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To compare short term visual and anatomical outcomes of single intravitreal injection of triamcinolone acetonide (4 mg/0.1 ml) versus single intravitreal injection of bevacizumab (1.25 mg/0.05 ml) in diabetic macular edema at the end of one month

[1] Tejal Pundalik Deshmukh, [2]Aditya Vipul Sadalge, [3] Arundhati Malviya , [4] Shruti Subhash Patil, [5]Komal Satish Parikh

[1*]Student, [2] Student,[3]Professor,[4]Student,[5]Professor and Head of Department
[1-5]Ophthalmology
[1-5] NAMO medical hospital and research center silvasa, India
tejdeshmukh6@gmail.com

Abstract:
Purpose:
To compare the short-term efficacy and safety of intravitreal bevacizumab (IVB) versus intravitreal triamcinolone acetonide (IVTA) in the management of diabetic macular edema (DME).
Methods:
A randomized, comparative, interventional study was conducted on 40 eyes of patients with DME, divided equally into two groups (n=20 each). Group 1 received 1.25 mg/0.05 mL IVB, while Group 2 received 4 mg/0.1 mL IVTA. Baseline characteristics, including age, sex, duration of diabetes, best corrected visual acuity (BCVA), and central macular thickness (CMT), were comparable between the groups. BCVA (logMAR) and CMT were assessed at baseline and at 1 month post-injection.
Results:
At 1 month, both groups demonstrated statistically significant improvement in BCVA and CMT compared to baseline ($p < 0.0475$). The IVTA group showed significantly greater improvement in BCVA ($p = 0.0074$) and a larger reduction in CMT compared to the IVB group. A statistically significant increase in intraocular pressure (IOP) was observed in the IVTA group at 1 month, with 3 eyes (15%) exhibiting an elevation of ≥4 mmHg from baseline, which was managed successfully with topical anti-glaucoma medications. No other complications were recorded in either group.
Conclusion:
A single intravitreal injection of triamcinolone acetonide produces superior short-term improvements in visual acuity and macular thickness compared to bevacizumab in patients with DME. However, the associated risk of IOP elevation with IVTA requires careful post-injection monitoring.

***Keywords*- Diabetic macular edema, intravitreal triamcinolone acetonide, intravitreal bevacizumab, central macular thickness, visual acuity, intraocular pressure**

INTRODUCTION

Over the past two decades, significant progress has been made in understanding and managing diabetic retinopathy (DR) and diabetic macular edema (DME), two major ocular complications of diabetes mellitus and leading causes of vision loss in working-age individuals(1). Despite advancements in knowledge, full implementation of preventive and treatment strategies remains a challenge. Diabetic retinopathy is a progressive retinal vascular disorder driven by chronic hyperglycemia(2). It is classified into non-proliferative (NPDR) and proliferative (PDR) stages. The duration of diabetes is the strongest predictor of retinopathy development. DME, characterized by fluid accumulation in the macula, can occur at any stage of DR and results from increased vascular permeability. Traditionally, laser photocoagulation has been the standard treatment for DME, particularly focal edema(3). However, it is less effective in diffuse DME and carries risks such as foveal burns, scotomas, and subretinal fibrosis. Furthermore, laser therapy does not address the underlying pathogenesis involving VEGF and other growth factors. Newer treatments target these pathways. Anti-VEGF agents (pegaptanib, ranibizumab, bevacizumab) and intravitreal corticosteroids like triamcinolone acetonide have shown promise by reducing vascular permeability and inflammation(4). This study aims to compare the short-term efficacy and safety of a single intravitreal injection of triamcinolone acetonide (4 mg/0.1 ml) versus bevacizumab (1.25 mg/0.05 ml) in patients with DME, focusing on changes in best corrected visual acuity (BCVA), central macular thickness (CMT), and associated complications.

