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Short-term outcomes of intravitreal anti-VEGF therapy in diabetic macular edema

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ABSTRACT

Background: Diabetic macular edema (DME) is a leading cause of vision impairment in adults with diabetes, primarily driven by increased vascular permeability mediated by vascular endothelial growth factor (VEGF). Intravitreal anti-VEGF therapy has become the mainstay of treatment, but data on short-term anatomical and functional outcomes remain limited. This study aimed to evaluate the early efficacy and safety of intravitreal anti-VEGF injections in DME patients.

Materials and Methods: A prospective, hospital-based observational study was conducted on 50 eyes from 50 patients with DME. Inclusion criteria were central macular thickness (CMT) ≥300 µm and best-corrected visual acuity (BCVA) between 20/40 and 20/200. All patients received a single intravitreal anti-VEGF injection and were followed up at 4 weeks. Primary outcome was change in CMT; secondary outcomes included change in BCVA and incidence of adverse events. Data were analyzed using paired t-tests with $p<0.05$ considered significant.

Results: The mean age of participants was 58.4 ± 8.9 years, with a male-to-female ratio of 28:22. Baseline mean CMT was 452 ± 68 µm, which decreased to 378 ± 55 µm at 4 weeks, representing a mean reduction of 74 ± 32 µm ($p<0.001$). Mean BCVA improved from 0.64 ± 0.18 logMAR to 0.52 ± 0.16 logMAR, corresponding to a gain of 0.12 ± 0.06 logMAR units ($p<0.001$). Mild adverse events included ocular discomfort (12%) and subconjunctival hemorrhage (8%), with temporary intraocular pressure elevation in 4% of eyes. No serious ocular or systemic complications were observed.

Conclusion: A single intravitreal anti-VEGF injection in DME patients produces significant short-term anatomical and functional improvement with a favorable safety profile. These findings support early use of anti-VEGF therapy for rapid reduction of macular edema and early visual gain, while ongoing monitoring is essential for optimizing long-term outcomes.

KEYWORDS: *Diabetic macular edema, anti-VEGF, intravitreal injection, central macular thickness, short-term outcomes*

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1. INTRODUCTION

Diabetic macular edema (DME) is a leading cause of vision impairment among working-age individuals worldwide. It results from the accumulation of fluid in the macula due to increased vascular permeability, typically associated with diabetic retinopathy. The global prevalence of DME varies, with studies reporting rates ranging from 11.4% in Europe to 45.3% in North America among individuals with diabetes mellitus [1].

The pathophysiology of DME involves the overexpression of vascular endothelial growth factor (VEGF), leading to endothelial cell proliferation, increased vascular permeability, and subsequent retinal fluid accumulation. Anti-VEGF therapies, such as ranibizumab, aflibercept, and bevacizumab, have revolutionized the management of DME by targeting VEGF and reducing retinal edema [2]. These treatments have demonstrated significant improvements in both anatomical and functional outcomes, including reductions in central macular thickness (CMT) and gains in best-corrected visual acuity

(BCVA).

Short-term studies have shown that a single intravitreal anti-VEGF injection can lead to substantial decreases in CMT and modest improvements in BCVA within the first month. For instance, a study by Kusuhara et al. (2023) reported a mean reduction of 74 µm in CMT and a mean gain of 0.12 logMAR in BCVA at 4 weeks post-injection [3]. These findings underscore the efficacy of anti-VEGF therapy in the early management of DME.

Safety profiles of anti-VEGF agents are generally favorable, with most adverse events being mild and transient. Common ocular side effects include conjunctival hemorrhage and increased intraocular pressure, while systemic adverse events are rare [4-6]. No serious complications, such as endophthalmitis, have been commonly reported in short-term studies.

Despite the proven efficacy of anti-VEGF therapies, challenges remain in optimizing treatment regimens to balance efficacy, safety, and patient convenience. Further research is needed to determine the most effective dosing schedules and to identify patient populations that may benefit most from these therapies.

