SCIENTIFIC REPORT

Photographic estimation of the duration of high dose intravitreal triamcinolone in the vitrectomised eye

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Aim: To determine the duration of residence of triamcinolone in the vitrectomised eye.

Methods: 23 eyes of 23 patients underwent intravitreal injection of high dose (20 mg) decanted triamcinolone acetonide (Kenalog) at the conclusion of vitrectomy surgery or in previously vitrectomised eyes with macular oedema from diabetes, uveitis, cataract surgery, or other surgery.

Results: The median time to disappearance of triamcinolone in the vitrectomised eye was 113 days (95% confidence interval (CI) 85 to 191). In the phakic eyes the median time to disappearance was 191 days (95% CI 148 to 191). In the pseudophakic eyes the median time to disappearance was 102 days (95% CI 85 to 113). This difference was not significant ($p=0.12$). There were no cases of endophthalmitis or severe inflammatory reaction. Five eyes (22%) experienced intraocular pressure rise ≥ 10 mm Hg.

Conclusions: High dose decanted intravitreal triamcinolone has a median residence time of 113 days in the vitrectomised eye. Although this appears to be shorter than in the non-vitrectomised eye, this study suggests that a sufficient duration of action will be present to be clinically useful.

The standard of care for initial treatment of macular oedema secondary to inflammatory ocular disease has been posterior sub-Tenon's injection of repository corticosteroids (methylprednisolone in polyethylene glycol, triamcinolone, betamethasone).^{1,2} Recently, intravitreal administration of corticosteroids via direct trans pars plana injection of triamcinolone acetonide has received much attention in the ophthalmic literature. The earliest experimental work by Peyman^{3–5} and associates, and later Machemer^{6–9} and associates, served as the foundation for the present clinical use of intravitreal triamcinolone. Important milestones in the early clinical use of intravitreal triamcinolone were its application in exudative macular degeneration. Penfold¹⁰ and Challa¹¹ and associates reported the earliest clinical trial involving a 4 mg intravitreal triamcinolone injection for exudative age related macular degeneration (ARMD). Danis¹² and associates published the first randomised controlled trial utilising intravitreal triamcinolone, comparing the 4 mg dose versus observation in exudative ARMD. In addition to exudative age related macular degeneration,^{10–16} intravitreal triamcinolone has been studied in choroidal neovascularisation from uveitis,^{17,18} macular edema secondary to multiple aetiologies including uveitis,^{19–21} diabetes,^{22–24} vein occlusion,^{25–29} cataract surgery,^{30–32} radiation therapy,³³ retinitis pigmentosa,³⁴ and idiopathic,³⁵ plus proliferative vitreoretinopathy,³⁶ proliferative diabetic retinopathy,³⁷ neovascular glaucoma,³⁸ idiopathic juxtafoveal telangiectasis,³⁹ ischaemic ophthalmopathy,⁴⁰ ocular hypotony,⁴¹ blind, painful eyes,⁴² and corneal graft rejection.⁴³

The pharmacokinetics of intravitreal triamcinolone in human eyes has been incompletely studied. The earliest reports were in rabbit eyes. Schindler and associates reported that the clearance of a single 0.5 mg injection of triamcinolone in 30 rabbit eyes ranged from an average of 41 (SD 20.6) days in non-vitrectomised eyes to 16.8 (5.6) days in vitrectomised eyes, and 6.5 (1.5) days in eyes that underwent vitrectomy and lensectomy. Detection of triamcinolone was performed utilising direct ophthalmoscopic observation of the crystals with colorimetric analysis for residual triamcinolone once no crystals were seen in the vitreous cavity or in the anterior chamber angle. The colorimetric analysis of ocular tissues for triamcinolone correlated well with clinical disappearance of the triamcinolone crystals. The authors concluded that examination of the eye is sufficient to determine when levels of triamcinolone are low enough to potentially warrant re-injection.⁹

Machemer and associates reported visible traces of triamcinolone after intravitreal injection of 1 mg in rabbit eyes to last at least 1 month (64 eyes).^{7,8} Hui and associates reported clearance of triamcinolone from the vitreous after 1 mg injection in rabbit eyes to average 45.5 days, ranging from 35–63 days (eight eyes).⁴⁴

