnosis codes that included but were not limited to ophthalmia nodosa, iridocyclitis, cyclitis, panuveitis, pars planitis, sympathetic uveitis, vitreous abscess, vitreous disorders, and endophthalmitis.
[b]Suspected endophthalmitis cases included infectious and non-infectious endophthalmitis and were identified using ICD-9 or ICD-10 diagnosis codes that were based on published literature and ophthalmologist review.
[c]Date of aflibercept injection.
ICD, International Classification of Diseases.

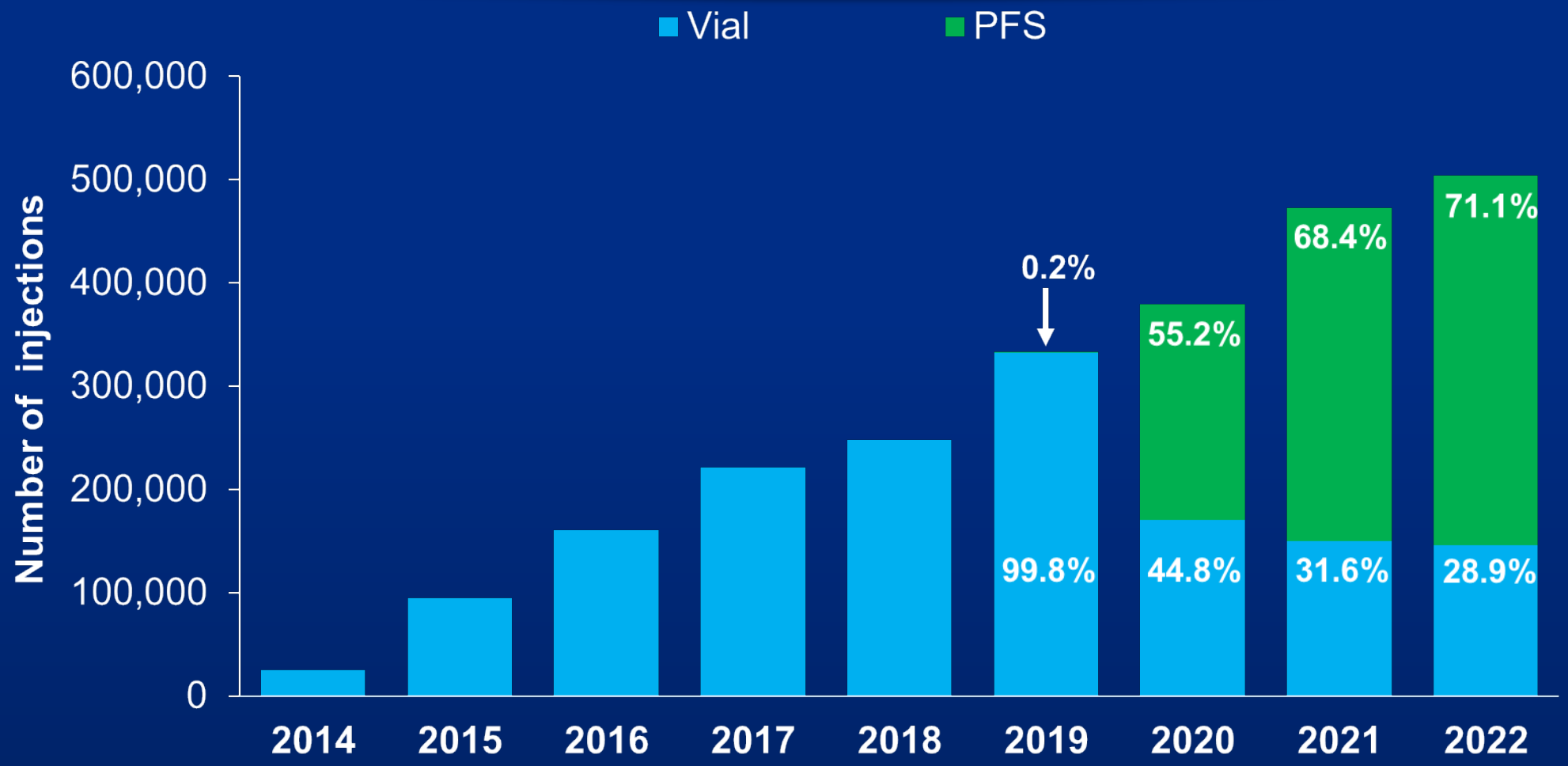
Patient Characteristics, Aflibercept Treatment Patterns, and IOI Cases

