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Comparison of 4 mg versus 20 mg intravitreal triamcinolone acetonide injections

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Abstract

Aims—To compare the non-decanted (standard) 4 mg versus the decanted 20 mg intravitreal triamcinolone acetonide (IVTA) injections and to assess their effect on intraocular pressure (IOP).

Methods—We retrospectively reviewed the records of 92 consecutive eyes, which received an intravitreal injection of either dose of triamcinolone acetonide, at a single retina centre. The change in IOP (elevation of at least 5 mm Hg from baseline or above 21 mm Hg) was analysed with a multivariate logistic analysis. The mean follow-up period in both groups was 27 weeks. A subgroup analysis comparing vitrectomised to non-vitrectomised eyes in both groups was also performed.

Results—Of the 92 eyes, 46% (23 of 51) in the 4 mg group versus 30% (12 of 41) in the 20 mg group had an IOP >21 mm of Hg ($p = 0.14$) after a mean follow-up period of 27 weeks. The vitrectomised eyes (3 of 24) in the 20 mg group had a significantly lower rate of IVTA induced IOP elevation than the non-vitrectomised eyes (9 of 17) ($p = 0.013$). The IOP elevation occurred significantly earlier in the 4 mg group (vitrectomised eyes 27 (SD 43) days and non-vitrectomised eyes 61 (52) days) than in the 20 mg group (vitrectomised eyes 104 (56) days and non-vitrectomised eyes 119 (82) days), independent of the vitreous status (vitrectomised $p = 0.05$ and non-vitrectomised $p = 0.04$). The mean value of initial high IOP in the non-vitrectomised eyes was higher in the 4 mg group than in the corresponding 20 mg group ($p = 0.048$).

Conclusion—Decanted 20 mg IVTA may not pose a significantly greater risk of IOP elevation than the 4 mg non-decanted IVTA.

Intravitreal triamcinolone acetonide (IVTA) has been used in the treatment of various intraocular oedematous, inflammatory, neo-vascular and proliferative conditions.[1–10] One of the two most common side effects of IVTA is elevation of intraocular pressure (IOP) with ocular hypertension from 28% to 77%.[1–10] Doses used range from 4–8 mg to 20–25 mg in a small volume after removing the diluents from the commercially available preparation (decanted triamcinolone acetonide (TA)).[3 4 11–15] The efficacy, duration of action and risk of side effects could be expected to increase with higher doses of IVTA. Spandau *et al*[16] performed a small study comparing 2–15 mg of IVTA and showed an increased duration of action with higher doses of IVTA. Studies suggest that the higher the dose, the longer is the duration of the steroid-induced ocular hypertension.[1 2 5–8 10 17–27] There is no study directly comparing the incidence and severity of side effects, particularly the raised IOP, among the different doses of IVTA. In this study, we, for the first time, directly compared the two most

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commonly used doses of IVTA, 4 mg (standard) and 20 mg (decanted), and assessed the changes in IOP. We also assessed the risk of development of high IOP after a second injection.

PATIENTS AND METHODS

We retrospectively reviewed the charts of all patients who had an IVTA injection at one institution between September 2002 and September 2005 with the approval of the Institutional Review Board. The study population consisted of two groups of patients; the patients treated with non-decanted 4 mg IVTA by one of the authors (MHG) and the patients treated with 20 mg decanted IVTA by another author (WRF). The indications of IVTA injection in these patients are shown in table 1. We excluded eyes with a documented history of glaucoma or any raised IOP (>21 mm Hg) or ongoing use of topical and/or systemic steroids within 3 months prior to injection in order to assess the triamcinolone effect.

The preparation of the 4 mg TA included vigorous shaking of the phial (40 mg/1 ml, Bristol-Myers Squibb Company, Wallingford, CT) prior to drug loading. A 27 G needle was then used to inject 100 μl of the suspension through the pars plana. In preparing 20 mg of TA, the phial was placed on a desk at a 45° angle with the top up for at least 2 h before removing the supernatant (0.8 ml);[28] 100 μl of the remaining slurry was then loaded into a 1 ml syringe and injected using a 27 G needle. IOP-lowering drugs were not used in conjunction with the IVTA in either cohort.

