# Study of Comparison of Effect and Complications of Intravitreal Triamcinolone Injection of 1 mg, 2 mg and 4 mg in Macular Edema of Vascular Origin

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## Abstract:

**Introduction:** The present study aimed to compare the efficacy and safety of different doses (1 mg, 2 mg and 4 mg) of triamcinolone acetonide (IVTA) in treatment of eyes with macular edema of vascular origin. **Methods:** Using simple random sampling among patients attending our tertiary healthcare referral centre, 60 patients fulfilling selection criteria were divided into 3 groups and were followed up for a period of 16 weeks. Following IVTA injections of different doses, patients were observed for changes in best-corrected visual acuity (BCVA), central foveal thickness (CFT) on optical coherence tomography (OCT), intraocular pressure (IOP) and cataract occurrence/ progression in all three groups at 1 week , 4 weeks, 12 weeks and 16 weeks. **Results:** Following IVTA injection in all three groups (1 mg, 2 mg and 4 mg), mean BCVA improved from baseline but no statistically significant difference was observed in mean BCVA at different follow ups between the three groups. Mean CFT significantly improved from baseline in all three groups but no statistically significant difference was observed at different follow ups between groups. Mean IOP increased from baseline in all three groups but no statistically significant difference was observed among groups at different follow ups. Anti glaucoma treatment was required at end of 16 weeks postoperatively in 0, 1 and 3 eyes receiving 1 mg, 2 mg and 4 mg IVTA respectively. Lenticular changes at the end of 16 weeks postoperatively were found in 0, 1 and 2 eyes with 1 mg, 2 mg and 4 mg IVTA respectively. **Conclusion**: 4 mg dose of IVTA improves the functional and anatomical outcome in macular edema of vascular origin in most patients followed by 2 mg dose. 1 mg and 2 mg dose of IVTA has less incidence of steroid induced elevation of IOP and lenticular opacity development or progression. Further large scale studies are recommended to compare the effectiveness and safety of different doses of IVTA.

**Keywords:** Triamcinolone Acetonide, Macular edema, diabetic retinopathy, retinal vein occlusion

## Introduction

Macular edema (ME) is one of the commonest causes of legal blindness in working population.[1] ME is the effect of fluid accumulation in the retinal layers around the fovea. It causes vision loss by altering the functional cell relationship in the retina and promoting an inflammatory response.[2] ME may occur in a wide variety of ocular conditions including uveitis, trauma, intraocular surgery, vascular retinopathies, vitreoretinal adhesions and age-related macular degeneration, but >90% of cases are caused by vascular etiology such as Diabetic retinopathy (DR), retinal vein occlusion (RVO) and choroidal neovascular membrane.[2] Recent advances in Optical coherence tomography (OCT) imaging is useful in monitoring the progression of ME and response to treatment. There are various modalities for treatment of macular edema including topical eye drops, laser treatments, intravitreal injection of steroids, anti-VEGFs etc.[3] Corticosteroids are effective in the treatment of various forms of ME due to their anti-angiogenic, anti-

edematous, anti-inflammatory, anti-proliferative and blood retinal barrier stabilizing effects. These drugs activate the glucocorticoid receptors which is protective to the retinal photoreceptors due to its anti-apoptotic effect. The commonly used intravitreal steroid is triamcinolone acetonide. Intravitreal triamcinolone acetonide (IVTA) injection is cost effective and also shows beneficial effect in reducing retinal thickness in ME. IVTA can be chosen as primary treatment for CME of vascular origin. It can also be given for refractory cases not responding to laser in diabetic macular edema and macular edemas due to BRVO, in patients from low socioeconomic strata and those with pseudophakic eyes. Patients having contraindications for Anti VEGF therapy or those with inability to afford repeated Anti VEGF injections can undergo IVTA as an adjunctive treatment. Judicious use with proper patient selection and consideration of side effects is important for maximum benefits from this modality of treatment. Intravitreal triamcinolone acetonide can cause side effects, like rise in intraocular pressure and progression of nuclear sclerosis. In this study, comparative analysis of various doses (1 mg, 2 mg and 4 mg) of triamcinolone acetonide has been performed with regards to effect on macular edema and intraocular complications.