Human studies have been primarily limited to clinical observations of disappearance of triamcinolone after intravitreal injection to give an estimated duration of action. The dosage of triamcinolone acetonide injected correlates with duration of action. Most authors have studied a 4 mg dose,^{10–13,15–19,23,26,29,33–35,39,47} obtained by shaking the commercial 40 mg/1 ml Kenalog vial and removing and injecting 0.1 ml of the triamcinolone, which is suspended in a 0.99% benzyl alcohol solution. Doses of 1 mg,³⁰ 2 mg,^{20,27} 8 mg,³¹ and 12.5 mg⁴² have also been studied based on injecting a proportionately lower or higher volume from the 40 mg/1 ml vial. Higher doses of 15–25 mg have been studied by Jonas and associates.^{14,22,24,25,32,36,37,38,40,41,43,45,46} To obtain this higher dose, one must remove the benzyl alcohol supernatant to concentrate the crystals. This has been performed by decanting the supernatant off the crystals³⁶ or washing the crystals by passing them through a Millipore filter.¹⁴ Jonas has reported that the 15–20 mg dose of triamcinolone lasts approximately 6 months via clinical inspection in 29 eyes after vitrectomy. In this study 17 patients had a silicone oil fill and 12 patients had saline fill. However, the authors did not separate the two groups for reporting the duration of visible crystals.³⁷ Jonas and colleagues have also reported measurable concentrations of triamcinolone in silicone oil up to 8 months (three patients) after vitrectomy with silicone oil instillation accompanied by simultaneous intravitreal injection of 25 mg triamcinolone.⁴⁵ This group also reported measurable concentrations of triamcinolone in the aqueous up to 6 months (three patients) after intravitreal injection of

Abbreviations: ARMD, age related macular degeneration; IOP, intraocular pressure; POAG, primary open angle glaucoma

25 mg triamcinolone, though this study did not specify whether the patients have undergone previous vitrectomy.⁴⁶

With regard to the lower 4 mg dose of triamcinolone, Beer⁴⁷ and associates reported the mean elimination half life of a single intravitreal injection of 4 mg of triamcinolone in four non-vitrectomised eyes at 18.6 days with measurable concentrations expected to last for 93 (28) days. The half life in one eye of one patient who had undergone vitrectomy was 3.2 days. Concentrations of triamcinolone were determined using high performance liquid chromatography based on aqueous humour samples obtained via anterior chamber paracentesis.

We wished to determine dissolution kinetics of high dose intravitreal triamcinolone injected in the vitrectomised eye. This is important because many eyes with macular oedema that may be treated with triamcinolone are vitrectomised. For this reason we observed our cohort of eyes that were vitrectomised and had high dose decanted triamcinolone injected at the completion of vitrectomy surgery or in the outpatient clinic setting for disappearance of the visible crystals. We relied on the observations of Schindler that once the crystals disappear, therapeutic levels of triamcinolone do not exist in the eye.⁹

METHODS

This prospective case series reports the duration of high dose (20 mg) intravitreal decanted triamcinolone in the vitrectomised eye utilising clinical and photographic documentation of the presence or absence of triamcinolone crystals within the vitreous cavity. Twenty three consecutive patients who underwent injection either at the conclusion of vitrectomy surgery or in a previously vitrectomised eye were selected and followed prospectively with clinical examinations and photographic documentation of the triamcinolone depot within the eye. Thirteen patients (57%) were male. The mean age was 66 (SD 14). Thirteen patients (57%) were pseudophakic and one patient was aphakic in the injected eye. Twenty patients (87%) had triamcinolone administered via trans pars plana

Figure 1 (A) Visible triamcinolone at 1 month. (B) Visible triamcinolone at 3 months.

Figure 2 Survival plot for triamcinolone presence in the vitreous cavity (23 eyes).

injection at the completion of a vitrectomy procedure. Three patients with a history of previous vitrectomy received triamcinolone as an outpatient trans pars plana injection during a clinic visit. Patients in the study were treated for macular oedema secondary to uveitis, diabetes, vein occlusion, and cataract surgery, in addition to oedema persisting following repair of a chronic retinal detachment, plus proliferative vitreoretinopathy. Two patients (9%) had a history of primary open angle glaucoma (POAG). Two patients (9%) had a history of glaucoma related to uveitis plus possible previous steroid response.

The injection of triamcinolone was performed by first decanting the vehicle (approximately 0.8 ml) from a 1 ml commercial vial of Kenalog 40 mg that had been placed to allow the crystals to settle inferiorly. After this the triamcinolone crystals and remaining vehicle (approximately 0.2 ml) were removed and 0.1 ml (approximately 20 mg) was injected via a pars plana approach. This is similar to the decanting method described by Jonas.³⁶ This decanting procedure was done to both concentrate the crystals and to reduce the volume of benzyl alcohol contained in the vehicle. During follow up dilated fundus examinations plus photographic documentation were used to monitor the presence of triamcinolone crystals (fig 1). Scleral depressed examination was utilised to confirm absence of triamcinolone crystals in all eyes. Kaplan-Meier analysis was used to establish the duration of triamcinolone within the eye of vitrectomised patients.

