

Single-injection intravitreal bevacizumab versus bevacizumab–triamcinolone for diabetic macular edema: a prospective comparative observational study evaluating efficacy, durability and intraocular pressure safety during 12 weeks of follow-up.

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Abstract

Background:

It is the leading cause of visual impairment in DR patients. Intravitreal bevacizumab has become a first-line treatment, and the use of intravitreal triamcinolone has been suggested to augment the response to treatment by inhibiting inflammatory pathways.

Objective:

To evaluate the efficacy, durability, and safety in terms of intraocular pressure of a single intravitreal injection of bevacizumab versus intravitreal bevacizumab–triamcinolone combination in patients with DME during 12 weeks' follow-up.

Methods:

A Prospective Comparative observational study was done at the Regional Institute of Ophthalmology (RIMS), Ranchi. A total of 29 patients with diabetic macular edema (DME) were divided into two groups. Group 1 (n = 14) received a single intravitreal injection of bevacizumab (1.25 mg/0.05 mL), while Group 2 (n = 15) received a single intravitreal combination of bevacizumab (1.25 mg/0.05 mL) and triamcinolone acetonide (4 mg/0.1 mL). Best-corrected visual acuity (BCVA), central macular thickness (CMT), and intraocular pressure (IOP) were assessed at baseline and at 1, 4, and 12 weeks after treatment.

Result:

In the follow-up, the improvement in BCVA and decrease in CMT were similar in both treatment groups. Numerically, the combination therapy group had a greater functional and anatomical improvement; however, differences among the groups were not statistically significant. Patients treated with bevacizumab–triamcinolone had significantly higher IOPs at 4 weeks and 12 weeks (both *p* = 0.023 and 0.002, respectively) than bevacizumab alone.

Conclusion:

Single intravitreal bevacizumab effectively improved visual acuity and reduced central macular thickness with a favourable safety profile. Although combination therapy showed numerically greater anatomical and functional improvement, differences were not statistically significant. However, it significantly increased intraocular pressure, necessitating careful patient selection and regular intraocular pressure monitoring.

Keywords: Diabetic macular edema, Diabetic retinopathy, Bevacizumab, Triamcinolone acetonide, Intravitreal injection, Central macular thickness, Intraocular pressure.

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Introduction

Diabetes mellitus is a significant public health issue worldwide, and its incidence has been on a rising trend in urban areas, low physical activity rates, and an aging population [1]. Diabetic retinopathy (DR) is the most prevalent microvascular complication of diabetes and a major cause of preventable vision loss in working-age adults

around the world. DME is the main cause of vision loss in people with DR and is caused by a buildup of fluid between the cells in the macula [2]. Chronic hyperglycemia adversely affects the retinal microvasculature, causing a rise in vascular permeability, disruption of the blood–retinal barrier, and progressive retinal thickening that leads to a decrease in central vision.

DME is a multifactorial disease characterized by metabolic, inflammatory, and vascular mechanisms [3]. Chronic hyperglycemia leads to oxidative stress, stimulation of the polyol pathway, increased advanced glycation end products (AGE), and activation of protein kinase C (PKC), resulting in endothelial dysfunction and retinal ischemia. These changes cause a release of the main factor, vascular endothelial growth factor (VEGF), that is responsible for increased vascular permeability and neovascularization [4,5]. This increase in VEGF causes the tight junctions between the endothelial cells to leak and allow plasma to enter the retina, causing macular edema. However, the fact that several inflammatory cytokines such as “interleukin-6, interleukin-1 β , tumor necrosis factor- α , and monocyte chemoattractant protein-1 are also known to contribute to the maintenance of retinal inflammation and blood–retinal barrier breakdown suggests that DME is not only a VEGF-driven disease [6]. Anti-VEGF agents are now the first line of treatment for DME, with the introduction of this therapy changing the world of DME treatment [7]. A full-length humanized monoclonal antibody against VEGF-A, bevacizumab, decreases vascular permeability by inhibiting all biologically active VEGF-A isoforms, helps to improve visual acuity, and decreases retinal edema. However, a significant percentage of patients continue to have an incomplete anatomical or functional response to repeated injections, indicating that inflammatory mechanisms may play a very important role in disease persistence. Triamcinolone acetonide is an intravitreal corticosteroid that has anti-inflammatory and anti-angiogenic properties by inhibiting inflammatory cytokines, down-regulating expression of vascular endothelial growth factor (VEGF), smoothing endothelial tight junctions, and restoring the blood–retinal barrier (BRB) [8]. Owing to its longer intraocular duration of action, it has proven to be an attractive adjunctive agent to anti-VEGF therapy. The addition of bevacizumab and triamcinolone may provide simultaneous blocking of VEGF-induced vascular leakage and inflammation-induced retinal damage that could improve anatomical improvement and extend treatment duration following intravitreal injection [9]. The use of corticosteroid therapy, however, can have side effects, including an increase in intraocular pressure and progression of cataracts, and must be carefully evaluated for risk–benefit [10]. The results of previous randomised clinical trials (RCTs) on the superiority of combination therapy versus bevacizumab monotherapy have been varied. Some studies reported higher early decreases in central macular thickness, while others did not show any significant late improvement in BCVA, and noted an increased risk of steroid-induced ocular hypertension [11]. Furthermore, there are only short-term follow-up data that specifically assess the efficacy, durability, and safety of intraocular pressure of a single-injection combination regimen.

