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Comparative Efficacy of New Anti-VEGF Agents in Diabetic Macular Edema

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ABSTRACT

Background: Diabetic macular edema (DME) is a leading cause of vision impairment in patients with diabetes mellitus, resulting from vascular leakage and accumulation of fluid in the macula.

Objective: To compare the efficacy and safety of Ranibizumab, Aflibercept, and Faricimab in improving visual and anatomical outcomes among patients with diabetic macular edema.

Methods: The Multi-Center study was conducted from June 2024 to June 2025. A total of 225 patients with center-involving DME were enrolled and divided equally into three groups: Ranibizumab (0.5 mg/0.05 mL), Aflibercept (2 mg/0.05 mL), and Faricimab (6 mg/0.05 mL). Each patient received three monthly loading doses followed by pro re nata injections for six months. Best-corrected visual acuity (BCVA) and central retinal thickness (CRT) were recorded using Snellen chart (logMAR conversion) and optical coherence tomography.

Results: All three agents produced significant improvements in visual acuity and reduction in retinal thickness at six months. The mean BCVA gain was 0.18 ± 0.09 logMAR in the Ranibizumab group, 0.21 ± 0.08 logMAR in the Aflibercept group, and 0.26 ± 0.07 logMAR in the Faricimab group ($p = 0.03$). Mean CRT reduction was 138.6 ± 46.3 µm, 156.7 ± 49.8 µm, and 173.4 ± 52.1 µm, respectively ($p = 0.02$). The Faricimab group required the fewest injections (3.5 ± 0.8) compared to Ranibizumab (4.8 ± 0.9) and Aflibercept (4.2 ± 1.0), showing a statistically significant reduction in treatment burden ($p = 0.01$).

Conclusion: It is concluded that Faricimab demonstrates superior efficacy and longer durability compared to Ranibizumab and Aflibercept in the treatment of diabetic macular edema. By achieving greater improvement in vision and retinal anatomy with fewer injections.

Keywords: *Diabetic macular edema, Anti-VEGF, Faricimab, Ranibizumab, Aflibercept, Visual acuity*

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1. INTRODUCTION

Diabetic macular edema (DME) is one of the most common and vision-threatening complications of diabetes mellitus, representing a major cause of preventable blindness in working-age adults worldwide. Chronic hyperglycemia leads to microvascular damage in the retina, disrupting the blood–retinal barrier and resulting in fluid accumulation within the macula [1]. This persistent leakage causes retinal thickening, distortion of the foveal architecture, and ultimately a decline in central vision that significantly affects patients' quality of life. The burden of DME continues to rise in parallel with the increasing prevalence of diabetes, making it a major public health challenge and an important therapeutic target in ophthalmology [2]. For decades, focal and grid laser photocoagulation served as the gold standard in the management of DME. Although laser therapy reduced the risk of moderate vision loss and helped stabilize the disease, its ability to restore vision was limited [3]. In addition, it often caused collateral retinal damage and was less effective in cases of diffuse or center-involving edema. The need for more effective, targeted, and vision-restoring therapies led to the exploration of the molecular mechanisms underlying macular edema, eventually identifying vascular endothelial growth factor (VEGF) as a central mediator of vascular permeability and angiogenesis in the diabetic retina [4].

The introduction of anti-VEGF therapy transformed the management of DME. By blocking VEGF-mediated pathways, these agents effectively reduce vascular leakage, resolve macular swelling, and improve visual acuity in a significant proportion of patients. First-generation anti-VEGF drugs such as bevacizumab, ranibizumab, and aflibercept have demonstrated remarkable success, offering substantial improvements over laser therapy and corticosteroids [5]. However, these treatments are not without limitations. Many patients exhibit suboptimal or incomplete responses, often requiring frequent intravitreal injections to maintain vision gains [6]. This high treatment burden, combined with the economic cost, patient discomfort, and compliance challenges, has prompted the search for agents with longer duration of action and improved efficacy. In recent years, the development of new anti-VEGF agents has aimed to address these limitations by enhancing drug potency, durability, and overall treatment convenience [7]. Novel molecules with dual or extended mechanisms of action have been designed to provide better control of retinal vascular permeability and inflammation. Among these, faricimab, a bispecific antibody targeting both VEGF-A and angiopoietin-2, has shown promise in prolonging dosing intervals while maintaining or improving clinical outcomes [8]. Other emerging therapies focus on improving drug delivery systems, such as sustained-release implants or refillable reservoirs, to reduce the frequency of injections and enhance patient adherence [9].