## Material and Methods

Ethical clearance for the study was obtained from our Institutional Ethics Committee (IEC approval number: ECR/72/Inst/GJ/2013/RR-2019). Informed consent was obtained from every subject after explaining the procedure, before their enrolment into the study. This prospective, comparative, interventional study was conducted among 60 eyes of 60 patients diagnosed to have vascular origin macular edema attending our tertiary healthcare referral centre between December 2018 to December 2019, who were followed up for a period of 16 weeks.

**Inclusion criteria**

- Age ≥ 30 years of any gender.
- Patients with complains of Diminution of Vision (DOV) and metamorphopsia.
- Blood pressure (in hypertensive patients) and Blood sugar level (in diabetic patients) within normal limits prior to study (FBS <140 mg/dL, PPBS <180 mg/dL, HbA1c <7.5%).
- Intraocular pressure <20 mmHg.
- Fundoscopy showing physiological cupping.
- On slit lamp examination, clear cornea, normal anterior chamber depth without any anterior chamber reaction and relatively clear lens status in phakic patients and Pseudo-phakic patients (in which cataract surgery was performed at least before 3 months) with clear visual axis.
- Pre-intervention OCT: Central foveal thickness (CFT) ≥ 250 mm with macular edema due to vascular etiology (esp. due to DR, RVO disease).

**Exclusion criteria**

- Prior episode of macular edema.
- History of treatment with Anti VEGF or intra-vitreal steroid, topical steroids or topical Anti inflammatory drugs (Nepafenac, Bromfenac etc) in the study eye or treatment with oral steroids within 3 months prior to study.
- History of laser treatment
- Past history of uveitis, glaucoma, retinal detachment or vitreous haemorrhage.

**Methodology**

Detailed clinical history and examination of patients was done pre and post-operatively including Best Corrected Visual Acuity (BCVA)**,** slit lamp examination, Intraocular pressure (IOP) by Applanation tonometry, Fundus examination by slit lamp biomicroscopy using 90D, Direct and Indirect ophthalmoscopy and OCT (Optical Coherence Tomography).

Patients having Macular edema were diagnosed and divided into 3 groups randomly using simple random sampling. All three groups (Group A, Group B and Group C) consisted of 20 patients each. Sample size was estimated at 60 patients, which was determined by the formula $N=z^2pq/e^2$, where N= sample size, z=confidence level at 95%, p=prevalence rate of vascular origin macular edema[4,5], q=1-p, e=allowable error (5%). These groups received intravitreal triamcinolone acetonide (1 mg/0.025ml, 2 mg/0.05ml and 4 mg/0.1ml) respectively. All intravitreal injections were administered according to standard aseptic protocol in the operation theatre with an operation microscope. After obtaining

informed consent from patients, affected eye was prepared using a drop of proparacaine hydrochloride (0.05%) for topical anaesthesia, followed by topical application of 5% povidone–iodine. Triamcinolone of decided dose was slowly injected into the vitreous cavity via the pars plana, 3.5 mm posterior to the limbus (inferotemporal quadrant) in pseudo-phakic eyes and 4 mm posterior to the limbus in phakic eyes using a 26G needle and tuberculin syringe. After injection, topical antibiotic moxifloxacin 0.5% eye drops was applied and eyes were patched for 4 hours. Patients were instructed to instill topical antibiotics four times daily for 3 days. Patients were kept under observation for 4 hours and were called for follow up on day-1, at 1 week, 4 weeks, 12 weeks and 16 weeks. BCVA and IOP were noted in 3 groups at every visit. Efficacies of 3 different doses of IVTA compared using BCVA and CFT on OCT at 1 week, 4 weeks, 12 weeks and 16 weeks. Each patient's BCVA was measured in Snellen's lines and converted into logarithm of minimum angle of resolution (logMAR) scale for analysis. Microsoft Excel sheet was used for data entry and analysis was done using frequency and percentage distribution. Data was presented as Mean±SD and compared using ANOVA test. *P* value less than 0.05 was considered as statistically significant.

