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LETTER

Impact of injection therapy on retinal patients with diabetic macular edema or retinal vein occlusion

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John Hall

Alimera Sciences Ltd., Aldershot, Hampshire, UK

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Dear editor

I read "Impact of injection therapy on retinal patients with diabetic macular edema or retinal vein occlusion" published in May 2016 by Sobha Sivaprasad and Sesan Oyetunde. The article is extremely important as it explains why short- and long-acting corticosteroids are so important in reducing intravitreal injections in clinic practices and the number of visits to the clinic. The authors present a valid point that this can be achieved with no impact on visual outcomes in diabetic macular edema (DME) and retinal vein occlusion. However, having read the article in detail, I would like to raise two important oversights that the authors have failed to address and are potentially misleading, and these are highlighted in the following section.

Iluvien® (fluocinolone acetonide [FAc] implant, 0.2 µg/day; Alimera Sciences, Alpharetta, GA, USA) is a long-acting corticosteroid that delivers FAc for up to 3 years.[1] The effectiveness of FAc implant was demonstrated in the FAME trials (NCT00344968; https://ClinicalTrials.gov/), where patients with DME who showed an insufficient response to laser were then treated with a 0.2 µg/day implant and compared with sham-control treated patients.[2] The FAME trials met their primary end point and showed that significantly more patients with chronic DME treated with the 0.2 µg/day FAc implant experienced a ≥15-letter improvement in visual acuity at month 24 than sham-control patients (34.4% vs 13.4%; $P<0.001$) and that this benefit was sustained to month 36. The trial results led to the approval of FAc implant for the treatment of vision impairment associated with chronic DME, considered insufficiently responsive to available therapies.[3] The authors have described the prior therapies as "anti-VEGF agents, other corticosteroids, or laser," but the prior therapy in the FAME trials was laser, which has now largely been replaced by the first-line use of intravitreal anti-VEGF injections. Hence, the indication in the Summary of Product Characteristics (SmPC)[3] for FAc implant refers to the current standard of care in clinical practice, which is now considered to be anti-VEGF.

The second point relates to the number of injections. The authors state that "The number of intravitreal injections required with anti-VEGFs is greater than that with corticosteroids, such as Ozurdex® (0.7 mg dexamethasone; Allergan, Inc., Irvine, CA, USA) and FAc implant (FAc; Alimera Sciences), and the injection regimen associated with anti-VEGF efficacy in clinical trials (7–12 injections/year) may be difficult to achieve in clinical practice." However, the authors did not clarify the different number of injections needed for a short-acting corticosteroid, such as dexamethasone, and

Correspondence: John Hall
Alimera Sciences Ltd., Royal Pavilion, Wellesley Road, Aldershot, Hampshire GU11 1PZ, UK
Tel +44 1252 354 036
Fax +44 1252 354 012
Email john.hall@alimerasciences.com

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a long-acting one, such as FAc. A number of studies have recently reported the duration of action of dexamethasone (Stewart et al[4]). Over a 3-year period, the mean number of injections reported in the MEAD trial was 4.1,[5] but given the duration of action being reported to be anywhere between 3 and 6 months,[4,6] the injection number would be expected to be higher in real-world clinical usage. Although the SmPC[6] does state "There is currently no experience of the efficacy or safety of repeat administrations in DME beyond 7 implants." In contrast, the FAME trials showed that over a 3-year period, 76.1% of patients required one implant, 18.7% required two implants, and 5.3% required ≥3 implants.[2] The duration of action is important as this relates back to the conclusions made by the authors and the impact of multiple injections. A point well made in the article where it is stated that the "Patients' quality of life is clearly very affected by having to manage an intensive intravitreal injection regimen, with a considerable treatment burden having a large negative effect."

These two points need to be highlighted to the reader as they are relevant to the marketed products in Europe. I would like to point the reader to a number of papers that have been published on the pharmacokinetic, pharmacodynamic, and safety profile of FAc implant.[1,2] The reader can also access the SmPC which is available online.[3]

Disclosure

The author reports no conflicts of interest in this communication.

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