Early real-world experience with the 0.2 µg/day fluocinolone acetonide (FAc; ILUVIEN®) implant in non infectious uveitis affecting the posterior segment of the eye (NIU-PS)

Bradford Teaching Hospitals NHS Foundation Trust

H Devonport, Bradford Teaching Hospitals NHS Foundation Trust

Contact helen.devonport@bthft.nhs.uk

Background Recurrent intraocular inflammation in non-infectious uveitis can result in cumulative damage associated with significant visual morbidity.

Systemic corticosteroid and immunosuppressive therapies are a mainstay of treatment, but are associated with systemic side effects. Local corticosteroid delivery with the intravitreal dexamethasone implant (Dex) can reduce systemic burden, but chronic or recurrent uveitis, requires repeated treatments. The fluocinolone acetonide implant, ILUVIEN, is a long acting corticosteroid implant that reduces recurrent inflammatory episodes with fewer procedures. **ILUVIEN is licenced for the prevention of relapse of recurrent NI Uveitis affecting posterior segment**

Aim To evaluate the efficacy and safety of the ILUVIEN implant in patients with NIU affecting the posterior segment, in a real-world NHS setting

Methods A Retrospective, observational study. Data collected from electronic medical records of all patients treated with ILUVIEN for NIU at Bradford Teaching Hospitals from March 2019 to December 2020. OCT monitoring was carried out using the Heidelberg SPECTRALIS® The impact on disease recurrence* and overall treatment burden was evaluated, alongside intraocular pressure (IOP) events.

*Recurrences were calculated according to the following criteria; ≥ 2 grade increase in vitreous haze score; or ≥ 2 grade increase in A/C cells; or ≥ 15 letter loss of VA; or a 20% increase in central foveal thickness; or any escalation in treatment, other than when specifically identified as not related to NIU-PS

Results: *Baseline Characteristics*

- **24 eyes of 18 patients received ILUVIEN, 14 females and 4 males, mean age 48.9 years ±19.4**
- **Mean disease duration at baseline was 84.5 months ±67.0**
- **21/24 (87.5%) eyes were quiet at baseline (0/0.5+ AC or Vitreous activity)**
- **17 eyes (70.8%) were pseudophakic**

Results: *Baseline Characteristics*

- **All eyes previously treated with Dex. Mean of 6.6 implants ±7.1 range 1-25**
- **Mean interval from Dex. to ILUVIEN was 70.1 days ± 21.2**
- **8 diagnostic subtypes (*table 1*.)**

Idiopathic	11 (45.8%)	TINU	1
TB	4 (1 bilateral)	Serpiginous	1
C-ANCA Vasculitis	2 (bilateral)	Seronegative arthritis	1
Retinitis Pigmentosa (RP)	3 (1 bilateral)	B27 Ankylosing spondylitis	1

Table 1. No. of eyes per diagnostic subtype

Results: *Efficacy*

During a mean follow-up of 387.1 days (176.6), range 28-636,

- **16 of 24 eyes (66.7%) had no recurrence of inflammation**
- **87.5% of the eyes which were pseudophakic at baseline** (n=17) **gained (37.5%) or maintained (50%) visual acuity**
- **7 eyes (29.2%) had their systemic treatment reduced or stopped** (*table 2*)
- **Need for systemic therapy was reduced from 50.0% to 37.5% of eyes**
- **50% fewer eyes required systemic corticosteroid**

		Pre ILIVIEN	Post ILUVIEN
Systemic Treatment	Corticosteroid	10(41.7%)	5(20.8%)
	Immunosuppressant	10(41.7%)	8(33.3%)
	TNFα	5(20.8%)	5(20.8%)
Total Systemic Treatment Burden	1xSystemic Therapy	2(8.3%)	3(12.5%)
	2xSytemic Therapies	6(25%)	4(16.7%)
	3xSytemic Therapies	4(16.7%)	2(8.3%)
	No systemic Therapy	12(50%)	15(62.5%)

Table 2. Systemic therapy pre and post ILUVIEN

Results: *Efficacy*

- **The mean interval between intravitreal Dex. implants was increased from 115.4 days pre ILUVIEN to 317.6 days post ILUVIEN.**

Results: *Efficacy*

- **8 of 24 eyes (33.3%) had a mean number of 1.6 ± 0.7 recurrences. Mean time to first recurrence was 191.0 days ± 92.0**
- **The mean time to treatment escalation was 240.2 days ±91.3**
- **4 eyes (16.7%) received new/increased treatment: intravitreal x 4 eyes, of which 3 also had new/increased systemic treatment**
- **4 eyes required a mean of 1.8 Dex. Implants (range 1-2) and mean interval from ILUVIEN implant to Dex implant was 268.5 days ±108**

Results: *IOP Events*

At baseline, 21 eyes (87.5%) had a history of a prior IOP rise, 8 (33%) were on active IOP lowering drops and 4 eyes (16.7%) had undergone prior glaucoma surgery.

Post ILUVIEN 9 eyes (37.5%) required new or increased IOP lowering therapy. IOP changes shown in *table 3*

Increase of ≥ 10mmHg	4 (16.7%)
Δ to IOP ≥ 25mmHg	6 (25.0%)
Δ to IOP ≥ 30mmHg	2 (8.3%)

Table 3 No. of eyes with Post ILUVIEN IOP rise

Mean time to peak IOP was 144.8 days ±124.6
Only 1 eye required IOP lowering surgery

Conclusions: Early real-world experience in NIU-PS suggests ILUVIEN may help reduce inflammatory episodes and treatment burden in this intensively treated group of patients. This study included patients with treated TB, those on IOP lowering therapy and patients with RP associated cystoid macula oedema who would have been excluded from RCTs, despite this, vision was largely maintained or improved, with fewer treatments and no new safety signals were identified. Disease progressed in the eye with serpiginous choroiditis, suggesting a lack of efficacy in pure choroidal disease.

More eyes and longer follow up are required for meaningful comparison of benefits in different subtypes of Uveitis.

Special thanks to Yvonne Imrie for help with data analysis