Characteristics of Patients Receiving Aflibercept Injections From 2014–2022

	Patients[a] (N=168,572)
Female, n (%)	91,136 (54.1)
Age, mean (SD), years	71.6 (13.3)
Indications, n (%)	
nAMD	79,845 (47.4)
DME	48,505 (28.8)
RVO	26,480 (15.7)
Other	8881 (5.3)
DR	4861 (2.9)
Follow-up time, n (%)	
<12 months	66,697 (39.6)
12+ months	101,875 (60.4)
24+ months	70,987 (42.1)
36+ months	49,413 (29.3)
48+ months	32,528 (19.3)
60+ months	21,211 (12.6)
Aflibercept injections per patient, mean (SD)	13.8 (16.3)
Duration of treatment[b], mean (SD), months	20.3 (22.0)

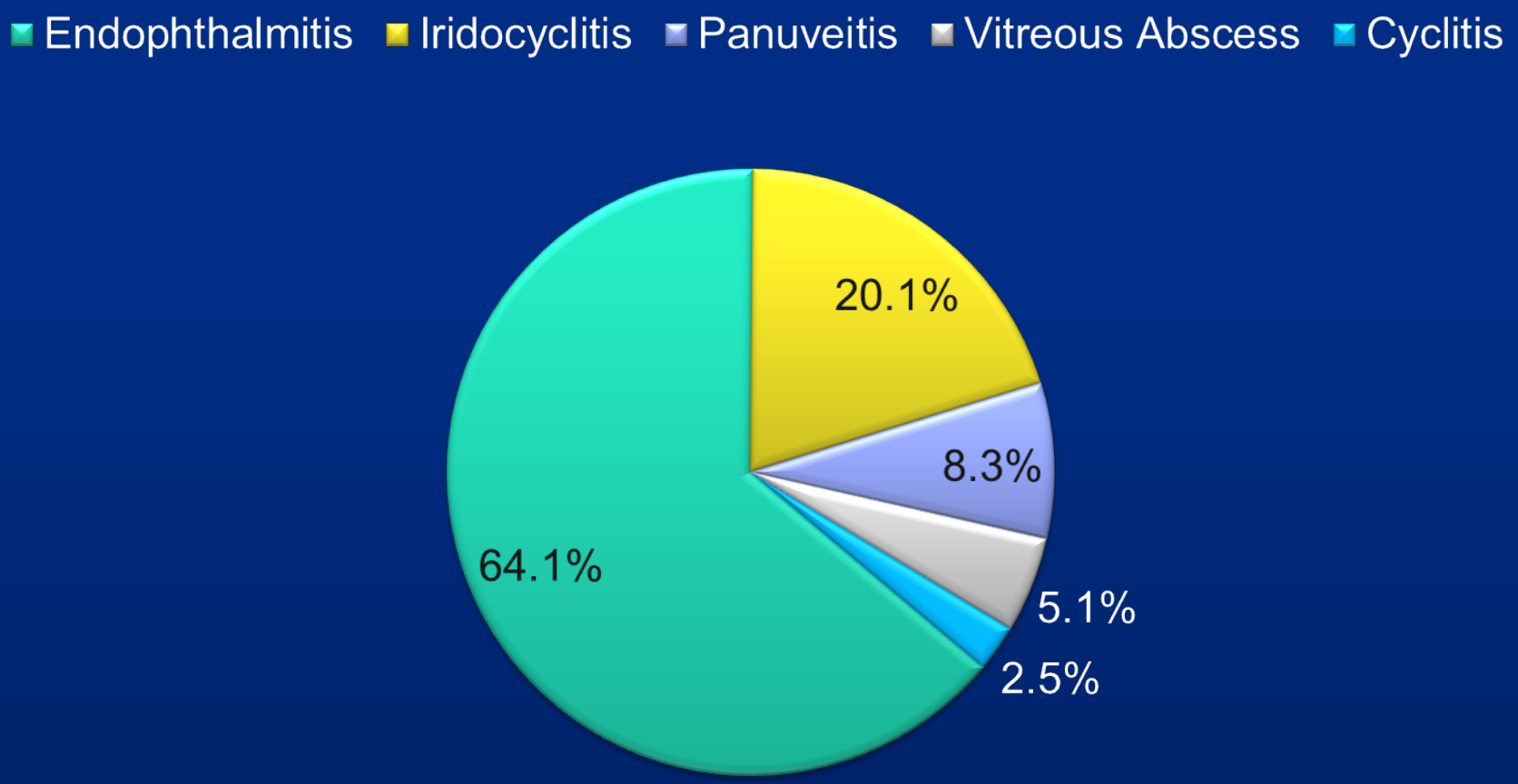
[a]Patients were administered a total of 2,438,002 aflibercept injections.
[b]Time between first and last aflibercept injection irrespective of any treatments that occurred between both treatments.
DME, diabetic macular edema; DR, diabetic retinopathy; nAMD, neovascular age-related macular degeneration; RVO, retinal vein occlusion.