Despite encouraging advancements, the comparative performance of these new anti-VEGF agents remains a subject of ongoing debate. Differences in patient populations, baseline disease severity, dosing intervals, and follow-up durations across studies have made it difficult to establish clear superiority among agents [10]. Moreover, while clinical trials provide valuable evidence, real-world outcomes often differ due to variations in adherence, comorbidities, and access to care. Therefore, a comprehensive comparative analysis that considers both clinical efficacy and practical applicability is necessary to guide evidence-based decision-making in DME management [11-13].

Objective

To compare the efficacy and safety of Ranibizumab, Aflibercept, and Faricimab in improving visual and anatomical outcomes among patients with diabetic macular edema.

2. METHODOLOGY

The Multi-Center study was conducted from June 2024 to June 2025. A total of 225 patients diagnosed with center-involving diabetic macular edema were enrolled after meeting the inclusion criteria. Non-probability consecutive sampling was employed. Every eligible patient presenting during the study.

Inclusion Criteria

Patients aged 30–75 years with type 1 or type 2 diabetes mellitus.

Clinically significant or center-involving DME confirmed by optical coherence tomography (OCT).

Best-corrected visual acuity (BCVA) ranging from 20/40 to 20/400.

Patients willing to comply with follow-up visits and treatment schedule.

Exclusion Criteria

Previous treatment with anti-VEGF, corticosteroid, or laser within the past six months.

Presence of other retinal pathologies such as vein occlusion, uveitis, or age-related macular degeneration.

Significant media opacities interfering with fundus evaluation.

Uncontrolled glaucoma or intraocular pressure >25 mmHg.

Systemic contraindications to intravitreal injections (e.g., recent myocardial infarction or stroke).

Data Collection

Baseline evaluation included comprehensive ophthalmic assessment with BCVA measured using a Snellen chart and converted to logarithm of the minimum angle of resolution (logMAR) for analysis.

Participants were divided into three groups based on the anti-VEGF agent administered:

Group A: Ranibizumab (0.5 mg/0.05 mL)

Group B: Aflibercept (2 mg/0.05 mL)

Group C: Faricimab (6 mg/0.05 mL)

Each patient received three consecutive monthly injections (loading dose), followed by additional injections as required based on disease activity and OCT findings. Central retinal thickness (CRT) was measured using spectral-domain OCT, and the presence of intraretinal or subretinal fluid was documented. Follow-up assessments were performed monthly for six months after the initial injection series. During each visit, visual acuity, CRT, and ocular findings were recorded, along with the number of injections received and any adverse events, including intraocular inflammation, raised intraocular pressure, or endophthalmitis.The primary outcome of the study was the improvement in best-corrected visual acuity at six months compared to baseline. Secondary outcomes included changes in central retinal thickness, the number of injections required during the follow-up period, and the frequency and nature of treatment-related adverse events.

Statistical Analysis

All collected data were entered and analyzed using SPSS version 26. Quantitative variables, such as visual acuity and retinal thickness, were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Intergroup comparisons were performed using one-way analysis of variance for continuous variables and chi-square test for categorical data. A p-value of 0.05 or less was considered statistically significant.

3. RESULTS

A total of 225 patients with center-involving diabetic macular edema were included in the final analysis. The mean age of patients in the Ranibizumab group was 59.1 ± 8.6 years, in the Aflibercept group 59.5 ± 8.9 years, and in the Faricimab group 59.3 ± 8.7 years, showing no significant difference ($p = 0.88$). Gender distribution was nearly equal across groups, with male-to-female ratios of 39:36, 40:35, and 39:36, respectively. The mean duration of diabetes was 12.4 ± 5.3 years in the Ranibizumab group, 12.1 ± 5.6 years in the Aflibercept group, and 12.6 ± 5.4 years in the Faricimab group ($p = 0.79$). Baseline best-corrected visual acuity (BCVA) was 0.72 ± 0.16 logMAR for Ranibizumab, 0.74 ± 0.17 for Aflibercept, and 0.73 ± 0.15 for Faricimab ($p = 0.84$). Similarly, baseline central retinal thickness (CRT) values were comparable at 482.5 ± 63.4 µm, 479.8 ± 59.6 µm, and 481.2 ± 61.8 µm, respectively ($p = 0.91$).

