



## Original Research Article

# Intravitreal triamcinolone acetonide could be a first line medication for patients with DME in a community setting

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## ABSTRACT

**Purpose:** Study aims to establish the efficacy and safety of intravitreal triamcinolone injections in the denovo treatment of DME in a rural poor socio-economic set up.

**Materials and Methods:** 4 mg Intravitreal injections of 0.4 mg of triamcinolone acetonide (IVTA) was given to 50 DME patients as an initial treatment. Best corrected visual acuity (BCVA), central retinal thickness (CMT) and intraocular pressure (IOP) were analysed before and after the treatment at intervals of 1 week, 1 month, 3 months and 6 months.

**Result:** Statistically significant improvements were observed in BCVA, as well as a decrease in CMT after all time-intervals following IVTA. IOP increases were observed 1 week, 1 and 3 months after IVTA, but not at 6 months after IVTA. No sight-threatening side effects of IVTA were observed.

**Conclusion:** IVTA is effective therapeutic measure in control of DME; it could be a therapeutic option of choice in patients with poor socioeconomic status.

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## 1. Introduction

Diabetes Mellitus (DM) is a disorder of carbohydrate metabolism, with the main characteristic features of hyperglycemia with metabolism of fats and proteins is also affected. Diabetic Retinopathy (DR) is a serious complication of DM and is the leading cause of visual disability in diabetics.<sup>1</sup>

According to The International Diabetes Federation, by 2035 the prevalence of DM will reach around 9.9% and there will be huge rise in diabetic population to 592 million people. The latest 2016 data from the world health organization [WHO] has shown that, globally, an estimated 422 million adults are living with diabetes mellitus. In India, the diabetic population has doubled from 3.2 crore in 2000 to 6.3 crore in 2013 and is likely to increase to 10.12 crore in coming 15 years.<sup>2</sup>

One out of 3 people with diabetes develop DR, with reported rates of Diabetic Macular Oedema (DME) reaching

7% in this group of patients.<sup>3</sup> In fact, DME is the leading cause of visual loss and legal blindness in people with diabetes. DME represents a significant burden due to the increasing incidence and prevalence of DM in the Indian subcontinent as also the limited availability of public health resources

It has been shown by The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) that in type 1 diabetics the 14-year incidence of DME is 26%.<sup>4</sup> Similarly the Diabetes Control and Complications Trial (DCCT) reported that there is an increased risk of developing DME in type 1 diabetes and 27% patients develop DME within 9 years of onset.<sup>5</sup> It has been reported that the in older patients with type 2 DM, DME has even higher incidence.<sup>6</sup>

Damage to the endothelial blood–retinal barrier resulting in the breakdown of blood retinal barrier, is an important pathophysiological process leading to DME. Over the last decade, understanding of this complex process has resulted in advancement of new therapeutic approaches.<sup>7</sup> Many ocular inflammatory agents have been implicated in the causation of DME. Release of vascular permeability factors

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such as vascular endothelial growth factor (VEGF) has been studied in detail.<sup>8</sup>

There have been many approaches to treat DME. Grid laser with 532/810 laser has been in vogue. However, presently intra-vitreous injection of anti-VEGF agents/steroids is gaining practice. Anti-VEGF agents are costly particularly to the population living in rural areas who are predominantly daily wage earners. The same is true with depot steroids. However, Triamcinolone Acetonide (TA) is a very affordable option.

TA when given intra-vitreally leads to inhibition of the pathway of arachidonic acid, of which prostaglandin is a product. Intravitreal Triamcinolone Acetonide (IVTA) has a positive effect on DME,<sup>9</sup> as it causes increase in tight junction proteins and subsequently local vasoconstrictive effect<sup>10</sup> which eventually diminishes vessel leakage. It also inhibits Vascular Endothelial Growth Factor (VEGF) exhibiting angiostatic properties.<sup>11</sup> In addition, IVTA injection has reduced the breakdown of the blood retinal barrier significantly.<sup>12</sup>

In view of the above a study has been undertaken to assess anatomical and functional outcome post intravitreal triamcinolone acetonide in patients with DME who have not been subjected to any other treatment.