MATERIAL AND METHODS

Study design and Participants:

A prospective, randomized, interventional clinical trial was performed on 40 human eyes with center-involving DME. Institutional ethics committee approval and informed consent from all patients were taken. Patients who were eligible were known diabetics, treated regularly with well-controlled blood glucose levels. They had retinal thickening or hard exudates within one disc diameter from the center of the macula, a best corrected visual acuity (BCVA) by logMAR of 0.3 or poorer, and a central macular thickness (CMT) of more than 250 microns on optical coherence tomography (OCT). Only patients above the age of 50 years without previous treatment of macular edema were enrolled. Exclusion criteria included patients who were younger than 50 years, with any other macular disorder like ARMD or macular scars, or with evidence of vitreomacular traction on OCT. Eyes that had a history of previous vitreoretinal surgery or any other ocular disease, with the exception of early cataracts, were also excluded. Patients with uncontrolled diabetes, uncontrolled hypertension, chronic kidney failure, or with a history of blood clots were also excluded. Lastly, patients who did not want to give written consent were excluded. The patients were divided into two groups randomly. Group A was given intravitreal Bevacizumab (1.25 mg/0.05 ml). Group B was administered intravitreal Triamcinolone Acetonide (4 mg/0.1 ml). All the injections were done under strict asepsis. The patients were assessed at the beginning and followed up after a month. The evaluation comprised best corrected visual acuity (BCVA), which was assessed with logMAR, intraocular pressure (IOP) with Goldmann applanation tonometry, and central macular thickness (CMT) with optical coherence tomography (OCT). Adverse effects were also observed during the study.

RESULTS

Statistical Analysis:
Data analyzed using SPSS v22. Student's Unpaired t test
$P < 0.05$ considered statistically significant

Table 1 - Comparsion of Age

- Baseline characteristics (age, sex, diabetes duration, BCVA, CMT) were statistically comparable between groups.
- CMT decreased significantly in both groups, with greater reduction in the IVTA group ($p < 0.05$).
- IOP rise was seen in 3 eyes (15%) in the IVTA group, controlled with topical medication.
- No other complications were noted.

Table 1: Comparsion of Age

Age (years)	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value
Mean +_ SD	60.80 +_ 6.510	62.70 +_ 5.222	0.3151 *

Table 1 displayed Unpaired t test, Two tailed p value > 0.05 Not Significant (@95% Cl) The average age in the Bevacizumab group was 60.80 ± 6.510 years (range 51-72 years) and that in the Triamcinolone group was 62.70 ±

5.222 years (range 54-72 years). Both the groups were comparable with respect to mean age and no statistically significant difference was found (P Value 0.3151)

Gender	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value
Male	17(85%)	12(60%)	0.1552$
Female	3(15%)	8(40%)	
Total	20 (100%)	20(100%)	

Table 2 – Comparsion of Gender

Table 2 displayed $ Fisher's Exact test, p value >0.05 Not Significant (@95% CI) Out of 20 patients in the Bevacizumab group 17(85%) were males and 3(15%) were females. In the Triamcinolone group 12(60%) were males and 8(40%) were females. Both the groups were comparable with respect to gender distribution and no statistically significant difference was found (P Value-0.1552).

Duration (years)	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value
Mean +_ SD	9.200+_ 1.399	10.00 +_ 1.298	0.0685*

Table 3 – Duration of Diabetes

Table 3 displayed * Unpaired t test, Two tailed p value > 0.05 Not Significant (@95% Cl) The mean duration of diabetes in the Bevacizumab group was 9.200 ± 1.399 years (range 6-12 years) and that in the Triamcinolone group was 10.00 ± 1.298 years (range 8-12 years). Both the groups were comparable with respect to mean duration of diabetes and no statistically significant difference was found (P Value-0.0685).

TABLE 4 Comparison of BCVA by logMAR scale

• BCVA improved significantly in both groups post-injection ($p < 0.05$).

•The IVTA group showed significantly greater BCVA improvement than the IVB group ($p = 0.0074$).