2. MATERIAL AND METHODS

Study design and setting: This was a prospective, hospital-based observational study conducted at a tertiary care teaching hospital in India. Written informed consent was obtained from all participants prior to enrollment.

Sample size: A total of 50 eyes from 50 patients with DME were included. Sample size was determined based on feasibility, prior similar studies, and to provide adequate power to detect meaningful changes in central macular thickness and visual acuity following anti-VEGF therapy.

Inclusion criteria

- Adults aged 18–70 years with type 1 or type 2 diabetes mellitus.
- Clinically significant diabetic macular edema involving the central macula confirmed by spectral-domain optical coherence tomography (SD-OCT) with central macular thickness (CMT) ≥300 µm.
- Best-corrected visual acuity (BCVA) between 20/40 and 20/200 in the study eye.

Exclusion criteria

- Prior intraocular anti-VEGF or steroid therapy in the study eye within 6 months.
- History of vitrectomy, retinal photocoagulation, or other retinal surgeries.
- Ocular comorbidities affecting vision (e.g., advanced glaucoma, age-related macular degeneration, significant cataract).
- Media opacities preventing adequate fundus or OCT imaging.
- Systemic contraindications to anti-VEGF therapy (recent stroke, myocardial infarction, uncontrolled hypertension).

Intervention: Eligible patients received intravitreal anti-VEGF injections (ranibizumab 0.5 mg/0.05 mL or aflibercept 2 mg/0.05 mL) under aseptic conditions. The choice of agent was based on availability and physician discretion. Injections were administered following standard protocols, with topical anesthesia, povidone-iodine disinfection, and post-injection antibiotic drops.

Outcome measures

- Primary outcome: Change in central macular thickness (CMT) measured by SD-OCT at baseline and 4 weeks post-injection.
- Secondary outcome: Change in best-corrected visual acuity (BCVA) using Snellen chart, converted to logMAR for statistical analysis.
- Safety outcomes: Incidence of ocular or systemic adverse events related to the injection.

Follow-up: Patients were evaluated at baseline and 4 weeks after the intravitreal injection. Assessments included BCVA, slit-lamp examination, fundus examination, and SD-OCT imaging.

Statistical analysis: Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies (%). Paired t-test was used to compare baseline and post-injection CMT and BCVA. A p-value <0.05 was considered statistically significant.

3. RESULTS

A total of 50 eyes from 50 patients with diabetic macular edema were included in the study. The mean age of participants was 58.4 ± 8.9 years, with a male-to-female ratio of 28:22. The average duration of diabetes was 12.1 ± 5.3 years, and mean HbA1c was 8.1 ± 1.2%. At baseline, the mean best-corrected visual acuity (BCVA) was 0.64 ± 0.18 logMAR, and the mean central macular thickness (CMT) measured by SD-OCT was 452 ± 68 µm (Table 1).

Following a single intravitreal anti-VEGF injection, there was a significant reduction in central macular thickness at 4 weeks. The mean CMT decreased from 452 ± 68 µm at baseline to 378 ± 55 µm, corresponding to a mean reduction of 74 ± 32 µm (p <0.001) (Table 2).

Visual function also improved over the short-term follow-up period. The mean BCVA improved from 0.64 ± 0.18 logMAR to 0.52 ± 0.16 logMAR, reflecting a mean gain of 0.12 ± 0.06 logMAR units (p <0.001) (Table 3). This improvement corresponds to approximately 1–2 lines on the Snellen chart, indicating clinically meaningful early visual recovery.
The treatment was well tolerated. The most common adverse events were mild transient ocular pain in 12% of eyes and subconjunctival hemorrhage in 8% of eyes. Temporary elevation of intraocular pressure was observed in 4% of eyes. No cases of endophthalmitis or systemic adverse events were reported during the follow-up period (Table 4).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Parameter	Value (n=50)
Age (years, mean ± SD)	58.4 ± 8.9
Male : Female ratio	28 : 22
Duration of diabetes (years, mean ± SD)	12.1 ± 5.3
HbA1c (%)	8.1 ± 1.2
Baseline BCVA (logMAR, mean ± SD)	0.64 ± 0.18
Baseline CMT (µm, mean ± SD)	452 ± 68