Table 1: Baseline Demographic and Clinical Characteristics of Patients (n = 225)

Variable	Ranibizumab (n = 75)	Aflibercept (n = 75)	Faricimab (n = 75)
Mean Age (years) ± SD	59.1 ± 8.6	59.5 ± 8.9	59.3 ± 8.7
Gender (Male/Female)	39 / 36	40 / 35	39 / 36
Duration of Diabetes (years) ± SD	12.4 ± 5.3	12.1 ± 5.6	12.6 ± 5.4
Baseline BCVA (logMAR) ± SD	0.72 ± 0.16	0.74 ± 0.17	0.73 ± 0.15
Baseline CRT (µm) ± SD	482.5 ± 63.4	479.8 ± 59.6	481.2 ± 61.8

All three anti-VEGF agents led to significant visual improvement, but the magnitude differed among groups. The mean BCVA gain was 0.18 ± 0.09 logMAR in the Ranibizumab group, 0.21 ± 0.08 logMAR in the Aflibercept group, and 0.26 ± 0.07 logMAR in the Faricimab group, showing a statistically significant difference ($p = 0.03$). A total of 58.7% of patients receiving Ranibizumab, 64.0% of those on Aflibercept, and 78.7% of those treated with Faricimab gained ≥10 letters on the ETDRS chart ($p = 0.02$). Similarly, 37.3%, 45.3%, and 61.3% of patients in the respective groups gained ≥15 letters ($p = 0.01$). The mean BCVA after six months of treatment was 0.54 ± 0.15 logMAR for Ranibizumab, 0.53 ± 0.13 for Aflibercept, and 0.47 ± 0.12 for Faricimab ($p = 0.04$), indicating that Faricimab provided the most pronounced visual recovery among the three agents.

Table 2: Visual Outcomes after 6 Months of Treatment

Parameter	Ranibizumab (n = 75)	Aflibercept (n = 75)	Faricimab (n = 75)	p-value
Mean BCVA Gain (logMAR) ± SD	0.18 ± 0.09	0.21 ± 0.08	0.26 ± 0.07	0.03*
% Patients Gaining ≥10 Letters	58.7%	64.0%	78.7%	0.02*
% Patients Gaining ≥15 Letters	37.3%	45.3%	61.3%	0.01*
Mean BCVA at 6 Months (logMAR) ± SD	0.54 ± 0.15	0.53 ± 0.13	0.47 ± 0.12	0.04*

(*Statistically significant)

The mean baseline CRT was 482.5 ± 63.4 µm in the Ranibizumab group, 479.8 ± 59.6 µm in the Aflibercept group, and 481.2 ± 61.8 µm in the Faricimab group (p = 0.91). After six months of treatment, mean CRT reduced to 343.9 ± 54.2 µm, 323.1 ± 50.4 µm, and 307.8 ± 48.6 µm, respectively. The mean reduction in CRT was greatest in the Faricimab group at 173.4 ± 52.1 µm, compared to 156.7 ± 49.8 µm with Aflibercept and 138.6 ± 46.3 µm with Ranibizumab (p = 0.02). Complete fluid resolution on optical coherence tomography was achieved in 54.7% of patients in the Ranibizumab group, 61.3% in the Aflibercept group, and 74.7% in the Faricimab group (p = 0.01).

Table 3: Anatomical Outcomes (Change in Central Retinal Thickness at 6 Months)

Parameter	Ranibizumab (n = 75)	Aflibercept (n = 75)	Faricimab (n = 75)	p-value
Baseline CRT (µm) ± SD	482.5 ± 63.4	479.8 ± 59.6	481.2 ± 61.8	0.91
CRT at 6 Months (µm) ± SD	343.9 ± 54.2	323.1 ± 50.4	307.8 ± 48.6	0.02*
Mean Reduction in CRT (µm) ± SD	138.6 ± 46.3	156.7 ± 49.8	173.4 ± 52.1	0.02*
Complete Fluid Resolution (%)	54.7%	61.3%	74.7%	0.01*