## Results

Out of 60 patients, 25 (41.66%) patients belonged to the age group of 60-69 years, followed by 18 (30%) patients between the age group of 50-59 years, 7 (11.66%) patients between the age group of 40-49 years, 6 (10%) patients between the age group of 70-79 years, 2 (3.33%) patients between the age group of 80-89 years and 2(3.33%) patients between age group of 30-39 years. Men were more (46, 76.66%) than women (14, 23.33%) in the study population. Maximum number of patients (32, 53.33%) were known cases of Diabetes mellitus. Risk factor wise distribution of patients is shown in figure 1. Out of 60 patients, 33(55%) patients had macular edema due to Diabetic Retinopathy. Detailed etiology wise distribution is shown in figure 2.

**Figure 1: Risk factors wise distribution of patients having macular edema of vascular origin (n=60)**

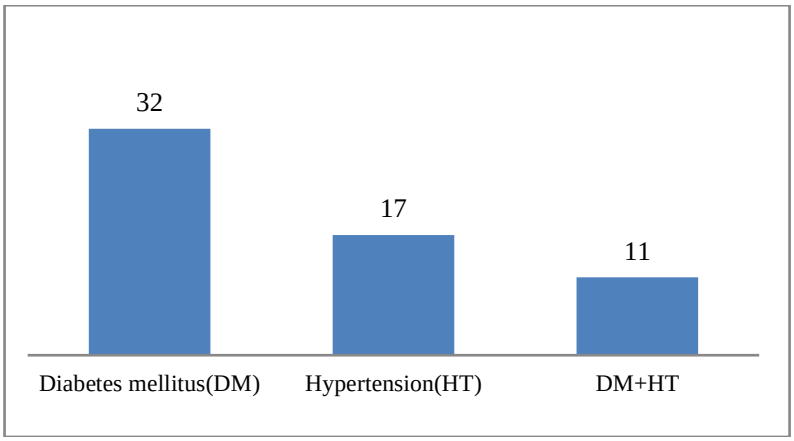
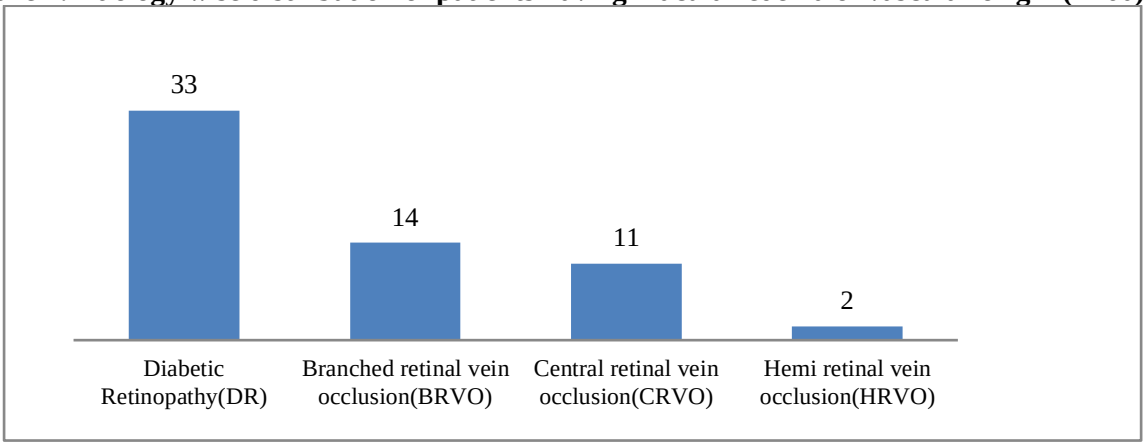
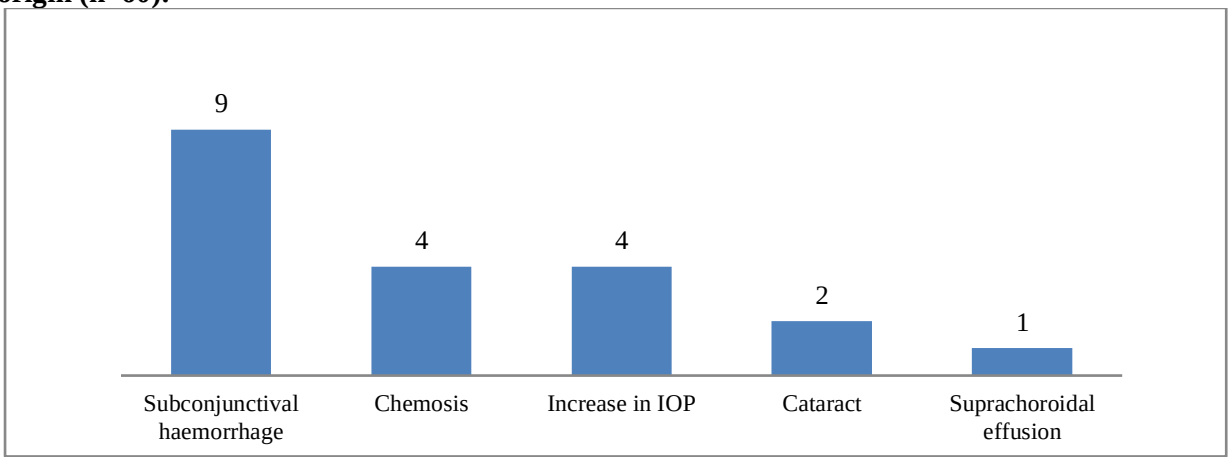