Time	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value
PREINJECTION Mean +_ SD	0.8800+_0.1508	0.8000+_0.1947	0.1544*
POSTINJECTION Mean +_ SD	0.4200+_0.1704	0.2950+_0.09987	0.0074*
P – Value	<0.0001@	<0.0001@	

Table 4 displayed * Unpaired t test, Two tailed p value < 0.05 Significant (@95% Cl) Pre-injection BCVA by logMAR scale in the Bevacizumab was 0.8800 ± 0.1508 while it was 0.8000 ± 0.1947 in the Triamcinolone group and both the groups were comparable at baseline with respect to BCVA by logMAR scale with no statistically significant difference (p value-0.1544) Post-injection BCVA by logMAR scale at the end of 1 month, in the Bevacizumab group was 0.4200 ± 0.1704 while it was 0.2950 ± 0.09987 in the Triamcinolone group. Statistically significant difference was found in both the groups with respect to BCVA by logMAR scale with significant improvement in Triamcinolone group as compared to Bevacizumab Group. (p value-0.0074) However, within the group, both Bevacizumab and Triamcinolone group showed statistically significant improvement in BCVA by logMAR scale post-injection at the end of 1 month as compare to pre-injection (p value- <0.0001)

TABLE 5 Comparison of CMT on OCT

• CMT decreased significantly in both groups, with greater reduction in the IVTA group ($p < 0.05$).

Time	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value

PREINJECTION (Microns) Mean +_ SD	407.0+_ 67.74	408.8 +_ 62.25	0.9288*
POSTINJECTION (Microns) Mean +_ SD	266.7 +_ 59.31	238.4+_16.97	0.0475*
P – Value	<0.0001@	<0.0001@	

Table 5 displayed * Unpaired t test, Two tailed p value > 0.05 Not Significant (@95% Cl) @paired t test, Two tailed p value < 0.05 Significant (@95% Cl) Preinjection CMT on OCT in the Bevacizumab group was 407.0 ± 67.74 micron while it was 408.8 ± 62.25 micron in the Triamcinolone group and both the groups were comparable at baseline with respect to CMT on OCT with no statistically significant difference (p value-0.9288) Post-injection CMT on OCT (At the end of 1 month) in the Bevacizumab group was 266.7 ± 59.31 micron while it was 238.4 ± 16.97 micron in the Triamcinolone group. Statistically significant difference was found in both the groups with respect to CMT with significant improvement in Triamcinolone group as compared to Bevacizumab Group (p value-0.0475). However, within the group, both Bevacizumab and Triamcinolone group showed statistically significant improvement in CMT at post-injection (at the end of 1 month) as compare to Pre-injection (p value-<0.0001)

TABLE 6 Comparison of Intraocular Pressure

Time	Bevacizumab (N=20)	Triamcinolone (N=20)	P -value
PREINJECTION (mm of HG) Mean +_ SD	15.80 +_ 2.505	15.65 +_ 2.110	0.8388*
POSTINJECTION (mm of HG) Mean +_ SD	15.25 +_ 2.221	16.70+_2.598	0.0654*
P – Value	0.1342@	0.0408@	

Table 6 displayed * Unpaired t test, Two tailed p value > 0.05 Not Significant (@95% Cl) @paired t test, Two tailed p value < 0.05 Significant (@95% Cl) Pre-injection intraocular pressure in the Bevacizumab group was 15.80 ± 2.505 mm Hg while it was 15.65 ± 2.110 mm Hg in the Triamcinolone group and both the groups were comparable at baseline with no statistically significant difference (p value-0.8388) Post-injection intraocular pressure at the end of 1 month, in the Bevacizumab was 15.25 ± 2.221 mm Hg while it was 16.70 ± 2.598 mm Hg in the Triamcinolone group. No Statistically significant difference was found in both the groups and both groups were comparable with respect to intraocular pressure (p value-0.0654). Also, within Bevacizumab group, no statistically significant difference was found in pre-injection and post-injection intraocular pressure (p value0.1342). However, in the Triamcinolone group there was a statistically significant increase in intraocular pressure at post-injection (after 1 month) (Mean + SD: 16.70 ± 2.598) as compared with Pre-injection IOP (Mean + SD: 15.65 ± 2.110) (p value-0.0408)