RESULTS

Utilising Kaplan-Meier analysis, the median duration of visible triamcinolone crystals was 113 days (95% CI 85 to 191 days) (fig 2). In the nine phakic eyes the median duration of visible crystals was 191 days (95% CI 148 to 191). In the 13 pseudophakic eyes the median duration of visible crystals was 102 days (95% CI 85 to 113) (fig 3). This

Figure 3 Survival plot for triamcinolone presence in the vitreous cavity. Broken line, pseudophakic eyes (13). Solid line, phakic eyes (nine).

difference between phakic and pseudophakic eyes was not statistically significant ($p = 0.12$). One patient was aphakic. The triamcinolone crystals disappeared in this eye between 29 days and 85 days.

No patient has experienced endophthalmitis. Nine eyes (39%) developed steroid related intraocular pressure (IOP) rises above 21 mm Hg. These IOP rises occurred during weeks 4–12 (mean week 9 (SD 3)). Eight have been controlled with IOP medications. Two additional patients had elevated IOP on postoperative day 1. Both of these patients have been controlled with IOP medications. Sixteen eyes (70%) had IOP rises >5 mm Hg. Five eyes (22%) has IOP rises >10 mm Hg. Six of nine phakic eyes experienced cataract progression after the injection evaluated with the Lens Opacities Classification System III (LOCS III).⁴⁸ However, no patients developed posterior subcapsular change typical of steroid administration. All six had nuclear colour change and one patient developed cortical changes.

DISCUSSION

This present study reports the duration of action of 20 mg decanted triamcinolone acetate after trans pars plana injection in a large series of vitrectomised eyes. The higher dose was studied based on personal experience and review of the literature suggesting that the 4 mg dose is very short lived in the vitrectomised, saline filled eye. Our study suggests that using the higher 20 mg decanted dose will result in fewer re-injections for patients, thus lowering the cumulative risk of endophthalmitis, vitreous haemorrhage, and retinal detachment if multiple injections are required. Culture positive endophthalmitis after intravitreal triamcinolone injection has been reported in multicentre retrospective analyses. Moshfeghi *et al* reported an incidence of 0.87% (8/922) from a multicentre analysis.⁴⁹ Nelson *et al* reported a 0.45% (2/440) incidence rate from a single centre analysis.⁵⁰ Jonas reported no culture proved endophthalmitis cases attributable to intravitreal triamcinolone in an analysis of 520 injections.⁵¹

In addition, the initial higher bolus injected may result in improved efficacy based on the higher concentrations obtained in the vitreous cavity. Similar to the reports of Jonas, no retinal or optic nerve toxicity has been seen in our study with the higher 20 mg dose. As with any intravitreal injection, care must be taken to adhere to a strict sterile technique, especially with our decanting procedure requiring two separate needle penetrations of the commercial Kenalog 1 ml vial.

The higher dose may result in a higher possibility of steroid related side effects including elevated IOP and cataract. However, compared to authors using a 4 mg triamcinolone dose in at least 10 eyes we saw a similar percentage of eyes with a 5 mm Hg or higher rise in IOP (70% *v* range from 30–75%) and a 10 mm Hg or higher rise in IOP (27% *v* range from 10–31%).^{11 23 29 52 53} Our data for percentage of eyes with IOP rises above 21 mm Hg was also similar to that for authors using the 4 mg dose in at least 10 eyes (39% *v* range from 25–50%).^{12 15 18 23 29} In addition, our data for IOP rise above 21 mm Hg was similar to that reported by Jonas utilising a 25 mg triamcinolone dose (39% versus 52%).⁵⁴ The potential for less frequent injections over a similar time period is of obvious benefit.

Limitations of our study include the size of the patient sample, though our study represents one of the largest to specifically look at the duration of a high dose of triamcinolone injected in the vitrectomised, saline filled eye. A larger patient sample would enable the trend of the shorter duration of triamcinolone in pseudophakic eyes to have more statistical power. In addition to the number of patients, more frequent patient follow up within the study period would permit tighter confidence intervals for our analysis.

These data cannot be extended to patients who have not undergone a vitrectomy procedure. However, in those patients, we would also expect longer time to disappearance than the 4 mg dose.

In summary, for a patient who may benefit from intravitreal injection of triamcinolone, the 20 mg decanted dose should be considered instead of 4 mg if the patient had previously undergone a vitrectomy procedure or will be undergoing a vitrectomy in combination with the triamcinolone injection.

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