**Figure 2: Etiology wise distribution of patients having macular edema of vascular origin (n=60)**



Subconjunctival Haemorrhage was detected on post operative day 1 in 9 (15%) patients. Detailed complications wise distribution is shown in figure 3. None of the patients suffered from post injection endophthalmitis, rhegmatogenous retinal detachment or Vitreous hemorrhage.

**Figure 3: Post operative complications observed in patients having macular edema of vascular origin (n=60):**



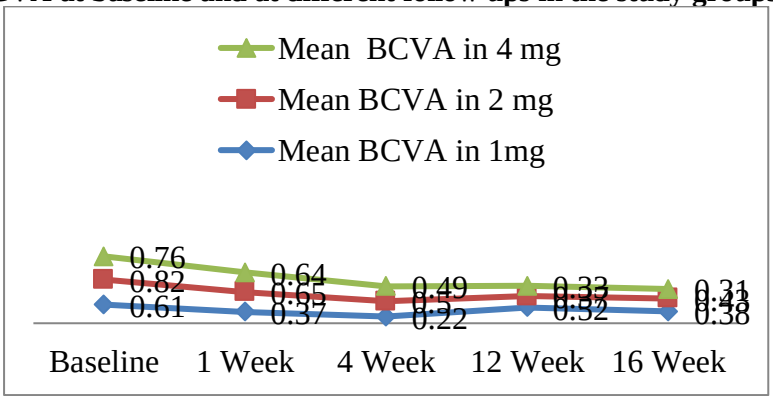

**Best Corrected Visual Acuity (BCVA) changes**

In the 1 mg group; 14 eyes (70%) showed improvement in BCVA, 5 eyes (25%) did not show improvement and 1 eye (5%) showed worsening after initial improvement in BCVA at the end of 16 weeks. Mean (±SD) baseline BCVA was 0.61±0.23 in 1 mg group. It showed significant improvement from baseline to 0.37±0.16 ($P$<0.0001), 0.22±0.13 ($P$<0.0001), 0.52±0.16 ($P$=0.0047) and 0.38±0.2 ($P$=0.0016) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.

In the 2 mg group, 18 eyes (90%) showed improvement in BCVA, 1 eye (5%) did not show improvement in BCVA and 1 eye (5%) showed worsening after initial improvement in BCVA at the end of 16 weeks. Mean (±SD) baseline BCVA was 0.82±0.21 in 2 mg group. It significantly improved from baseline to 0.65±0.22 ($P$ =0.008), 0.5±0.22 ($P$<0.0001), 0.37±0.22 ($P$<0.0001), 0.43±0.23 ($P$<0.0001) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.

In the 4 mg group, 19 eyes (95%) showed improvement in BCVA and 1 eye (5%) showed worsening after initial improvement in BCVA at the end of 16 weeks. Mean (±SD) baseline BCVA was 0.76±0.17 in 4 mg group. It significantly improved from baseline to 0.64±0.16 ($P$<0.0001), 0.49±0.15 ($P$< 0.0001), 0.33±0.18 ($P$<0.0001), 0.31±0.21 ($P$<0.0001) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.