Discussion and Conclusion

This study compared the short-term efficacy and safety of intravitreal bevacizumab (1.25 mg) and triamcinolone acetonide (4 mg) in 40 treatment eyes with diabetic macular edema (DME), divided equally into two groups of 20 each. The present study aimed to compare short term efficacy and safety of intravitreal bevacizumab and triamcinolone acetonide in eyes with diabetic macular edema that had received no prior treatment for DME. In our study 40 eyes of 40 patients with diabetic macular edema were randomly assigned into two groups of 20 each. One group received 1.25 mg/0.05 ml intravitreal injection bevacizumab and the other 4 mg/0.1 ml intravitreal triamcinolone acetonide. There was no statistically significant difference between the age, sex and duration of diabetes mellitus between the two groups. In a study by Paccola L et al(5) the duration of diabetes in the bevacizumab group was 12.33 + 5.34 years and in the triamcinolone acetonide group it was 12.66 + 5.69 years. Duration of diabetes strongly correlates with incidence and prevalence of macular edema.Comparison of Best corrected Visual Acuity (BCVA) and Central Macular Thickness (CMT) between the bevacizumab and the triamcinolone acetonide group Following injection both the groups showed improvement in BCVA and regression of macular edema at the end of one month. Post-injection BCVA by logMAR scale at the end of 1 month, in the Bevacizumab group was 0.4200 ± 0.1704 while it was 0.2950 ± 0.09987 in the Triamcinolone group. This difference was statistically significant. Improvement in logMAR BCVA was more in the Triamcinolone group than in the Bevacizumab Group. (p value-0.0074) Song JH et al (6)conducted retrospective, comparative case study in 58 eyes of 35 consecutive patients (IVTA group, 20 eyes; IVB group, 38 eyes) with DME. The effects of IVTA for BCVA were more favorable than were those of IVB and were consistent over eight weeks after injection. In our study, both the

Bevacizumab group and the Triamcinolone group showed statistically significant improvement in CMT at 1 month postinjection compared to Pre-injection CMT (p value-Edema formation in DME is hypothesized by two theories: 1) increased permeability of vessels and 2) increased water flux from vascular to the tissue compartment(7).VEGF is known to increase vascular permeability. In contrast, triamcinolone acetonide reduces the expression of VEGF and thereby prevents the accumulation of fluid in the extracellular space. Triamcinolone acetonide a corticosteroid, also suppresses the inflammation that leads to edema(8). Thus, triamcinolone acetonide is a multiple-potency drug, and therefore may be more useful in causing regression of DME when compared with bevacizumab, which only reduces the amount of circulating free VEGF in the eye. DME is related with not only VEGF, but also interleukin-6 (IL-6) and intercellular adhesion molecule-1 (ICAM-1)(9). Corticosteroids affects these different cytokines apart from VEGF. Rise in Intraocular pressure (IOP) Within the Bevacizumab group, No Statistically significant difference was found in pre-injection and post-injection intraocular pressure (p value0.1342). However, in the Triamcinolone group there was a statistically significant increase in intraocular pressure 1 month post-injection (Mean + SD: 16.70 ± 2.598) as compared with Pre-injection IOP (Mean + SD: 15.65 ± 2.110) (p value-0.0408) Shahin MM et al(103) found 16.7% patients showed a transient rise of IOP after a single intra-vitreal injection of 4 mg triamcinolone acetonide and all were controlled on topical anti-glaucoma medications. Khairallah M et al.(10) found intraocular pressure elevation occurred in 25% eyes after single intra-vitreal injection of 4 mg/0.1 ml of triamcinolone acetonide and was successfully treated by topical medication. No other complications were noted. Thus, the most common complication observed in my study in the triamcinolone group was rise of intraocular pressure which is similar to observations in Shahin MM et al (11) and Khairallah M et al(10)Steroid-induced IOP elevation is thought to occur secondary to a reduction in outflow facility of the trabecular meshwork due to accumulation of polymerised glycosaminoglycans(12) and probably debris accumulation in the meshwork due to inhibition of phagocytosis due to corticosteroids (13).

5. Conclusion

Triamcinolone acetonide offers better short-term visual and anatomical outcomes than bevacizumab for DME but requires monitoring for steroidinduced IOP rise. Both drugs are viable options for initial management.

6. Funding / Sources of Support

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7. Conflicts of Interest

The authors declare no conflicts of interest.

8. References

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