## 2. Aim of the Study

1. To find out the effectiveness of intravitreal Triamcinolone Acetonide in treatment of diabetic macular oedema.

## 3. Objectives of the Study

1. To assess the visual outcome in patients with diabetic macular oedema after intravitreal triamcinolone acetonide injection.
2. To study the regression of macular oedema clinically and by Optical Coherence Tomography after intravitreal triamcinolone acetonide injection.

## 4. Materials and Methods

A Prospective hospital-based study was undertaken at Department of Ophthalmology, GSL Medical College, Rajahmundry from October 2016 to Mar 2018.

Prior clearance by the institutional ethical Committee was taken.

### 4.1. Study material

1. All patients diagnosed with DM were screened.

### 4.2. Examination of these patients consisted of the following

1. Detailed ocular history and systemic history including the details of medication for DM.

2. Best Corrected Visual acuity (BCVA).
3. A thorough examination of the anterior segments by torchlight followed by slit lamp examination was conducted. Details of papillary reaction and the presence or absence of iris neo-vascularisation (NVI) was noted.
4. Detailed fundus examination was conducted under pharmacological dilatation.
  - a) Initial examination was done with a direct ophthalmoscope.
  - b) Examination under bio-microscope with 90D lens was then undertaken.
  - c) Indirect Ophthalmoscopy was done where required.
5. Intra-ocular pressure by Goldman Applanation Tonometry was done.
6. Clinically diagnosed cases of diabetic macular oedema (DME) were then subjected to laboratory investigations inclusive of evaluation of blood glucose levels and serum creatinine.
7. All suspected cases of DME were then subjected to OCT.
8. Oct procedure: OCT pictures were taken with ZEISS OCT machine (PRIMUS 200). The patient was made to seat in front of the OCT machine, details of the patient were entered, and the patient was asked to focus on green dot in OCT machine. Macular cube mode was selected, and pictures were taken. The thickness of the macula was noted. The characteristics of the DME when present were noted.)
9. Fluorescein angiography was done in if required in those cases that had normal serum creatinine levels with ZEISS fundus camera (PRIMUS 500).
10. Patients were then selected for intra-vitreous triamcinolone acetonide injection if the CMT was  $> 250 \mu$  with BCVA  $< 6/9$ .

These subjects were then selected for the study based on the following inclusion and exclusion criteria:

### 4.3. Inclusion criteria

1. DME in patients over 30 years of age.
2. Denovo foveal centre involving diabetic macular oedema in proliferative diabetic retinopathy or non proliferative diabetic retinopathy.

### 4.4. Exclusion criteria

1. Patients having previous history of macular photocoagulation.
2. Patients who already had intravitreal triamcinolone acetonide and anti-VEGF injection.
3. Patients already having any macular disease earlier.
4. Cases other than diabetic retinopathy which can give rise to macular oedema.
5. Myopes with glaucoma

6. Patients having any combined pathology like diabetic macular oedema with age related macular degeneration, venous occlusion or retinal vasculitis.
7. Any steroid responder.

IVTA was given intravitreally to the subjects who met the inclusion and exclusion criteria.