**Figure 4: Mean BCVA at baseline and at different follow ups in the study groups**

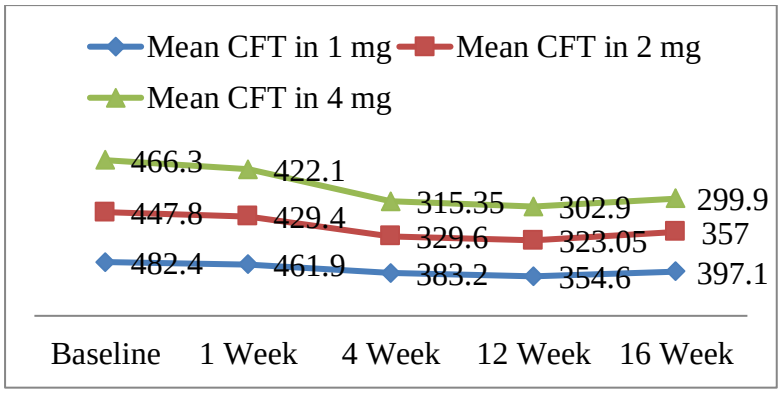



No statistically significant difference was present among groups in Mean BCVA at baseline. There was no statistically significant difference observed in the mean BCVA between three groups (1 mg, 2 mg and 4 mg) at 1week, 4 weeks, 12 weeks and 16 weeks.

**Central Foveal Thickness (CFT) changes**

Mean (±SD) baseline CFT was 482.4 (±164.6) µm in 1 mg group. Mean CFT significantly improved from baseline to 461.9 (±161.2) µm (*P*<0.0001), 382.2 (±121) µm (*P*=0.00051), 354.6 (±120.8) µm (*P*=0.00011), 397.1 ( ±143.8) µm (*P*=0.0032) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.
Mean (±SD) baseline CFT was 447.8 (±178.4) µm in the 2 mg group. Mean CFT significantly improved from baseline to 429.4 (±174.8) µm (*P*<0.0001), 329.6 (±117.3) µm (*P*=0.00012), 323 (±128) µm (*P*<0.0001), 357 (±159.3) µm (*P*<0.0001) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.
Mean (±SD) baseline CFT was 446.3 (±132) µm in the 4 mg group. Mean CFT significantly improved from baseline to 422.1 (±114.8) µm (*P*<0.00058), 315.3 (±99.2) µm (*P*=0.00020), 302.9 (±63.3) µm (*P*<0.0001), 299.9 (±67.9) (*P*<0.0001) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively.

**Figure 5: Mean CFT at baseline and different follow ups in the study groups**



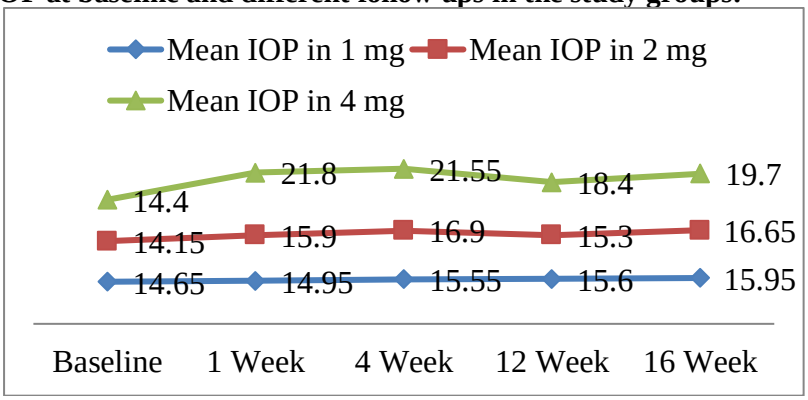

In all three groups, mean CFT improved from baseline. There was no statistically significant difference observed in mean CFT between the three groups (1 mg, 2 mg and 4 mg) at 1 week, 4 weeks, 12 weeks and 16 weeks.