Number of Administered Aflibercept Injections From Aflibercept PFS[a] and Vial, 2014–2022



[a]Aflibercept PFS were introduced in December 2019.

IOI Cases From 2014–2022

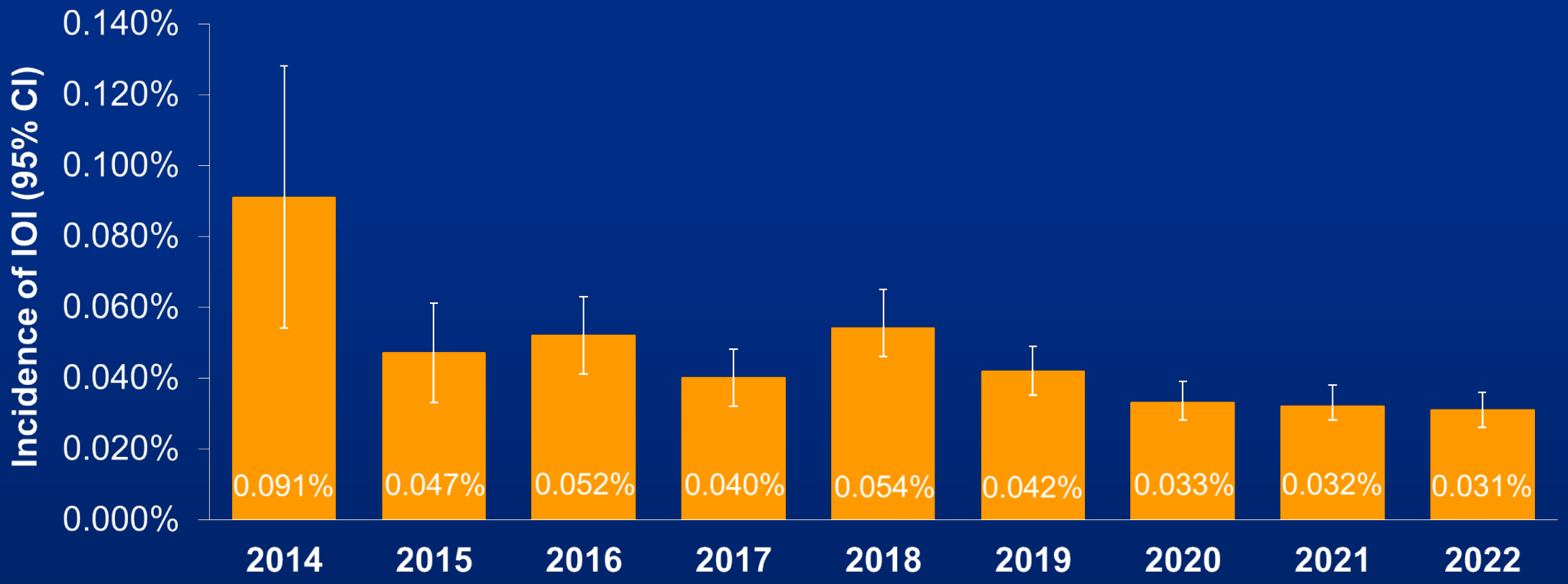


N=946 IOI cases[a]

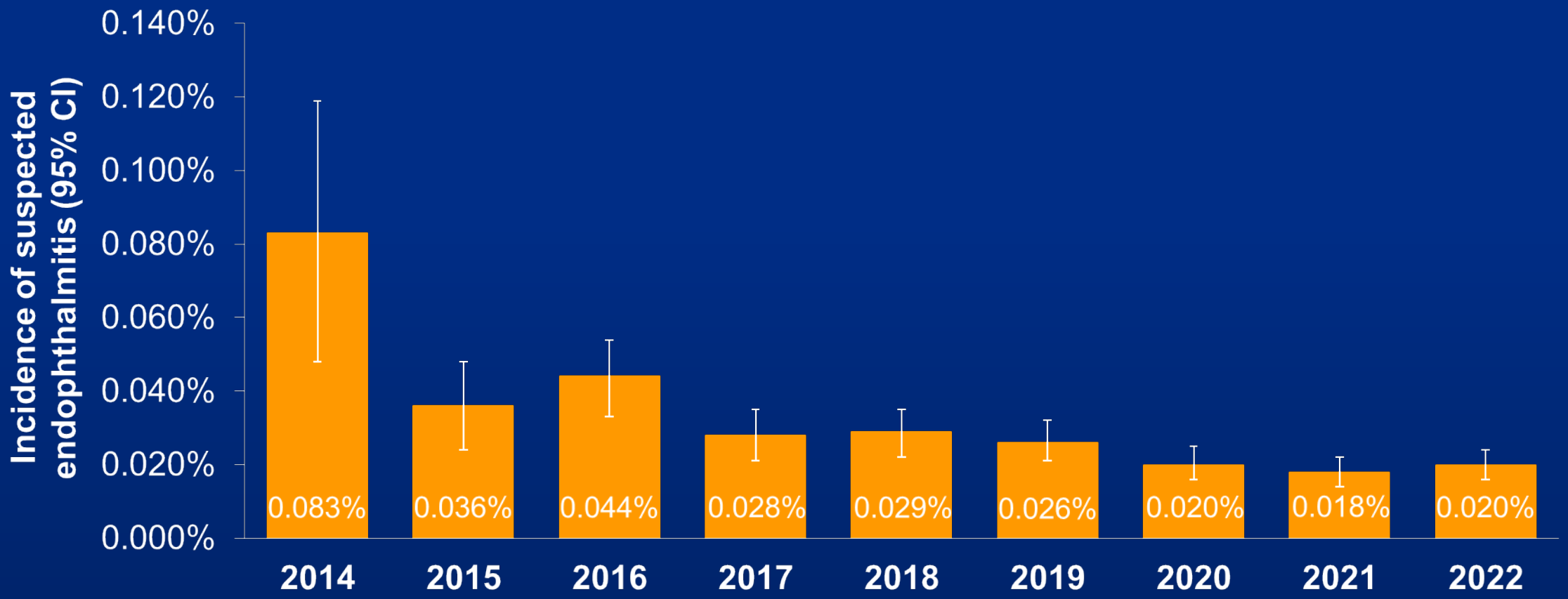
[a]A total of 2,438,002 aflibercept injections were evaluated.