Patients had baseline IOP checked using applanation on the day of injection and at each successive follow-up visit at the clinic. Patients having a follow-up of less than 8 weeks or lack of IOP documentation were eliminated from the study. On each follow-up visit, the visibility of the IVTA by indirect ophthalmoscopy was also noted on the patient chart. The patients who had had a second injection of IVTA were treated as a different population and analysed separately.

The following data were analysed; age, gender, diagnosis, baseline IOP status (if greater than 16), IOP elevation, vitreous status (natural or vitrectomised), lens status (natural or implant), date of triamcinolone injection and date of follow-up visits, triamcinolone visibility and any complications such as pseudo- or true endophthalmitis. We did not use a standardised assessment of lens opacity in phakic eyes and therefore did not study progression of lens opacity; however, data regarding the need for cataract extraction following IVTA were collected. All data analyses were performed using JMP software, version 5 (SAS, Cary, NC).

RESULTS

Initial injection

The initial IVTA injection study included 51 eyes injected with 4 mg TA and 41 eyes injected with 20 mg TA. The baseline characteristics of the patients are summarised in tables 2 and 3.

Due to the imbalance of cases with regard to vitreous status (natural versus vitrectomised) between the groups, a subanalysis was performed. All other parameters including lens status, sex, age and duration of follow-up (average follow-up period 27 weeks) were equivalent between the dose groups. In addition, we also performed a multivariate logistic regression analysis using IOP elevation as the response variable, and group, vitreous status, baseline IOP, gender and age as independent variables.

We evaluated pressure rise using three outcome parameters: proportion of eyes with an IOP over 21 mm Hg or with an increase by 5 mm Hg (from baseline), time to elevated pressure (over 21 mm Hg or an increase by 5 mm Hg or more) and the magnitude of the first elevation

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in pressure. These analyses suggested that not only was the high dose decanted 20 mg injection not associated with more problems in intraocular pressure rise but there were actually fewer problems than with the 4 mg non-decanted preparation. This was particularly true in vitrectomised eyes, where the proportion of eyes with elevated pressure was 54% in the 4 mg group versus 13% in the 20 mg group, p = 0.015. The time to an elevated pressure was also shorter after a 4 mg injection than after a 20 mg injection in both the vitrectomised and non-vitrectomised cohorts (27 (43) vs 104 (56) days in vitrectomised eyes, 61 (52) vs 119 (82) days in non-vitrectomised eyes). These values were also statistically significant (p = 0.05 in vitrectomised eyes and p = 0.04 in non-vitrectomised eyes).

The value of first IOP elevation was higher in the 4 mg group in both the cohorts; in the non-vitrectomised cohort, this was statistically significant as well (p = 0.048) (table 4). When we compared vitrectomised with non-vitrectomised eyes in 20 mg dose group, we found that the proportion of eyes with elevated IOP was higher in non-vitrectomised eyes (53 (9 of 17) vs 13% (3 of 24)). This was also significant (p = 0.013).

The multivariate logistic analysis revealed that only baseline IOP status was associated with IOP rise. The eyes with IOP greater than 16 mm Hg at baseline were 3.2 times more likely to have TA-associated IOP rise (95% CI 1.23 to 8.49, p = 0.02).

In all eyes except the two with the IOP rise after IVTA, IOP was well controlled with the topical IOP lowering drugs. Those two eyes required glaucoma surgery to control the elevated IOP. Both of them were non-vitrectomised eyes in the 4 mg group (table 5).

Second injection

Eighteen patients underwent a second IVTA injection in this series. There were nine such patients in each dose group. The follow-up length and times of visits are summarised in table 6. During the follow-up, only one eye that had a 4 mg re-injection had an IOP above 21 mm Hg, and this eye did not have an elevated IOP after the first injection. Seventy-seven days after the second injection, the IOP was 29 mm Hg. Three eyes (out of nine) that had received a 20 mg re-injection had an IOP above 21 mm Hg, and two of them had developed a high IOP after the first injection also. The third eye had an IOP of 27 mm Hg 3 days after the second injection. With the exclusion of two cases in the 20 mg group who had a history of IOP elevation after first injection, the incidence of high IOP after second injection was similar, based on this small sample study, between the 4 mg and 20 mg group (1 of 9 v/s 1 of 7 respectively, p = 0.8, Fisher exact test).