**Intraocular Pressure (IOP) changes**

Intra-ocular pressure remained within normal limits in 1 mg group patients. In 1 mg group, the mean baseline IOP was 14.65 (±1.87) mmHg. It increased from baseline to 14.95 (±1.23) mm Hg (*P*=0.00023), 15.55 (±2.55) mm Hg (*P*=0.0044), 15.6 (±2.13) mm Hg (*P*=0.0043), 15.95 (±2.18) mm Hg (*P*=0.001) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively. In 2 mg group, 3 patients showed rise in IOP >22 mm Hg at post op 1week. Over the period of time it normalized but in 1 case, IOP remained at > 22 mm Hg at end of 16$^{th}$ week. In 2 mg group, the mean baseline IOP was 14.15 (±1.95) mm Hg. It increased from baseline to 15.9 (±2.24) mm Hg (*P*=0.0021), 16.9 (±2.69) mm Hg (*P*=0.0046), 15.3 (±2.7) mm Hg (*P*=0.00022), 16.65 ( ±2.3) mm Hg (*P*=0.0035) at 1 week, 4 weeks, 12 weeks and 16 weeks respectively. In the 4 mg group, 12 patients showed rise in IOP >22 mm Hg at post op 1 week. Over the period of time it normalized, but in 3 cases, IOP remained > 22 mm Hg at end of 16$^{th}$ week. For this, IOP lowering drugs were required. In 4 mg group, the mean baseline IOP was 14.4 (±2.21) mm Hg. It increased from baseline to 21.8 (±5.67) mm Hg (*P*=0.00056), 21.55 (±5.77) mm Hg (*P*=0.0078), 18.4 (±3.26) mm Hg (*P*=0.0065), 19.7 (±4.32) mm Hg (*P*= 0.0047) at 1 week, 4 weeks, 12 weeks, and 16 weeks respectively.
Mean IOP increased from baseline in all three groups (1 mg, 2 mg and 4 mg). There was no statistically significant difference observed in mean IOP between three groups (1 mg, 2 mg and 4 mg) at 1 week, 4 weeks, 12 weeks and 16 weeks.

Lenticular changes at end of 16 weeks postoperatively were found in 0, 1 and 2 eyes with 1mg, 2mg and 4mg IVTA respectively. None of the patients in this study underwent a repeat injection of IVTA.

**Figure 6: Mean IOP at baseline and different follow ups in the study groups:**




## Discussion

This was a prospective study to compare intravitreal triamcinolone 1 mg, 2 mg and 4 mg for the management of macular edema secondary to vascular origin. BCVA, IOP and OCT were recorded pre and post injection to evaluate disease control. In our study, maximum number of patients were found between the age group of 60-69 years whereas Lodhi SA reported[6,7] maximum number of patients between 51-60 years. In our study we observed that males were more than female similar to study done by Lodhi SA.[6,7] In our study we observed distribution of co-morbidities like DR>BRVO>CRVO>HRVO similar to study done by Lodhi SA.[6,7]

**Best Corrected Visual Acuity (BCVA) changes**

In our study, 4 mg group showed maximum number of cases (19) with improvement of visual acuity with mean visual acuity of 0.31 (±0.21) on Log MAR scale (> 6/18 on Snellel's chart) with improvement in BCVA to more than 6/18 followed by 18 and 14 cases showing improvement in the 2 mg and 1 mg groups respectively. Thus, more number of patients responded in the 4-mg IVTA group followed by 2 mg group followed by 1 mg group. The results of DRCR net study,[8] SCORE-BRVO trial,[9] SCORE-CRVO trial,[10] Martidis et al,[11]and Patel PJ et al[12] studies are also similar to our study. DRCR net study[8] concluded that at 4 months, mean visual acuity was better in the 4 mg IVTA group than in the 1 mg IVTA group. SCORE-BRVO[9] and SCORE-CRVO trial[10] reported an early positive treatment response of gain in visual acuity letter score of 15 or more at 4 months in the 4 mg triamcinolone group compared with 1 mg triamcinolone. Martidis et al[11] reported an improvement in visual acuity of 2.4 and 1.3 Snellen lines at the 3-month and 6-month follow-up reviews after intravitreal injections of 4 mg of triamcinolone acetate in diabetic macular edema. Patel PJ et al[12] analysed the results of thirteen patients who received 4 mg of intravitreal triamcinolone for the treatment of macular edema due to vein occlusions. Eight eyes (62%) responded well with improved visual acuity and macular thickness 1–3 months post injection.

**Central Foveal Thickness (CFT) changes**

In our study at 16 weeks following surgery, mean CFT was improved in all three groups as compared to baseline. Similar results were observed in DRCR.net,[8] SCORE BRVO,[9] SCORE CRVO,[10] Massin et al,[13] and Park et al[14] studies.