Annual Incidences of IOI and Suspected Endophthalmitis From 2014–2022

Annual Incidence of IOI Following Aflibercept Injection From 2014–2022

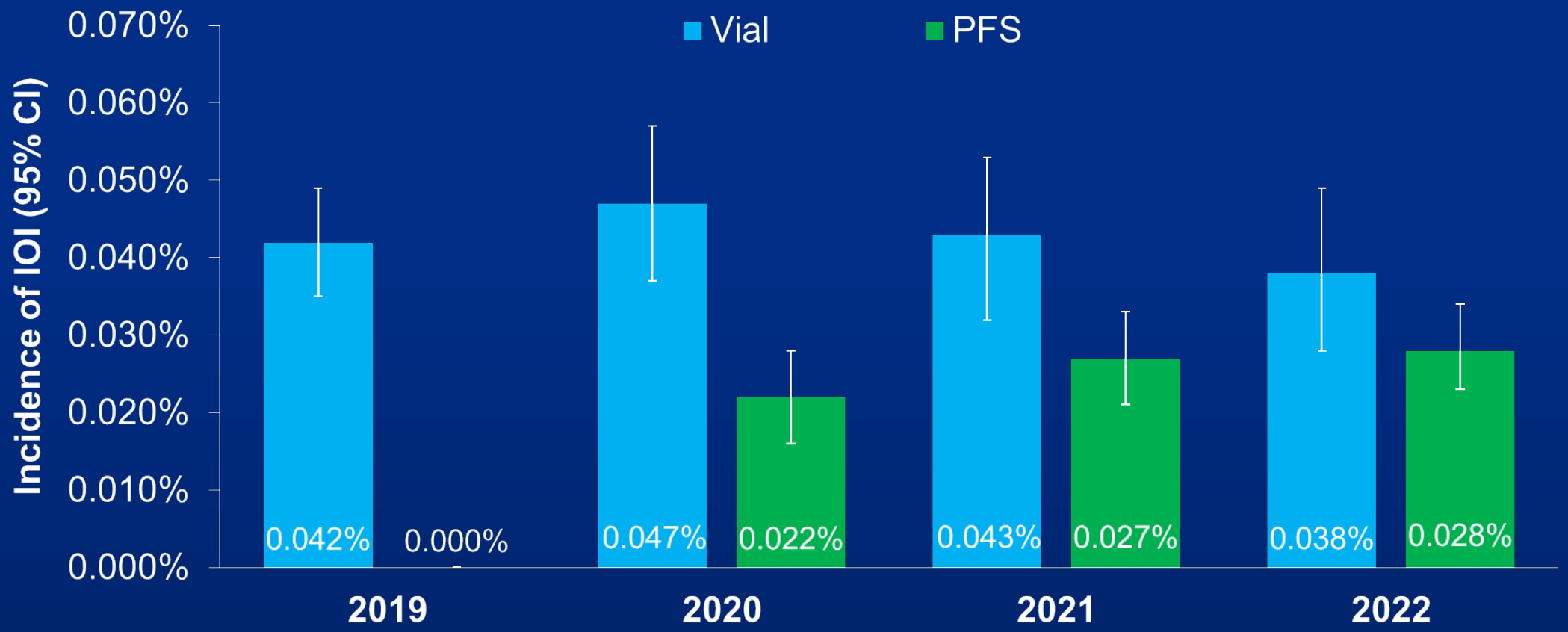


Annual Incidence of Suspected Endophthalmitis Following Aflibercept Injection From 2014–2022