#### 4.5. Procedure of IVTA

The procedure was done with meticulous aseptic precaution the central operating room. It was carried out under topical anaesthesia. A pre-injection single drop of Povidone-Iodine (5%) solution was applied to the eye followed by thorough cleaning of the eyelashes and application of a lid speculum. For topical anaesthesia, 0.5% proparacaine hydrochloride drops were applied. Triamcinolone acetonide in a single-use bottle (40 mg/ml, 1ml bottle), was drawn into a 1-cc tuberculin syringe after cleansing the top of the bottle with an alcohol wipe. A separate 26 gauge needle was placed onto the syringe, which was then inverted to remove air bubbles. The excess triamcinolone was discarded till 0.1 ml (4 mg) remained in the syringe. The injection was given at 2.5 mm from the limbus (in aphakic and pseudophakic patients) and 3.5 mm from the limbus in phakic patients. The needle was usually not introduced all the way to the hub. Using a single, purposeful continuous manoeuvre, the steroid was injected into the eye. The needle was removed simultaneously with the application of cotton-tipped applicator over its entry site to prevent regurgitation of the injected material. Indirect ophthalmoscopy to check for central retinal artery (CRA) pulsation and paracentesis (if CRA pulsation is present or the globe feels very tense) were carried out, a drop of topical antibiotic solution was administered and the eye was patched. The patient was usually put on a post-injection course of topical antibiotic eye drops for a week.

#### 4.6. Review of the patient

Patients were reviewed on day 1, day 7, day 30, day 90 and day 180. Each review consisted of the following:

1. BCVA.
2. Slit lamp biomicroscopy of anterior chamber specifically for any complications.
3. Funduscopy inclusive of 90D slit lamp biomicroscopy for evaluation of macula as well the retina for any complications.
4. OCT.
5. IOP by applanation tonometry.

The results were recorded and subjected to analysis.

Statistical analysis using SPSS Software version-20 and MS Excel 2013

Descriptive data was presented as mean  $\pm$  standard deviation, percentages, tabulated and graphically represented.

Study results were analysed by chi-square test and ANOVA test.

For all statistical analysis  $p < 0.05$  was considered as statistically significant.

Total of 50 cases were selected in the study for analysis.

## 5. Results and Observation

### 5.1. Distribution of Best corrected visual acuity (BCVA)

As depicted in Table 1, out of the cohort of 50 patients, there were 40 patients having BCVA  $< 6/24$  preoperatively. Out of these 22 patients had BCVA  $< 6/60$  and 18 patients had BCVA between  $6/36 - 6/24$ . This number decreased significantly to 03 patients having BCVA  $< 6/60$  on day 30 follow-up. On day 90 and day 180, all 50 patients had BCVA  $> 6/36$ . On day 180 maximum that is 34/50 patients had BCVA  $> 6/18$ . Chi-square test was done and results were statistically significant.

### 5.2. Distribution of central macular thickness (CMT)

In present study, out of 50 eyes 28 eyes (56%) had CMT between 386-685 microns and 22 (44%) eyes had CMT between 286-385 microns preoperatively. CMT significantly improved on day 90 after IVTA injection with 46 (92%) eyes having CMT in range of 186-385 microns. On day 180 all 50 eyes (100%) had CMT  $< 385$  microns with maximum i.e. 38 (76%) eyes having CMT  $< 285$  microns and 12 (24%) eyes had CMT in the range of 286-385 microns. ANOVA test was done and results were statistically significant. ( $P=0.000$ ).

### 5.3. Distribution of mean CMT

Mean CMT in the present study was 408.72 microns preoperatively and 373.12 micron, 313.12 microns, 275.82 microns, 255.42 microns on day 7, day 30, day 90 and day 180 respectively.

### 5.4. Distribution of IOP changes

As depicted in Table 4, on day 7 there was 1/50 eye had IOP  $> 21$  mmHg. On day 30 there were 5/50 eyes and on day 90 maximum i.e 12/50 eyes had raised IOP of  $> 21$  mmHg. On day 180 all 50 eyes had IOP within normal range i.e  $< 21$  mmHg. ANOVA test was done and results were statistically significant with  $p=0.000$ .

