

# Intra-Ocular Pressure after Injection of Intra-Vitreous Triamcinolone Acetonide in Patients with Diabetic Macular Edema

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PJO – Official Journal of  
Ophthalmological Society of Pakistan



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## ABSTRACT

**Purpose:** To determine the frequency of raised intraocular pressure and the pattern of intraocular pressure changes following intravitreal triamcinolone acetonide (IVTA) injection in patients with diabetic macular edema (DME) for three months follow up.

**Study Design:** Quasi experimental study.

**Place and Duration of Study:** Jinnah Postgraduate Medical Center, Karachi from January 2024 to June 2024.

**Methods:** A total of 150 patients, scheduled for IVTA injection for DME with central subfield thickness of  $\geq 250$   $\mu\text{m}$  were included. Patients with history, any other intraocular diseases and previous retinal surgery or anti-VEGF injections were excluded. After IVTA injection, patients were followed up at week 1, month 1 and month. Pre-injection and post-injection intraocular pressure (IOP) were measured at each visit. Data analysis was performed using SPSS version 22.

**Results:** The median (IQR) age of participants was 36.0 (34-42) years. There were 70.0% males. The median duration since diagnosis of DME was 5.0 (3-5) months, and median HbA1c was 10.3 (9.6-11.2)%. The median baseline IOP was 17 (16-18) mmHg. Following IVTA injection, the median IOP was 18.0 (17-19) mmHg at 1 week, 19 (17-20) mmHg at 1 month, and 18 (18-22) mmHg at 3 months ( $p < 0.001$ ). The frequency of raised IOP at 3 months post-injection was 41 patients (27.3%).

**Conclusion:** IVTA injection in patients with DME was associated with a significant rise in IOP, with 27.3% of patients developing raised IOP at 3 months. Careful monitoring of IOP is mandatory following IVTA therapy.

**Keywords:** Diabetes Mellitus, Intraocular Pressure, Triamcinolone Acetonide. Optical coherence tomography.

**How to Cite this Article:** Yousuf H, Tahir MA. Intra-Ocular Pressure after Injection of Intra-Vitreous Triamcinolone Acetonide in Patients with Diabetic Macular Edema. 2026;42(1):1-5. **Doi:10.36351/pjo.v42i1.2111**

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*Received: May 17, 2025  
Revised: October 31, 2025  
Accepted: November 24, 2025*

## INTRODUCTION

Diabetes mellitus is one of the major causes of vision impairment globally.<sup>1</sup> Diabetes causes macular edema by disrupting the blood-retinal barrier, producing advanced glycation products (AGEs), and activating inflammatory markers such as protein kinase C and vascular endothelial growth factor (VEGF).<sup>2</sup> Diabetic

macular edema (DME) is associated with altered vascular density, which can be measured using a range of tests, the most relevant of which are fluorescein angiography and optical coherence tomography angiography (OCTA).<sup>3,4</sup> When it comes to prevalence of DME in diabetic patients studies have shown great degree of variation with reported frequency ranging from as low as 3.7% to as high as 43.33%.<sup>5,6</sup>

Treatment of DME involves intravitreal injections of anti-vascular endothelial growth factors Bevacizumab, Ranibizumab and Aflibercept.<sup>7</sup> Another important intervention being used is intra-vitreous injection of Triamcinolone Acetonide.<sup>8</sup> It is especially useful in cases of diffuse diabetic macular edema where pan-retinal laser photocoagulation is no longer an effective treatment option. However, there is one of

**Table 1:** IOP base line and post intravitreal injection Triamcinolone.

Baseline	1 Week	1 Month	3 Months	p Value
17.00 (16-18)mmHg	18.00 (17-19) mmHg	19.00 (17-20) mmHg	18.00 (18-22.3)mmHg	(p < 0.001). (Friedman's two-way analysis of variance (ANOVA))

the complications that are associated with IVTA, which is raised IOP. The frequency of raised IOP after IVTA injection is reported to be 46.05% according to one study.<sup>9</sup> In another study, changes in the IOP were also assessed over a period of three months and it was found that the mean IOP increased from baseline value of  $14.95 \pm 3.15$  mmHg to a maximum of  $19.05 \pm 4.94$  mmHg after 3 months of injection.<sup>9</sup> Contradictory results were also reported showing no significant effect on IOP after IVTA injection.<sup>10</sup>

Contradictory reports regarding the effect of IVTA injections on IOP in patients with DME raise an important research question: does IVTA increase or decrease IOP in these patients? To address this, the present study was conducted with the objective of determining the frequency of raised IOP and the pattern of IOP changes following IVTA injection in DME patients. The findings from this study are expected to guide whether routine IOP monitoring should become a standard of care for all patients undergoing follow-up after IVTA injection. Furthermore, they may support early identification and timely management of patients at risk of developing elevated IOP.

## METHODS

This quasi experimental study was conducted at Jinnah Postgraduate Medical Center, Karachi from January 2024 to June 2024 after getting approval from research evaluation committee (No.F.2-81/2023-GENL/154/JPMC). Sample size calculation was performed using Open Epi sample size calculator with confidence level of 95%, absolute precision of 8% and anticipated frequency of raised IOP after IVTA injection in DME patients of 46.05%.<sup>9</sup> The sample size of 150 was selected by using non-probability consecutive sampling technique. Patients either male or female, age range from 30 to 55 years and scheduled to receive IVTA injection for DME with central subfield thickness of  $\geq 250$   $\mu$ m were included. Diagnosis of DME was made by consultant ophthalmologist with minimum of three years of

experience using ophthalmoscope and optical coherence tomography (OCT). Patients with history of cataract, glaucoma, central subfield thickness < 250  $\mu$ m, previous retinal surgery or anti-VEGF therapy were excluded.