The present study was performed to compare the efficacy of a single intravitreal bevacizumab injection with combined intravitreal bevacizumab and triamcinolone injection in

patients with DME for 12 weeks. The objective of the study is to assess the change in best-corrected visual acuity, central macular thickness, treatment durability, and intraocular pressure. Combination therapy is thought to result in better short-term anatomical response and long-term response than bevacizumab alone, but may also increase the risk of intraocular pressure (IOP) rise.

Materials and Methods

Study Design

This was a prospective comparative observational study conducted to compare the efficacy, durability, and safety of a single intravitreal injection of bevacizumab alone versus combined intravitreal bevacizumab and triamcinolone in patients with diabetic macular edema over a 12-week follow-up period.

Study Setting

The study was carried out in the Regional Institute of Ophthalmology (RIO), Rajendra Institute of Medical Sciences (RIMS), Ranchi, which is a tertiary care referral eye hospital having a specialty in the diagnosis and management of retinal disease. All clinical assessments, intravitreal injections, and follow-up exams were carried out by experienced ophthalmologists following a uniform institutional standard follow-up.

Study Period

Patient recruitment and follow-up were conducted from September 2024 to December 2025 at the Regional Institute of Ophthalmology, Rajendra Institute of Medical Sciences (RIMS), Ranchi, India.

Study Duration

The total study duration was 12 weeks. Patients were evaluated at baseline before treatment and subsequently at 1 week, 4 weeks, and 12 weeks following a single intravitreal injection to assess changes in best-corrected visual acuity, central macular thickness, intraocular pressure, treatment efficacy, and safety.

Sample Size

A total of 29 eligible patients diagnosed with diabetic macular edema were enrolled consecutively after fulfilling the eligibility criteria. Fourteen patients were allocated to the bevacizumab group (Group 1), while fifteen patients were allocated to the bevacizumab plus triamcinolone group (Group 2). The sample size was determined based on the number of eligible patients presenting during the study period who fulfilled the inclusion criteria and consented to participate.

Inclusion Criteria

The patients were eligible if they were older than 18 years, had either type 1 or type 2 diabetes mellitus, and had a

clinical diagnosis of diabetic macular edema (DME) confirmed by optical coherence tomography (OCT). Patients who had informed written consent to participate in the study and who showed willingness to adhere to the follow-up visits were included in the study.

Exclusion Criteria

Patients with a history of a previous intravitreal anti-VEGF or steroid injection, glaucoma or ocular hypertension, previous vitrectomy, significant media opacity which would affect the ability to assess the retina, a recent intraocular surgical procedure, active intraocular infection, or any other retinal pathology which would affect visual outcome were excluded from the study.