### 5.5. Distribution of mean IOP

As depicted in Table 5, mean IOP preoperatively was 15.31 which became 15.48 mmHg, 16.72 mmHg, 18.48 mmHg, 15.58 mm Hg on day 7, day 30, day 90 and day 180

**Table 1:** Distribution of Best corrected visual acuity

Best- corrected visual acuity	No. of eyes				
	Pre-op	Day 7	Day 30	Day 90	Day 180
< 3/60	1	0	0	0	0
4/60- 6/60	21	20	3	0	0
6/36-6/24	18	16	26	18	16
>6/18	10	14	21	32	34

**Table 2:** Distribution of central macular thickness

Central Macular Thickness [microns]	No. of eyes				
	Pre-op	7 Days	30 Days	90 Days	180 Days
<200	0	6	16	33	38
286-385	22	24	27	13	12
386-485	19	16	6	4	0
486-585	6	3	1	0	0
586-685	3	1	0	0	0

**Table 3:** Mean CMT distribution

	Pre op	Day 7	Day 30	Day 90	Day 180
MEAN CMT (microns)	408.72	373.12	313.12	275.82	255.42

**Table 4:** IOP changes distribution

	No of patients				
	Pre-op	Day 7	Day 30	Day 90	Day 180
<21 mmhg	50	49	45	38	50
>21 mmhg	0	1	5	12	0

**Table 5:** Distribution of mean IOP

	Pre-op	Day 7	Day 30	Day 90	Day 180
IOP (mmhg)	15.31	15.48	16.72	18.48	15.58

respectively.

## 6. Discussion

Patients were in age groups of 45-74 year. Study included 27 males and 23 females. Male: female ratio is 1.17: 1. Duration of diabetes of the study population ranged from 0- 20 years. In this study 37 patients were on OHA and 13 were on insulin treatment.

The morphology on OCT in maximum number of cases was cystoid macular oedema (42%) and spongy macular oedema (46%).

### 6.1. Distribution of Best corrected visual acuity (BCVA) [Table 1]

In the study group of total 50, 40 (80%) had pre op visual acuity <6/24. At the conclusion of the study period, 68% of the eyes had BCVA more than 6/18. This data is the gist of the entire study. The BCVA had increased from <6/24 to > 6/18 in 68% of the cases.

Distribution of visual acuity on day 7, graph is absolutely similar to preoperative bars with marginal increase in eyes having BCVA >6/18. But as the review increased to 30 days number of eyes with 6/36- 6/24 had gone up. Eyes with BCVA 4/60 -6/60 had grossly gone down. Number of eyes and BCVA further reversed on day 90. Minimum BCVA on day 90 was 6/36 -6/24. This improvement of vision was maintained on day 180 when all the patients were > 6/36- 6/24. This was a good improvement and on statistical analysis this improvement was highly significant with a p-value of 0.00

The present study also implies the fact that maximum improvement in BCVA would occur by day 90 and would remain so even on day 180.

Martidis et al<sup>13</sup> evaluated the safety and effectiveness of intravitreal injections of 4 mg TA. It was found that mean visual acuity improved. This improvement was at 01month of 2.4 Snellen lines, at 03 months again of 2.4 lines and at 06 months interval of 1.3 Snellen lines.

## 6.2. CMT [Table 2]

The CMT at baseline (pre-injection) was between 286 – 385 microns in 22/50 eyes (44%).

If the CMT block from 286 to 485 microns is taken into consideration, this would encompass 41/50 eyes (82%).

This data would imply that in majority of the eyes which present with DME the CMT would be about 450 microns.

DME beyond 486 microns constituted 9/50 (18%) of the study group. This would imply that DME as an entity would give a swelling of about 450 microns in usual circumstances.

On review on day 07, the number of eyes with less than 285 microns rose to 06 eyes (12%). However, majority 40/50 (80%) still had CMT between 286 to 485 microns. This implies that on day 07 there was not much difference in the CMT or in other words, the DME was yet to respond. The CMT over 486 microns had come down from 9/50 (18%) to 4/50 (8%). Therefore, it can be assumed that the higher CMT did come down to lesser values on day 7.