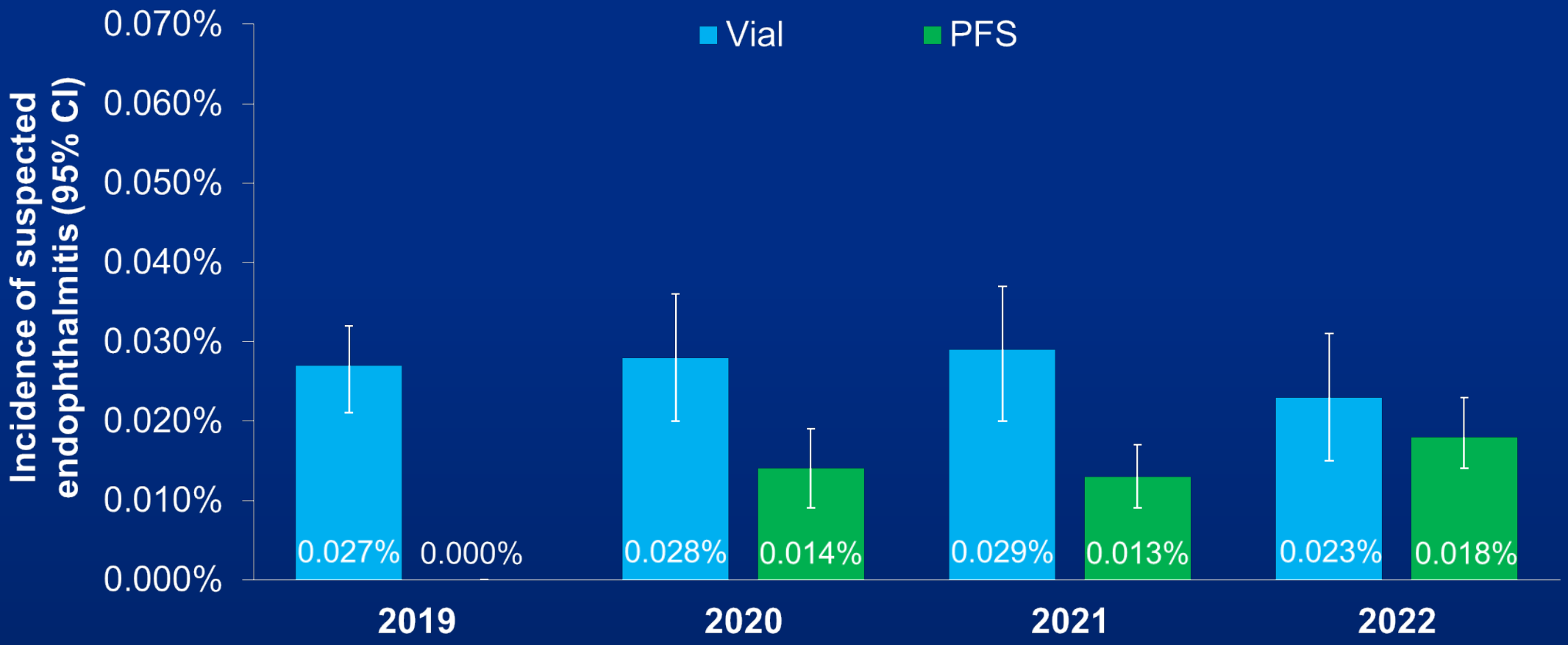
Annual Incidences of IOI and Suspected Endophthalmitis by Aflibercept PFS and Vial From 2019–2022

Annual Incidence of IOI With Aflibercept PFS[a] and Vial From 2019–2022



[a]Aflibercept PFS were introduced in December 2019.

Annual Incidence of Suspected Endophthalmitis With Aflibercept PFS[a] and Vial From 2019–2022