Study Groups

Patients in Group 1 received a single intravitreal injection of bevacizumab (1.25 mg/0.05 mL). Patients in Group 2 received a single intravitreal injection of bevacizumab (1.25 mg/0.05 mL) combined with triamcinolone acetonide (4 mg/0.1 mL). All intravitreal injections were administered under strict aseptic conditions in the operating theatre according to standard institutional guidelines for intravitreal injection.

Outcome Measures

The main outcome measures were the changes in best corrected visual acuity (BCVA) measured by Snellen charts and central macular thickness (CMT) measured by spectral domain optical coherence tomography (SD OCT). Other secondary outcome measures included intraocular pressure (IOP) changes, adverse events that occurred as a result of treatment, and the persistence of the therapeutic effect throughout the 12-week follow-up period.

Follow-up

Baseline and 1, 4, and 12 weeks after-treatment comprehensive ophthalmic examinations were performed in all patients. At each follow-up visit, best-corrected visual acuity was determined, slit-lamp biomicroscopy was performed, intraocular pressure was measured by Goldmann applanation tonometry, dilated fundus examination was done, and OCT imaging was used for evaluation of central macular thickness. Ocular and/or systemic adverse events that were noted during the study period were recorded.

Bias

To minimize selection bias, all eligible consecutive patients fulfilling the inclusion criteria during the study period were recruited. Standardized examination techniques, identical follow-up schedules, uniform OCT measurements, and identical treatment protocols were used for all participants. Data collection and outcome assessment followed the same institutional protocol throughout the study.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed by Statistical Package for the Social Sciences (SPSS) Version 25.0. The continuous variables were presented as mean $\pm$ SD, and the categorical variables were presented as frequencies and percentages. An independent samples t-test was used for between-group comparisons, and a paired t-test was used for follow-up visit comparisons within groups. The Chi-squared test was used to compare categorical variables. Statistically significant was defined as a p-value < 0.05 .

Ethical Considerations

The study was approved by the Institutional Ethics Committee (IEC), Rajendra Institute of Medical Sciences (RIMS), Ranchi (Approval Letter No. 121, dated 08 February 2025). The IEC is registered with the Department of Health Research, Government of India (IEC Registration No. ECR/769/INST/JH/2015/RR-21). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Results

This prospective comparative observational study included 29 patients who had DME. A total of 14 patients were treated with the intravitreal injection of bevacizumab alone (Group 1), and 15 patients were treated with intravitreal bevacizumab and triamcinolone (Group 2). There were no differences between the treatment groups in baseline demographic characteristics that were suggestive of different patient profiles. The mean age was slightly higher in Group 1 (57.7 ± 9.55 years) than in Group 2 (55.4 ± 8.45 years). In both groups, the male predominance was seen with 71.4% of patients in Group 1 and 53.3% of patients in Group 2 (Table 1).

Table 1. Demographic Characteristics of Study Participants

Characteristic	Group 1 (Bevacizumab)	Group 2 (Bevacizumab + Triamcinolone)
Number of patients	14	15
Age (years), Mean $\pm$ SD	57.7 ± 9.55	55.4 ± 8.45
Median Age	58	56
95% Confidence Interval	52.41–62.99	50.72–60.08
Male, n (%)	10 (71.4)	8 (53.3)
Female, n (%)	4 (28.6)	7 (46.7)

Both treatment groups showed similar demographic characteristics. The mean age was 57.7 ± 9.55 years in Group 1 and 55.4 ± 8.45 years in Group 2. Male participants predominated in both groups.

