Real-world safety and efficacy of 0.19 mg fluocinolone acetonide intravitreal implant in the management of recurrent non-infectious uveitis

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Real-world safety and efficacy of 0.19 mg fluocinolone acetonide intravitreal implant in the management of recurrent non-infectious uveitis

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Introduction

The 0.19 mg fluocinolone acetonide intravitreal implant (Iluvien®) was recently approved in several European countries for the treatment of recurrent non-infectious uveitis affecting the posterior segment of the eye (NIU-PS). The device releases a continuous low dose of corticosteroid into the vitreous for up to 36 months and thus offers a systemic therapy-sparing treatment option. Clinical trial data have shown promising efficacy and an acceptable safety profile[1]. Real-world studies are now starting to emerge, supplementing clinical trial results by providing valuable data on outcomes in everyday clinical practice.

Aim

To review the current landscape of real-world evidence on the use of Iluvien® for the treatment of recurrent NIU-PS in terms of:

1) Efficacy outcomes (macular edema, visual acuity, recurrences)
2) Safety outcomes (intraocular pressure, need for cataract surgery, other)

Methods

Systematic literature review adhering to PRISMA guidelines. Searches were carried out in PubMed, EMBASE and Web of Science from database inception until 2nd July 2022.

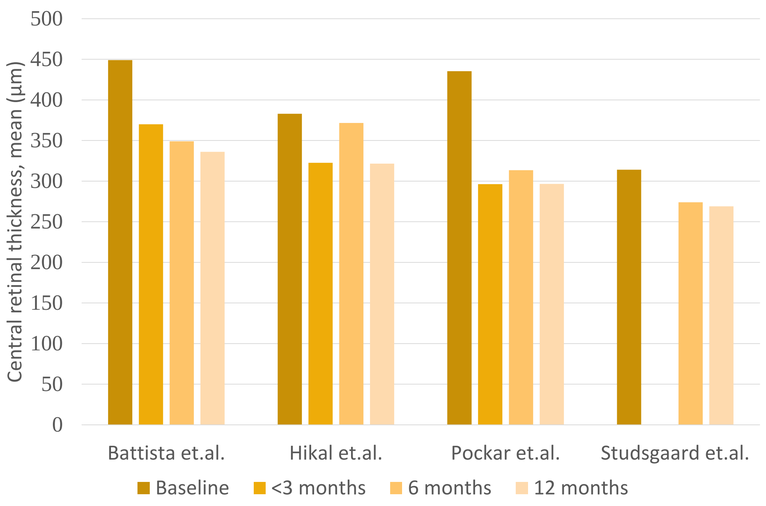
Results

6 real-world studies were eligible for inclusion, comprising a total of 91 patients (113 eyes)[2,3,4,5,6,7]. A seventh eligible study was identified, but data overlapped with the findings of another included study (Hikal et.al) and were therefore excluded[8]. Below, we present preliminary results from the systematic review.

Uveitic macular edema (UME)

An improvement in mean or median central retinal thickness (CRT) was observed in all studies within the first year after Iluvien® implantation.

Figure 1. Four of six studies provided data on mean central retinal thickness at baseline and during the first year of treatment



The studies by Hikal et.al. and Studsgaard et.al. provided data beyond the first year; improvements in mean CRT were sustained at 36 and 24 months, respectively.

The remaining studies not presented in Figure 1:

1) Kriegel et.al.: median CRT
At baseline: 455 µm
At 3 months follow-up: 345 µm (p=0.0008)

2) Ajamil-Rodanes et.al. (birdshot chorioretinitis only): 3 patients had UME at baseline, which resolved in all patients after injection of Iluvien®. There were no UME recurrences during 36 months of follow-up.

Visual acuity (VA)

In all included studies, mean or median visual acuity was either stable or improved within the first year after Iluvien® implantation.