Third injection

In the 4 mm Hg group, only one eye received a third injection, and this eye did show a high IOP after the previous two injections. Eighty-eight days after the third injection, this eye recorded an IOP of 34 mm Hg. Two patients in the 20 mg group had a third injection. Neither showed an elevated IOP after the previous injections. One hundred and nineteen days and 4 days after a third injection, the recorded IOPs were 26 and 25 mm Hg, respectively.

DISCUSSION

IVTA injection is associated with common side effects such as raised IOP, cataract and pseudo- or true infectious endophthalmitis.[3 8 29 30] The most commonly reported side effect is elevation of IOP.[2–4 10] Direct comparison of IOP changes after the injection of non-decanted 4 mg and decanted 20 mg TA has not been previously reported. The technique of decanting the TA allows for an injection of a high dose in a small volume with a very small amount of potentially toxic benzyl alcohol. Using HPLC, we had previously reported that decanting decreases the dose of

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benzyl alcohol going into the eye by 80% and allows a higher amount of triamcinolone to be used.[31] We acknowledge that our assumed 20 mg dose may not be exactly the intended dose due to the decanting. However, the dose should be between 14 and 20 mg, which is still four- to fivefold higher than the 4 mg dose.[32]

Our study showed that there was no greater incidence of IOP elevation in the 20 mg group than that in the 4 mg group. A review of previous[1 3–5 9 10 33] studies suggests that there may not be more glaucoma or raised IOP in eyes injected with high-dose triamcinolone, but those studies did not directly compare the two doses. A small prospective, randomised study of 27 eyes by Spandau *et al*,[16] comparing 2 mg with 15 mg doses, also showed no difference in IOP elevation. Our study is the largest series of eyes in which a standard and high dose of intravitreal triamcinolone were compared at a single institution. The statistical power of this study to detect differences in IOP elevation is relatively low, so a larger randomised trial might show changes, which we were unable to detect. In this retrospective study, the number of vitrectomised cases in the 20 mg group was greater than that in the 4 mg group. Therefore, in addition to the multivariate analysis, we analysed the incidence of the IOP elevation in subgroups of the vitrectomised and the non-vitrectomised patients.

In eyes that have undergone vitrectomy, the duration of action of the 20 mg dose is approximately 3–4 months (much longer than the 4 mg dose) thus making 20 mg injections particularly useful in such eyes.[28] In the high-dose (20 mg) vitrectomised eyes, there was a lower incidence of IOP elevation than the non-vitrectomised eyes (13% vs 53%). This may be due to the shorter half-life of vitreous fluid in the vitrectomised eyes.[34 35]

Interestingly, IOP elevation occurred earlier and was higher in the non-vitrectomised eyes receiving 4 mg vs 20 mg injections. This could be due to a higher free drug concentration in the supernatant fluid in the non-decanted 4 mg preparation or might be related to an effect of preservatives and stabilisers in the 4 mg preparation. However, this observation needs confirmation from further studies. In addition, this study found that a TA-associated IOP rise was correlated with a higher baseline IOP.

The average follow-up of 27 weeks in our study is sufficient to determine an elevated IOP with either dose, given that steroid-induced glaucoma typically is seen within 1 week to 6 months after injection.[7 28 36] It is encouraging that IOP was well controlled in most eyes with topical medication.

After a second and third injection, we saw a relatively low incidence of IOP rise, but the numbers of patients were too small to compare the IOP elevation. In addition, eyes receiving second or third injections did not have pressures that were difficult to control, so there was ascertainment bias in evaluating these eyes.

In summary, the current study suggests that a decanted 20 mg IVTA injection does not pose a significantly greater risk of IOP elevation than non-decanted 4 mg injections. Interestingly, decanted 20 mg injections showed a longer time to IOP rise and a lower magnitude of IOP elevation compared with a 4 mg injection. A larger prospective study is indicated.