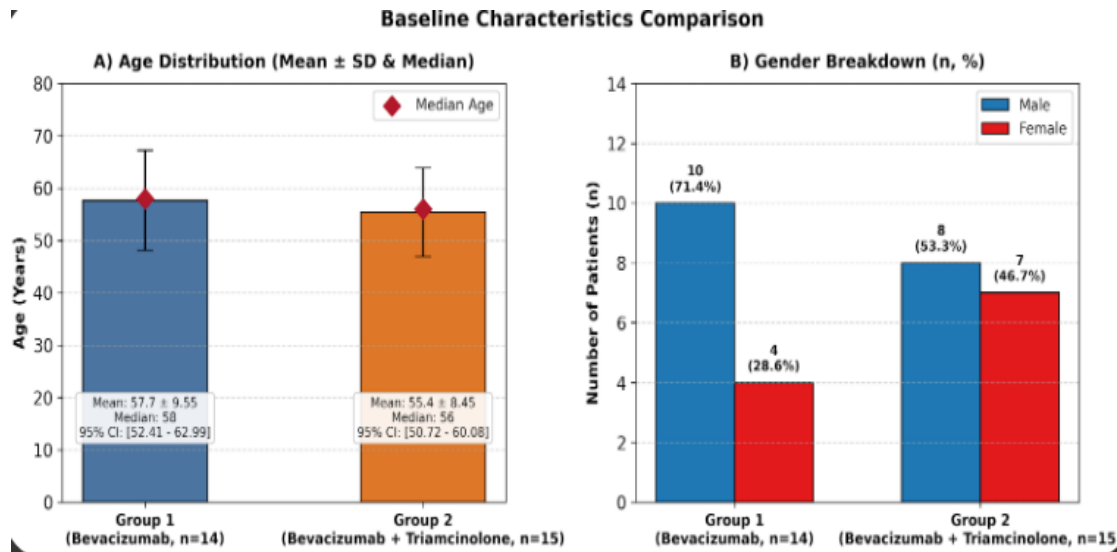


Figure 1. Baseline clinical characteristics

There was no difference between the two groups at baseline (Table 2). The mean baseline BCVA was 0.92 ± 0.22 LogMAR in Group 1 and 0.90 ± 0.22 LogMAR in Group 2 ($p = 0.809$). Baseline central macular thickness (CMT) and

intraocular pressure (IOP) were also comparable across the groups, thus eliminating any significant differences in baseline characteristics before treatment.

Table 2. Baseline Clinical Characteristics

Parameter	Group 1	Group 2	p-value
BCVA (LogMAR), Mean $\pm$ SD	0.92 ± 0.22	0.90 ± 0.22	0.809
Central Macular Thickness (μ m)	502.86 ± 119.07	442.33 ± 100.84	0.144
Intraocular Pressure (mmHg)	16.26 ± 2.12	16.13 ± 3.33	0.897

Baseline BCVA, central macular thickness, and intraocular pressure were comparable between both treatment groups with no statistically significant differences.

Both treatment groups experienced progressive improvement in visual acuity during follow-up (Table 3). At

1, 4 and 12 weeks, group 2 always had a numerically superior visual outcome to group 1. However, none of the differences between the groups were statistically significant (all $p > 0.05$), meaning that both treatments had similar effects on visual acuity after 12 weeks.

Table 3. Best-Corrected Visual Acuity (LogMAR)

Follow-up	Group 1	Group 2	p-value
Baseline	0.92 ± 0.22	0.90 ± 0.22	0.809
1 Week	0.83 ± 0.19	0.78 ± 0.17	0.502
4 Weeks	0.73 ± 0.21	0.66 ± 0.21	0.357
12 Weeks	0.80 ± 0.25	0.68 ± 0.23	0.215

Progressive improvement in BCVA was observed in both treatment groups during follow-up. Although combination therapy demonstrated numerically greater improvement at each visit, differences between groups were not statistically significant.