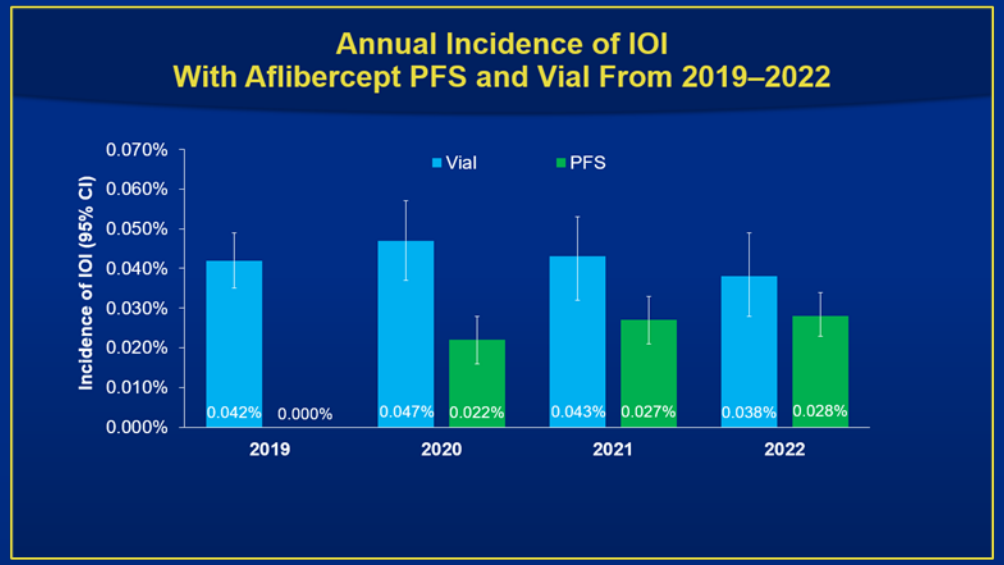


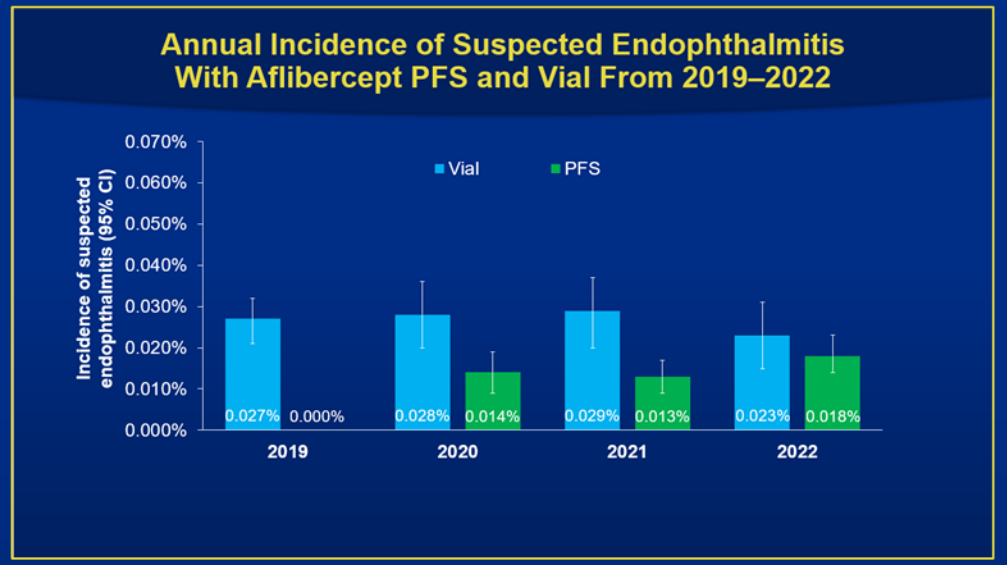
[a]Aflibercept PFS were introduced in December 2019.

Limitations

- The distinction between culture-positive and sterile endophthalmitis was not possible based on available data
- Factors underlying differences in the incidences of IOI and suspected endophthalmitis between aflibercept PFS and vials were not identified

Conclusions





- Overall incidences of IOI and suspected endophthalmitis following intravitreal aflibercept injection decreased from 2014 to 2022
- Incidences of IOI and suspected endophthalmitis were lower with PFS than with vials in 2020 and 2021, with no conclusive difference in 2022
- Further studies are warranted to identify factors that may be associated with observed trends in the incidences of IOI with aflibercept PFS and vials