On day 30, eye with CMT more than 486 was only 01 (2%). This data would highlight the timing of efficacy of IVTA, if the same data was read with 16/50 (32%) eyes with CMT less than 285 microns. An assumption can be made that the effect of IVTA in lowering the CMT would start by day 30 (04 weeks).

Day 90 and day 180 show almost similar results. On day 90, there were still 04 eyes (08%) with CMT more than 386 microns which had reduced by day 180.

On day 180 all 50 eyes (100%) had CMT <385 microns with maximum i.e. 38 (76%) eyes having CMT <285 microns and 12 (24%) eyes had CMT in the range of 286-385.

There was good improvement in CMT, and on statistical analysis it was highly significant with p- value 0.000.

The inference which has been received from this data of CMT reduction date wise after an intra-vitreous injection of TA would be that the action would start by day 30 (04 weeks) and would plateau by day 90 (12 weeks).

## 6.3. BCVA & CMT

The data on BCVA and its understanding would be incomplete without the study of corresponding macular thickness (CMT) as measured by OCT. The CMT in this study had decreased as follows:

The mean CMT and median BCVA in this study have been running *pari passu*. The analysis that has been reached in the study of CMT all through the study has been corroborated by the median BCVA. The BCVA jumped to 6/24 on day 30 and this improvement got enhanced by day 90 to 6/18 to remain so till the last review. This aspect has been subjected to statistical analysis and it should be seen that the difference in vision as well as the decrease in CMT have been statistically significant.

Martidis et al studied the safety and efficacy of intravitreal injection of 4mg TA in 16 eyes with CSME which did not respond to at least 2 sessions of laser photocoagulation. There was significant reduction in CMT as measured by OCT, which reduced to 55% at 01 month, to 57% at 03 months and to 38% at 06m follow up intervals. However in this study no case with prior laser photocoagulation has been included.

Another similar study by Taygan Yilmaz et al<sup>14</sup> in 2008, efficacy as determined by change in CMT was assessed, which was considered a strong prognostic measure of level of DME. Central macular thickness was significantly reduced at 3month (p<0.00001) and 6 months (p= 0.04) of follow up.

## 6.4. IOP Changes [Table 4]

Intraocular Pressure (IOP) of 21 mm Hg by applanation tonometry was taken as abnormal in this study and the eye with raised IOP was followed up weekly with the institution of anti-glaucoma medication as applicable.

The changes in IOP In this study have been depicted in Table 4.

1. Pre operatively none of the 50 patients had IOP more than 21 mm Hg with mean IOP being 15.31mm Hg.
2. On 07 day follow-up visit, 1 patient developed IOP more than 21 mm Hg and mean IOP in study group on day 07 was 15.48 mm Hg.
3. On day 30, 5/ 50 (04%) eyes had IOP more than 21 mm Hg with mean IOP in study population being 16.72mm Hg.
4. On day 90, out of 50 eyes, 12 eyes had IOP more than 21 mm Hg and 38 eyes had IOP value less than 21mmhg with mean IOP being 18.48mm Hg.
5. On day 180, all 50 eyes had IOP value within normal range that is less than 21 mm Hg. Mean IOP value in entire study group was 15.58mm Hg.

There were a total of 12 eyes which had IOP of 21 mm hg or more in the entire study from day 7 to day 90. Raised IOP was controlled with anti-glaucoma medications.

On analysing the mean IOP of the study group on the day of the review, it has been seen that maximum mean IOP of 27 mm Hg was seen on day 30 and mean IOP of 26 mm Hg on day 90. The mean IOP of the study group was 20 mm Hg on day 180 in the study group. This difference of mean IOP in the study group from pre-injection to mean IOP on various review dates with the mean IOP on day 180 was seen to be statistically significant with a p value of 0.000.