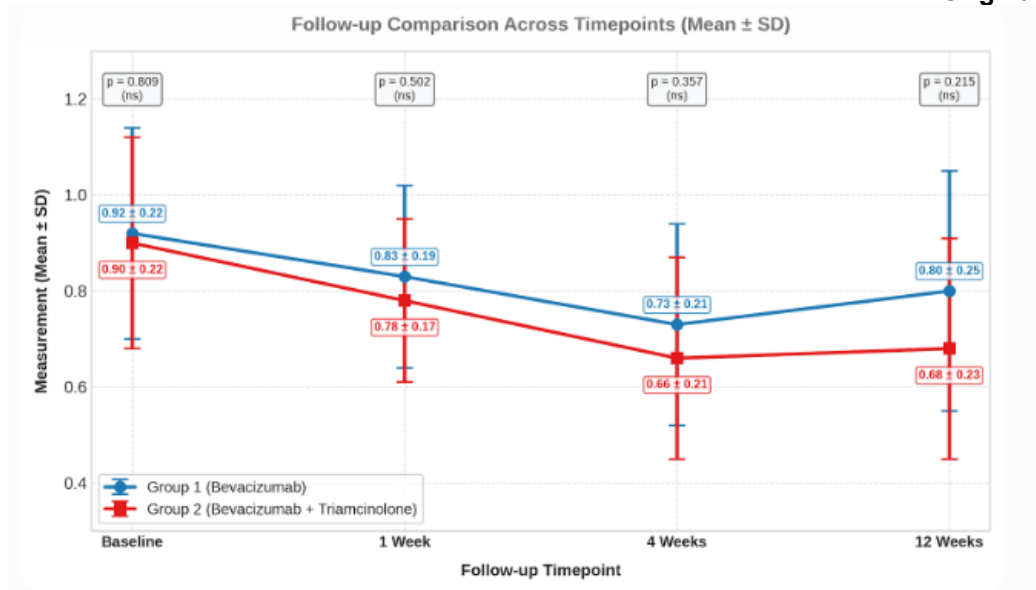


Figure 2. Baseline Comparison of best-corrected visual acuity (BCVA) between Group 1 and Group 2 at baseline, 1 week, 4 weeks, and 12 weeks

Both treatment groups demonstrated a progressive reduction in central macular thickness (CMT) following treatment (Table 4). The combination therapy group consistently showed numerically lower mean CMT values at all follow-

up visits, indicating greater anatomical improvement. However, the differences between the two groups were not statistically significant at any follow-up visit (all $p > 0.05$).

Table 4. Central Macular Thickness (μm)

Follow-up	Group 1	Group 2	p-value
Baseline	502.86 ± 119.07	442.33 ± 100.84	0.144
1 Week	453.46 ± 117.89	385.00 ± 102.94	0.101
4 Weeks	406.66 ± 114.49	338.20 ± 98.98	0.091
12 Weeks	370.73 ± 86.24	344.93 ± 81.01	0.406

Central macular thickness progressively decreased in both groups. The combination therapy group showed consistently lower CMT values than bevacizumab alone; however, these differences were not statistically significant.

A summary of changes in intraocular pressure is provided in Table 5. No differences in baseline IOP were found across groups. Group 2 had slight elevation of IOP at one week, but this was not statistically significant ($p = 0.378$) compared to Group 1. The mean IOP (19.46 ± 4.10 mmHg) of the

combination therapy group was significantly higher compared with the bevacizumab-alone group (16.40 ± 2.74 mmHg; $p = 0.023$) at 4 weeks. The difference continued at 12 weeks, with Group 2 having significantly higher IOP (19.73 ± 3.61 mmHg) than Group 1 (15.86 ± 2.56 mmHg; $p = 0.002$). This study suggests that steroid conjunctival preparations combined with triamcinolone may offer good anatomical results, but may also increase the risk of steroid-induced intraocular pressure elevation.

Table 5. Intraocular Pressure (mmHg)

Follow-up	Group 1	Group 2	p-value
Baseline	16.26 ± 2.12	16.13 ± 3.33	0.897
1 Week	17.46 ± 2.87	18.66 ± 4.32	0.378
4 Weeks	16.40 ± 2.74	19.46 ± 4.10	0.023
12 Weeks	15.86 ± 2.56	19.73 ± 3.61	0.002

Intraocular pressure remained stable in the bevacizumab group throughout follow-up. In contrast, the combination

therapy group demonstrated significantly higher intraocular pressure at both 4 weeks ($p=0.023$) and 12 weeks ($p=0.002$).

Discussion

The aim of the present prospective comparative observational study was to assess the efficacy and safety of intravitreal bevacizumab monotherapy compared with combination therapy (bevacizumab plus intravitreal triamcinolone) for the treatment of diabetic macular edema during a 12-week follow-up period. Both treatment modalities were shown to significantly improve visual acuity and decrease central macular thickness from baseline, as shown by the main findings. The overall improvement in both functional and anatomical outcomes for combination therapy was numerically higher, but was not measured to be significant at the various follow-up visits. There was, however, a marked increase in the intraocular pressure in patients treated with bevacizumab and triamcinolone during the more recent follow-up period, which suggests that intraocular hypertension risk was higher with bevacizumab and triamcinolone.