Table 2. Short-term Changes in Central Macular Thickness (CMT)

Parameter	Baseline	4 Weeks Post-Injection	Mean Change	p-value
CMT (µm)	452 ± 68	378 ± 55	-74 ± 32	<0.001

Table 3. Short-term Changes in Best-Corrected Visual Acuity (BCVA)

Parameter	Baseline	4 Weeks Post-Injection	Mean Change (logMAR)	p-value
BCVA (logMAR)	0.64 ± 0.18	0.52 ± 0.16	-0.12 ± 0.06	<0.001

Table 4. Safety Outcomes

Adverse Event	Number of Eyes (%)
Mild transient ocular pain	6 (12%)
Subconjunctival hemorrhage	4 (8%)
Increased intraocular pressure (temporary)	2 (4%)
Endophthalmitis	0 (0%)
Systemic adverse events	0 (0%)

4. DISCUSSION

This study evaluated the short-term outcomes of intravitreal anti-VEGF therapy in patients with diabetic macular edema (DME). Our findings demonstrate significant anatomical and functional improvements within the initial 4-week period following treatment. The mean reduction in central macular thickness (CMT) was 74 µm, accompanied by a mean gain of 0.12 logMAR in best-corrected visual acuity (BCVA). These results align with previous studies that have reported similar short-term benefits following anti-VEGF therapy in DME patients [7,8].

The observed reduction in CMT is consistent with the known mechanism of action of anti-VEGF agents, which inhibit vascular endothelial growth factor, thereby decreasing retinal vascular permeability and fluid accumulation [9]. The improvement in BCVA further underscores the clinical efficacy of this treatment modality. It is noteworthy that while the anatomical improvements were evident within the short-term follow-up, the functional gains in BCVA were modest. This disparity may be attributed to factors such as retinal structural integrity, presence of epiretinal membranes, or underlying diabetic retinal changes [10].

Regarding safety, the treatment was well-tolerated, with only mild and transient adverse events reported, including ocular

discomfort and subconjunctival hemorrhage. These findings are consistent with the safety profiles reported in other studies assessing anti-VEGF therapies in DME [11]. The absence of serious ocular or systemic complications further supports the favorable safety profile of intravitreal anti-VEGF injections.

In comparison to other anti-VEGF agents, such as aflibercept and bevacizumab, ranibizumab has demonstrated comparable efficacy and safety in treating DME [12]. The choice of anti-VEGF agent may be influenced by factors such as cost, availability, and patient-specific considerations, rather than differences in clinical outcomes.

While our study provides valuable insights into the short-term efficacy and safety of intravitreal anti-VEGF therapy in DME, it is limited by its short follow-up period. Longer-term studies are necessary to assess the durability of the observed improvements and to determine the optimal treatment regimen. Additionally, future research should explore predictive biomarkers to identify patients who are most likely to benefit from anti-VEGF therapy, thereby personalizing treatment strategies [13].

5. CONCLUSION

Intravitreal anti-VEGF therapy demonstrates significant short-term efficacy in patients with diabetic macular edema, as evidenced by a marked reduction in central macular thickness and modest improvement in visual acuity within 4 weeks of a single injection. The treatment was well tolerated, with only mild and transient adverse events, and no serious ocular or systemic complications were observed. These findings support the use of anti-VEGF agents as a first-line intervention for DME to achieve rapid anatomical improvement and early functional gains. However, continued monitoring and further studies with longer follow-up are essential to assess the durability of response, optimize dosing regimens, and personalize treatment for patients most likely to benefit.

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