Informed written consent was obtained from every patient. Baseline characteristics including age, gender, HbA1C, duration of DME and IOP were documented. IOP was measured using Goldmann applanation tonometry. Patients were called for follow up at week one, month one and month three. At each visit, IOP was checked and documented. During the three months follow up, patients were assessed for presence of raised IOP defined as IOP of more than 21 mmHg. All the patients with raised IOP were examined and seen by consultant ophthalmologists and appropriate treatment was provided.

Data was analyzed using SPSS version 22. Quantitative variables (age, duration of diabetic macular edema, HbA1C, IOP) were presented as median interquartile range (IQR) after checking normality of data by Shapiro-Wilk test which showed that these were not distributed normally. Qualitative variables (gender and presence of raised IOP) were presented as frequency and percentages. Friedman's two-way analysis of variance (ANOVA) by ranks test was used to compare the median IOP values at baseline with IOP values at week one, month one and month three. A p-value of  $\leq 0.05$  was considered as statistically significant.

## RESULTS

A total of 150 eyes of 150 patients were included. Median (IQR) age was 36.00 (34-42) years. There were 105 (70.00%) male and 45 (30.00%) female patients. Median duration since DME diagnosis was 5.00 (3-5) months. Median HbA1C % was 10.30 (9.6-11.2). Change in IOP during the follow up is presented in Table 1. Frequency of raised IOP at three months after IVTA injection in patients with DME was 41 (27.30%).

## DISCUSSION

Diabetes mellitus is on the rise in Pakistan as well as other parts of the world.<sup>11-13</sup> Its effective management is of utmost importance as it can lead to irreversible loss of vision which has significant impact on the quality of life of the patients.<sup>14</sup> One of the intervention that has been considered effective for management of DME is the administration of IVTA.<sup>15</sup> Present study focused on one of the potential complication, i.e., rise in the IOP after IVTA.

In the present study, most of the patients with DME were males constituting 70% of the whole study population which demonstrates a clear male predominance for this disease with a male to female ratio of 2.33:1. Lundeen et al,<sup>16</sup> analyzed trend of DME over a decade and reported predominance of male for DME.<sup>16</sup> Contrary to this, Lin et al, had higher frequency of females with DME.<sup>17</sup> The male predominance demonstrated in the present study can be attributed to the gender disparities in the ease of accessibility to healthcare facilities with males having much more easier access to healthcare services than females who are dependent on their male partners or guardians to seek medical help. Similar gender disparity was demonstrated by Bowe et al, who reported males to be more likely to be part of a clinical trial than females.<sup>18</sup>

Average HbA1C in DME patients was above 10% demonstrating a poor glycemic control, which is an expected possibility since poorly controlled diabetes is the primary reason for development of this potentially blinding complication.<sup>19,20</sup> When the change in intraocular pressure (IOP) from baseline to three months post-intervention was analyzed, a significant rise was noted during the first week and at one month. By the three-month follow-up, IOP had begun to decline, although it remained higher than the baseline level. Similar incremental trend of IOP was demonstrated by Orii et al.<sup>8</sup> However, they found the rise of IOP for a much longer duration after IVTA as compared to the present study. Balyen et al, also reported similar progressively rising IOP trend after IVTA injection in DME.<sup>10</sup> Changes in the cellularity of trabecular meshwork and the outflow tract of the aqueous humor by the steroids result in raised IOP.<sup>21</sup>

The frequency of raised IOP in our patients was 27.3%. Compared to this, Karakahya et al, found raised IOP in 46.05% which is much higher than current study.<sup>9</sup> In another study conducted by Mahar

et al,<sup>22</sup> even higher frequency of raised IOP (65%) was observed among DME patients who were treated with IVTA injection.<sup>22</sup> The difference of this IOP could be due to the differences in the therapeutic protocol of IVTA administration, IVTA injection dosage and frequency of administration, and the differences in the sample sizes among the studies.

Based on the results of current study, it is evident that rise in IOP can occur quite frequently in patients who undergo IVTA injection for DME, but the frequency is not of the magnitude which may discourage the use of this potentially effective intervention to manage DME. Through careful monitoring and watchful management, rise in IOP can be easily managed. Therefore, it is strongly recommended that IOP of all the patients who undergo IVTA injection therapy for DME should be monitored for IOP after the intervention.

This study has several limitations. Being a quasi-experimental and single-center study without a control group, the findings may not be generalizable to wider populations. The follow-up period was limited to 3 months, which does not capture longer-term IOP changes. Exclusion of patients with glaucoma, cataract, or prior retinal surgery may underestimate the true risk of IOP elevation in real-world settings. Although the sample size was reasonable, it may not have been sufficient to detect less common adverse outcomes. Finally, the study focused primarily on IOP and did not correlate these changes with visual acuity or structural improvement on OCT.

## CONCLUSION

IVTA injection in patients with DME was associated with a significant rise in IOP, with 27.3% of patients developing raised IOP at 3 months. Careful monitoring of IOP is mandatory following IVTA therapy.

**Funding:** This study was not funded by any organization.

**Patient's Consent:** Researchers followed the guidelines set forth in the Declaration of Helsinki.

**Conflict of Interest:** Authors declared no conflict of interest.

**Ethical Approval:** The study was approved by the Institutional review board/Ethical review board (No.F.2-81/2023-GENL/154/JPMC).

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### **Authors Designation and Contribution**

Hadia Yousaf; Postgraduate Trainee: *Concepts, Design, Literature Search, Data Acquisition, Data Analysis, Statistical Analysis, Manuscript Preparation, Manuscript Editing, Manuscript Review.*

Muhammad Ali Tahir: VR Consultant: *Concepts, Design, Literature Search, Manuscript Preparation, Manuscript Review.*