Clinical and demographic parameters were similar in both treatment arms, highlighting a good study population homogeneity. The age of the patients was comparable between the two groups, and the ages of patients with DME ranged mostly between the fifth and sixth decades. The distribution by sex was similar to that seen during the period of the study, with the majority being male. Follow-up differences were mainly due to therapeutic interventions, and not to baseline differences since similar visual acuity, CMT, and IOP were obtained at baseline.

Both treatment groups had improvement in best corrected visual acuity during this study. Slightly better visual outcomes at 1, 4, and 12 weeks were observed in the combination therapy group compared to the bevacizumab-only group. They reported no significant differences, however, indicating that triamcinolone did not yield better short-term visual recovery after the one injection. The results of these studies suggest that bevacizumab alone is effective for improving visual function, and that the extra benefit of corticosteroid on visual function during these 12 weeks is modest.

Both groups showed a significant change in CMT following therapy. The mean macular thicknesses were consistently lower in the combination therapy group at each follow-up visit, but the difference between groups was not significant. The greater anatomical improvement with combination therapy might be due to the complementary mechanisms of action of the two drugs. Bevacizumab is an agent that inhibits vascular permeability caused by VEGF, and triamcinolone is an agent that slows down the inflammation in the retina, stabilizes the blood-retinal barrier, and inhibits inflammatory cytokines. Although theoretically these benefits exist, the anatomical benefit seen in the present study was not associated with statistically significant improvement in visual acuity, perhaps due to the comparatively small number of patients and the relatively short follow-up interval.

The most significant safety finding of this study was the marked rise in intraocular pressure in the bevacizumab + triamcinolone group. One-week IOP and baseline IOP were similar between groups, but statistically significant increases were seen at 4 weeks and were maintained in the combination therapy group at 12 weeks. This rise is in line with what has been previously reported, which is a decrease in aqueous humour outflow from corticosteroid exposure. Patients treated with bevacizumab alone, on the other hand, had stable intraocular pressure during the follow-up period. The results of these studies indicate the combination therapy may offer some anatomic advantages, but the intraocular pressure needs to be closely monitored to prevent ocular complications associated with steroid use.

In the present study, BCVA improved from 0.92 ± 0.22 to 0.80 ± 0.25 LogMAR in the bevacizumab group and from 0.90 ± 0.22 to 0.68 ± 0.23 LogMAR in the combination group after 12 weeks. Similarly, central macular thickness decreased from $502.86 \pm 119.07 \mu\text{m}$ to $370.73 \pm 86.24 \mu\text{m}$ in Group 1 and from $442.33 \pm 100.84 \mu\text{m}$ to $344.93 \pm 81.01 \mu\text{m}$ in Group 2, demonstrating clinically meaningful anatomical improvement despite the absence of statistically significant differences between treatment groups.

The most important safety finding was the statistically significant increase in intraocular pressure observed in the combination therapy group at 4 weeks ($19.46 \pm 4.10 \text{ mmHg}$; $p=0.023$) and 12 weeks ($19.73 \pm 3.61 \text{ mmHg}$; $p=0.002$), whereas intraocular pressure remained stable in patients receiving bevacizumab monotherapy.

The results of this research study have significant clinical implications. Intravitreal bevacizumab was well tolerated and was effective at improving visual acuity and reducing macular edema in a single injection, and is thus a good first-line treatment for diabetic macular edema. Triamcinolone may be added in some cases of persistent or severe edema where inflammatory mechanisms are thought to be more important. The risks of intraocular pressure (IOP) rise do require regular ophthalmic follow-up and prompt treatment of any steroid complications.