In the study done by Lokman Balyen et al<sup>15</sup>, it was found that the mean IOP before injection of IVTA was 13.1+/- 1.6 mmHg (8-17 mmHg). Post IVTA injection, the mean IOP was 16.2+/- 2.4 mmHg (8-20 mmHg) on day 07, 16.5+/- 2.4 mmHg (8-20 mmHg) on day 30, 15.1 +/- 2.2 mmHg (10-20 mmHg) on day 90 and 13.9 +/- 1.8 mmHg (10-14 mmHg) on

**Table 6:** Mean CMT Pre-operatively: 408.72 microns & Median BCVA: 6/36

S. No.	Review Day	Mean CMT (microns)	% from baseline	% Difference	BCVA (Median)
1.	Day 7	373.12	91.28	8.72	6/36
2.	Day 30	313.12	76.60	23.40	6/24
3.	Day 90	275.82	67.48	33.52	6/18
4.	Day 180	255.42	62.49	37.51	6/18

day 150 follow-up. Increase in mean IOP were 22%, 24.2%, and 14.4% at 7 days, 30 days and 90 days; respectively. When patient was followed up on day 150, the mean IOP was less than baseline measurement. The difference between mean IOP values at 1st week, 1st and 3<sup>rd</sup> month was statistically significant ( $p < 0.001$ ). None of the patients in the study of Balyen et al experienced IOP level higher than 21 mmHg and required medical treatment. This is the difference in the present study where there were 12 patients with IOP of 21 mm Hg or more.

## 7. Summery

This study “Anatomical and Functional Outcome in Diabetic Macular Oedema Post Intravitreal Triamcinolone Acetonide” was conducted at the Department of Ophthalmology, GSL Medical College, Rajahmundry from October 2016 to Mar 2018 after obtaining ethical clearance.

In this prospective hospital based study 50 patients with diabetes (DM) having diabetic macular oedema were included.

The recruited cases were evaluated by taking detailed history, systemic and complete ophthalmic examination including OCT to quantify CMT. The study subjects were then subjected to IVTA of 04mg and were reviewed for the outcome by OCT and BCVA as also by complete ophthalmic examination to assess for complications if any. The results were as follows:

1. Patients were in age groups of 45-74 year.
2. Study included 27 males and 23 females. Male: female ratio is 1.17: 1
3. Duration of diabetes of the study population ranged from 0- 20 years.
4. In this study 37 patients were on OHA and 13 were on insulin treatment.
5. The morphology on OCT in maximum number of cases was cystoid macular oedema (42%) and spongy macular oedema (46%).
6. Maximum numbers of patients were in the age group of 51- 65 years.
7. Eighty percent 40/50 of the patients had pre op visual acuity  $< 6/24$ . At the conclusion of the study period, 78% of the eyes had BCVA of  $> 6/18$ . This data was found to be statistically significant. Maximum improvement in BCVA occurred by the day 90 and

remained so even on day 180.

8. Pre-op CMT ranged from 286- 685 microns with mean CMT 373.12 microns which significantly improved after intravitreal injection of triamcinolone acetonide with mean CMT of 275.82 at day 90 and 255.42 at day 180. This change in the CMT was statistically significant.
9. There were a total of 12 eyes which had IOP of 21 mm hg or more in the entire study from day 7 to day 90. Raised IOP was controlled by topical anti-glaucoma medications with all 50 patients having IOP  $< 21$  mmHg on conclusion of the study. The mean IOP was 15.58 mmHg on day 180 in the study group.
10. In this study no other complications were noted.

## 8. Conclusion

Single injection of 04 mg of triamcinolone acetonide into the vitreous in cases of diabetic macular oedema statistically significantly improves the functional outcome by improving visual acuity and also improves the anatomical outcome with pari passu statistically significant decrease in the central macular thickness as corroborated by OCT up to day 90 with transient increase in IOP being the only side-effect and is cost effective.

## 9. Source of Funding

None.

## 10. Conflict of Interest

None.

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