In DRCR net study,[8] the OCT results generally paralleled the visual acuity results, with a greater beneficial effect seen at 4 months in the 4 mg IVTA group compared to the1 mg group. No difference was observed between the 2 groups during the second year. SCORE-BRVO[9] and SCORE-CRVO Trials[10] concluded that at month 4, there was greater reduction in OCT measured center point thickness in the 4 mg IVTA group than the 1 mg group ($P$<0.001).

Massin et al.[13] studied the use of 4 mg of IVTA for refractory diffuse diabetic macular edema in 12 eyes. The macular thickness decreased from 509.6±143.5µm (mean±SD) (pre-injection) to 207±96.7 µm (after 12 weeks). In the study by Park et al.,[14] improvement in ME was reported with 4 mg IVTA in eyes with Cystoid Macular Edema Associated with Central Retinal Vein Occlusion.

**Intraocular Pressure (IOP) changes**

In our study, incidence of increase in IOP at post op 16 weeks was highest in the 4 mg group followed by 2 mg group. Intra-ocular pressure remained within normal limits in 1 mg group patients.

In 2 mg group, rise in IOP >22 mm Hg was present in 3 patients at post op 1 week, which was normalized at 12 week except in 1 case (5%) who had persistent raised IOP at the end of 16 weeks.

In the 4 mg group, rise in IOP >22 mm Hg was present in 12 patients at post op 1 week which was normalized at 12 weeks but 3 cases (15%) had raised IOP at the end of 16th week. For this, IOP lowering drugs were required.

In DRCR.net study,[8] 40% participants developed ocular hypertension in 1 mg group and 20% participants developed ocular hypertension in the 4 mg group. Glaucoma surgery was performed in 4 eyes in the 4-mg IVTA group. In SCORE-BRVO trial[9] and SCORE-CRVO trial,[10] more eyes in the 4 mg IVTA group required IOP-lowering medication through 12 months compared with the 1 mg IVTA group. In a randomized-controlled trial, Gillies et al[15] addressing the safety of 4 mg IVTA, 32 (42.7%) of the 75 patients in the treatment group developed an elevated IOP, and all were adequately controlled with topical anti-glaucoma drugs. Wingate RJ et al.[16] reported that increase in IOP is not dose-dependent.

**Development of Cataract**

In our study, incidence of lenticular changes was more in the 4 mg group than 2 mg group. In 1 mg group, none of the eyes developed lenticular changes, which is comparable to the DRCR.net[8], SCORE-BRVO[9] and Thompson JT[17] studies. DRCR.net study[8] concluded that more eyes required cataract surgery in the 4 mg IVTA (51%) than in the 1 mg IVTA group (23%). In SCORE-BRVO trial,[9] 25% and 35% patients with 1 mg and 4 mg IVTA, developed lenticular changes respectively at 12 months. Thompson JT (2006)[17] study demonstrated increased lenticular changes with 4 mg IVTA per year.

None of our patients had post injection endophthalmitis, rhegmatogenous retinal detachment or vitreal hemorrhage, however, a larger sample size was desirable. Incidence of non infectious endophthalmitis was reported as 0.6% (4 out of 200 cases) by Sutter and Gillis,[18] 6.7% (7 of 104 eyes) by Roth[19] and 0.2% (1 out of 454 cases) by Jones.[20] None of the patients in the current study underwent a repeat injection of IVTA. According to the literature, repeated injections of IVTA have lesser effect in terms of reduction of CFT and improvement in VA when compared to the initial injection.[21]

## Limitations of the study

Small sample size in all 3 groups, limited duration of follow-up, non-standardized guidelines for repeated injection and non-randomized trial are the limitations of the present study. Large prospective, randomized clinical trials are necessary to compare the long-term efficacy and safety of intravitreal triamcinolone acetonide for patients with macular oedema associated with vascular etiology.

## Conclusion

4 mg dose of IVTA improves the functional and anatomical outcome in macular edema of vascular origin in most patients followed by 2 mg dose. 1 mg and 2 mg dose of IVTA has less incidence of steroid induced elevation of IOP and lenticular opacity development or progression. Further large scale studies are recommended to compare the effectiveness and safety of different doses of IVTA.

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