Table 1. Four of six studies provided data on mean VA (logMAR) at baseline and during the first year of treatment

	Baseline	<3 months	6 months	12 months
Ajamil-Rodanes et.al.	0.16	0.17	0.15	0.15
Battista et.al.	0.67	0.54	0.51	0.45
Pockar et.al.	0.48	0.40	0.49	0.45
Studsgaard et.al.	0.38	NA	0.23	0.21

The remaining studies not presented in Table 1:

1) Kriegel et.al.: median VA (logMAR)
At baseline: 0.52
At 3 months follow-up: 0.40 (p=0.0005)

2) Hikal et.al.: 58.5% of eyes improved VA, 26.5% remained stable and 14.7% experienced worsening of VA (measured as maximal change of VA during follow-up).

Recurrence rates

Table 2. Proportion of eyes in each study with relapse of UME

	Follow-up	UME relapse
Ajamil-Rodanes et.al.	Up to 36 months	0 of 3 eyes (0%)
Battista et.al.	12 months	0 of 10 eyes (0%)
Hikal et.al.	Up to 60 months	5 of 34 eyes (14.7%)
Kriegel et.al.	3 months	0 of 23 eyes (0%)
Pockar et.al.	12 months	2 of 11 eyes (18.1%)
Studsgaard et.al.	Up to 24 months	4 of 14 eyes (28.6%)

Intraocular pressure (IOP)

A minority of patients required IOP lowering treatment after injection of Iluvien® (see Table 3). Most were glaucoma patients or patients with a history of steroid induced ocular hypertension.

Figure 2. Five of six studies provided data on mean IOP at baseline and during the first year of treatment

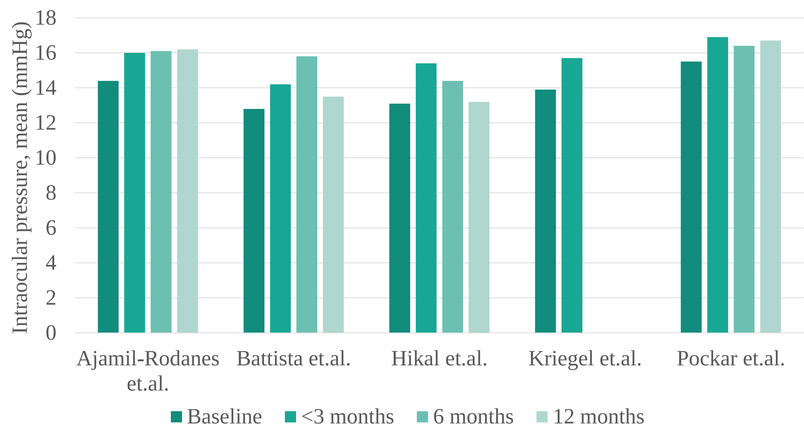


Table 3. Number of eyes that required additional IOP lowering treatment after injection of Iluvien®, some only temporarily

Study	Topical	Systemic carbon anhydrase inhibitor	Surgery
Ajamil-Rodanes et.al.	5 (33.3%)	0	0
Battista et.al.	1 (10%)	0	0
Hikal et.al.	3 (8.8%)	0	0
Kriegel et.al.	1 (4.3%)	0	0
Pockar et.al.	1 (9,1%)	0	0
Studsgaard et.al.	0	2 (10%)	2 (10%)

Other safety outcomes

14 of 15 phakic eyes with a clear lens at baseline developed cataract during follow-up. 1 study did not report on lens status[3].
Hypotony: 3 eyes
Retinal detachment: 1 eye (3 months after Iluvien® injection)
No other adverse events were reported

Conclusion

The currently existing real-world data support that Iluvien® is an effective treatment for achieving quiescence in uveitic activity in a selected group of patients with recurrent NIU-PS. Overall, Ilvuien® improved mean or median CRT, visual acuity (mean or median) was either stable or improved, recurrence rates were low and the treatment generally reduced the need for systemic therapy. Adverse effects were manageable (increased IOP, cataract formation, hypotony). Retinal detachment occurred in 1 patient 3 months after injection of Iluvien®. Cataract formation should be expected following Iluvien® implantation. The reported real-world data are overall in accordance with clinical trial findings[1].
More real-world evidence is needed to support the above findings. There is especially a need for data with long-term follow-up.

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