The results obtained in the present study are similar to the results obtained by several studies that compared intravitreal bevacizumab alone and with intravitreal triamcinolone for diabetic macular edema (DME). The findings of the present study should also be interpreted in the context of the treatment protocol used. Unlike the meta-analysis by Abdel-Maboud et al., which included randomized controlled trials evaluating repeated intravitreal injections over longer follow-up periods, the present study evaluated the efficacy and safety of a single intravitreal injection with only 12 weeks of follow-up. Repeated anti-VEGF therapy is known to provide cumulative anatomical and functional benefits over time, whereas the therapeutic response following a single injection may be less pronounced. Therefore, the absence of statistically significant differences between the two treatment groups in the present study does not necessarily contradict previous evidence but rather reflects differences in study design, treatment regimen, sample size,

and duration of follow-up. These methodological differences should be considered when comparing the present findings with those of larger randomized trials and meta-analyses. As in the current study, [12] found that the decrease in CMT was statistically significantly different between the combination and the bevacizumab group, but there was no significant difference in VA between the two groups. Similarly, [13] showed that the combined use of triamcinolone gave improved anatomical results during the early follow-up period, with no meaningful long-term visual improvement statistically. The marked increase in intraocular pressure reported in the combination therapy group in this study is also likely to be similar to what was previously reported by Gillies et al. and the SCORE Study, which found corticosteroid-induced ocular hypertension to be the most common side effect of intravitreal triamcinolone. Likewise, [14] found that steroid therapy is beneficial for reducing macular edema, but it has drawbacks because of the cataract progression and increased intraocular pressure associated with steroid use. These results corroborate the increasing evidence that bevacizumab treatment alone is effective in terms of visual and anatomical outcomes, while combination treatment may provide a slight additional anatomical advantage with a greater risk of a rise in intraocular pressure, which should be taken into consideration when choosing patients and closely monitored after surgery.

The present study has several strengths: firstly, the design was a prospective comparative study; secondly, treatment was uniform; thirdly, efficacy and safety assessments were performed at several follow-up visits using an objective method (OCT); and fourthly, follow-up was performed.

Generalizability

The findings of this study apply to adult patients with diabetic macular edema managed in tertiary ophthalmology centres with similar patient characteristics. However, extrapolation to different healthcare settings or populations should be undertaken cautiously because of the relatively small sample size and single-centre design.

Conclusion

The present study showed that intravitreal injection of bevacizumab alone and combined with intravitreal injection of triamcinolone was effective in achieving better BCVA and reduced CMT within 12 weeks of follow-up in DME patients. The overall results were more impressive in terms of the numerical improvements in both visual and anatomical outcomes, but these were not statistically significant as compared to bevacizumab monotherapy. Combination therapy, on the other hand, was linked to a significant rise in intraocular pressure after four and twelve weeks, suggesting a higher risk of the development of steroid-induced intraocular hypertension. The results indicate that bevacizumab is an effective and safe treatment for most patients with DME; the use of combination

treatment with bevacizumab and triamcinolone should be reserved for carefully selected patients who have close monitoring of intraocular pressure.

Limitations

This study had several limitations, including the relatively small sample size, single-centre design, short follow-up duration of 12 weeks, and evaluation of only a single intravitreal injection. Longer follow-up and larger multicentre randomized controlled studies are required to evaluate long-term efficacy, recurrence, cataract progression, and sustained intraocular pressure changes.

Recommendations

Future multicentre randomized controlled studies with larger sample sizes and longer follow-up periods should be undertaken to evaluate long-term visual outcomes, treatment durability, recurrence of diabetic macular edema, and long-term safety of combination therapy. Careful monitoring of intraocular pressure is recommended whenever intravitreal corticosteroids are administered.

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List of Abbreviations

BCVA – Best Corrected Visual Acuity

CMT – Central Macular Thickness

DME – Diabetic Macular Edema

DR – Diabetic Retinopathy

IOP – Intraocular Pressure

OCT – Optical Coherence Tomography

SD-OCT – Spectral Domain Optical Coherence Tomography

VEGF – Vascular Endothelial Growth Factor

BRB – Blood–Retinal Barrier

RIMS – Rajendra Institute of Medical Sciences.

Source of Funding

No external funding was received for this study.

Conflict of Interest

The authors declare that there is no conflict of interest.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Author Contributions

Dr. Mugdha Sumati: Conceptualization, patient recruitment, data collection, data interpretation, manuscript drafting, and final approval.

Dr. Marianus Deepak Lakra: Study supervision, methodology development, critical revision of the manuscript, statistical interpretation, and final approval.

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