



BACKGROUND AND IMPORTANCE

Sterile intraocular inflammation (SII) is a known complication of therapeutic intravitreal injections, particularly with all anti-vascular endothelial growth factor drugs. These events occur sporadically but there has been a sustained increase in the number of reported cases due to aflibercept¹.

AIM AND OBJECTIVES

To analyze the appearance of SII in patients with intravitreal aflibercept.

MATERIAL AND METHODS

Descriptive observational study of patients with SII after intravitreal aflibercept reported from **August-November 2021**.



Data collected

Sex, age, eye, pathology, pre-treatment, total doses and batch of aflibercept, time to presentation and description of symptoms, best-corrected visual acuity (BCVA) prior to last dose, after the onset of symptoms and at six months of follow-up.

Patients treated bilaterally were counted as two treatments.

RESULTS

SII was observed in 14 patients of the 110 patients treated (12.7%). 17 eyes were treated.

SEX	Females 57%. Males 43%
MEAN AGE	78.9 ± 8.3 years
RETINAL PATHOLOGY	Neovascular age-related macular degeneration 85.8% Diabetic macular oedema 7.1%. Branch retinal vein occlusion 7.1%
EYE TREATED	Right 28.6%. Left 50.0%. Bilateral 21.4%
PREVIOUS TREATMENTS	Patients previously received ranibizumab, bevacizumab and an average of 11 doses of aflibercept . All doses were from batch KT09625.
SYMPTOMS	Mean time to presentation symptoms was 22 days . Myodeopsis, precipitation in the vitreous with crystals of aspect of "starry sky", vitreous inflammation and decrease of the BCVA. No patient presented infectious endophthalmitis and one required vitrectomy
Mean BCVA (logMar)	Prior to last dose: 0.57±0.42 logMAR After the onset of symptoms: 0.56±0.27 logMAR To the six months : 0.66±0.39 logMAR

All adverse effects were reported to the Spanish Pharmacovigilance System, manufacturer laboratory of aflibercept and Drug Inspection and Control Department of the Spanish Agency for Medicines and Medical Devices.



CONCLUSIONS

- SII is associated with intravitreal antiangiogenic drugs, especially with aflibercept¹. However, the sudden onset of symptoms alerted the Ophthalmology Department.
- It was initially suspected to be related to the batch of aflibercept, but the results are inconclusive.
- After the appearance of symptoms, the clinic was important, without showing a sharp decrease in BCVA.
- Long-term monitoring of these patients is necessary to assess the resolution of the inflammation.
- Multidisciplinary pharmacovigilance coordination is crucial for the detection of known or unexpected adverse effects.

REFERENCES

1. Greenberg JP, Belin P, Butler J, Feiler D, Mueller C, Tye A, Friedlander SM, Emerson GG, Ferrone PJ; Aflibercept Sterile Inflammation Research Group. Aflibercept-Related Sterile Intraocular Inflammation Outcomes. *Ophthalmol Retina*. 2019 Sep;3(9):753-759. doi: 10.1016/j.oret.2019.04.006. Epub 2019 Apr 11. PMID: 31153850.