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Table 1

Clinical indications for intravitreal triamcinolone acetonide (IVTA) injection in both groups

Diagnostic serial no.	indications	No. of patients with 20 mg IVTA	No. of patients with 4 mg IVTA	p Value*
1	Diabetic macular oedema	10	10	0.34
2	Choroidal neo-vascularisation in age-related macular degeneration	9	9	0.36
3	Macular oedema in central retinal vein occlusion†	5	9	0.36
4	Macular oedema in branch retinal vein occlusion†	2	1	0.83
5	Epiretinal membrane with macular oedema	7	7	0.41
6	Pseudophakic cystoid macular oedema	3	7	0.34
7	Macular oedema in uveitis	3	2	0.58
8	Radiation retinopathy with macular oedema	0	2	0.50
9	others	2	4	0.62
	Total	41	51	

*Fisher exact test.

†No iris or retinal neovascularisation in the retinal vein occlusion patients.

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Table 2

Baseline characteristics of patients by groups and vitreous status

	No. of patients			Sex				Age in years mean (SD)		No. of phakic patients		Follow-up days mean (SD)	
				Male		Female							
Group	Vit	No vit	Total	Vit	No vit	Vit	No vit	Vit	No vit	Vit	No vit	Vit	No vit
4 mg	11	40	51	6	24	5	16	73(8) (M 75)	72 (14) (M 76)	2	19	190(129) (M 201)	200 (102) (M 196)
20 mg	24	17	41	16	9	8	8	71 (12) (M 74)	71 (11) (M 73)	4	12	191 (97) (M 189)	193 (95) (M 185)

M, median; No vit, non-vitrectomised; VIT, vitrectomised.

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Table 3

Baseline characteristics of patients

Group	No. of visits	Follow-up days (mean) (SD)	Patients with >3 months' follow-up	Patients with minimum 6 months' follow-up
4 mg	4	198.1 (106.7) (M 196)	43 (84%)	31 (60%)
20 mg	4	191.7 (94.6) (M 189)	38 (93%)	22 (54%)
p Value	0.98	0.76	0.2	0.5

M, median.

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Table 4

Results of intraocular pressure (I0P) changes after intravitreal triamcinolone acetonide injection stratified by the groups and the vitreous status

	No. of patients with IOP >21 mm Hg or increased by 5 mm Hg				Time to IOP >21 mm Hg (days) mean (SD)			Value of first elevated IOP mm Hg mean (SD)		
Group	**Vit**	**No vit**	**p Value**	**Total**	**Vit**	**No vit**	**p Value**	**Vit**	**No vit**	**p Value**
4 mg	6/11 (54%)	17/40 (43%)	0.5*	23/51 (46%)	27 (43)	61 (52)	0.17†	27.8 (6.2) (M 25)	27.4 (4.8) (M 28)	0.87†
20 mg	3/24 (13%)	9/17 (53%)	0.013*	12/41 (30%)	104 (56)	119 (82)	0.77†	25.7 (4.6) (M 23)	23.9 (2.0) (M 24)	0.35†
p Value (4 vs 20 mg)	0.015*	0.57*		0.14*	0.055†	0.04†		0.60†	0.048†	

M, median; No vit, non-vitrectomised; Vit, vitrectomised.

*Fisher exact test.

†t Test.

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Table 5

Numbers of cataract and glaucoma surgeries after intravitreal triamcinolone acetonide (IVTA)

	Cataract surgery after IVTA		Glaucoma surgery after IVTA	
Group	**Vit**	**No vit**	**Vit**	**No vit**
4 mg	2 (of two phakic eyes)	4 (of 19 phakic eyes)	0	2
20 mg	2 (of four phakic eyes)	1 (of 12 phakic eyes)	0	0
p Value		0.62		

IVTA, intravitreal triamcinolone acetonide; No vit, non-vitrectomised; VIT, vitrectomised.

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Table 6

Second IVTA injection

Group	No. of patients	Days of follow-up mean (SD)	No. of visits	Patients with IOP >21 mm Hg	Patients with IOP >21 mm Hg after 1st injection
4 mg	9 (Vit-1, No vit-8)	191 (72) (M 170)	M 4	1	0
20 mg	9 (Vit-9)	189 (113) (M 217)	M 4	3	2

IVTA, intravitreal triamcinolone acetonide; M, median; No vit, non-vitrectomised; VIT, vitrectomised.