The mean number of injections administered over six months was 4.8 ± 0.9 for Ranibizumab, 4.2 ± 1.0 for Aflibercept, and 3.5 ± 0.8 for Faricimab, showing a statistically significant reduction in injection frequency with Faricimab (p = 0.01). Raised intraocular pressure was observed in 4.0% of Ranibizumab-treated eyes, 2.7% of Aflibercept-treated eyes, and 2.7% of Faricimab-treated eyes (p = 0.77). Subconjunctival hemorrhage occurred in 6.7%, 5.3%, and 5.3% of cases, respectively (p = 0.89). No cases of endophthalmitis or severe intraocular inflammation were recorded in any group, and treatment discontinuation occurred in only 1.3% of Ranibizumab and Aflibercept patients, with none in the Faricimab group (p = 0.71).

Table 4: Treatment Burden and Safety Profile

Parameter	Ranibizumab (n = 75)	Aflibercept (n = 75)	Faricimab (n = 75)	p-value
Mean No. of Injections (6 Months) ± SD	4.8 ± 0.9	4.2 ± 1.0	3.5 ± 0.8	0.01*
Raised IOP Episodes (%)	4.0%	2.7%	2.7%	0.77
Subconjunctival Hemorrhage (%)	6.7%	5.3%	5.3%	0.89
Endophthalmitis / Severe Inflammation	0%	0%	0%	—
Treatment Discontinuation (%)	1.3%	1.3%	0%	0.71

(*Statistically significant)

4. DISCUSSION

The present study evaluated and compared the efficacy, anatomical outcomes, and treatment burden associated with three anti-VEGF agents Ranibizumab, Aflibercept, and Faricimab in patients with diabetic macular edema. With a total sample size of 225 patients, the study demonstrated that all three agents produced significant improvements in best-corrected visual acuity and central retinal thickness after six months of therapy. However, the magnitude of improvement was greatest in the Faricimab group, indicating its potential superiority over traditional anti-VEGF options. The results revealed that Faricimab led to the highest mean gain in visual acuity and the most pronounced reduction in central retinal thickness compared to Ranibizumab and Aflibercept. These findings align with emerging global evidence suggesting that Faricimab, due to its dual inhibition of VEGF-A and Angiopoietin-2, provides a more comprehensive blockade of vascular leakage and inflammation. This mechanism may explain its enhanced durability and efficacy, allowing for longer dosing intervals while maintaining or improving visual outcomes. Aflibercept also demonstrated strong anatomical and functional efficacy, consistent with its established position as one of the most potent VEGF inhibitors among earlier agents [14].

In addition to efficacy, treatment burden remains a critical consideration in managing diabetic macular edema. Frequent intravitreal injections are not only physically and psychologically taxing for patients but also contribute to increased healthcare costs and decreased adherence, especially in real-world settings. In this study, patients receiving Faricimab required fewer injections during the six-month follow-up period compared to those treated with Ranibizumab or Aflibercept [15]. This reduced injection frequency without compromising outcomes represents a significant advantage, as it can improve patient compliance and reduce overall clinic workload. Such real-world practicality is essential in resource-constrained environments, where patient follow-up and affordability often influence treatment success. The comparable baseline characteristics among groups confirm that the superior results observed with Faricimab were attributable to the pharmacologic differences between the agents rather than demographic or disease-related variations [16]. The statistically significant improvements in both functional and anatomical parameters with Faricimab highlight the therapeutic potential of newer, dual-pathway drugs in managing DME. The findings also reaffirm that early and sustained suppression of VEGF activity remains the cornerstone of DME treatment, but adjunct mechanisms such as Ang-2 blockade may further optimize outcomes in patients with persistent or refractory disease [17].

Safety analysis in this study showed that all agents were well tolerated, with no reports of serious ocular or systemic adverse events. Minor transient increases in intraocular pressure and mild subconjunctival hemorrhages were the most frequently observed side effects, occurring at similar rates across groups. The absence of severe inflammatory reactions or endophthalmitis further supports the safety of repeated intravitreal administration when performed under aseptic conditions [18]. These observations are consistent with previous clinical trial data and reinforce the established safety profiles of anti-VEGF therapies. The study's findings have important implications for clinical practice. The enhanced efficacy and longer durability of Faricimab suggest that it may become a preferred option, particularly for patients with poor adherence or those experiencing suboptimal response to standard agents [19]. Aflibercept continues to serve as a reliable and effective treatment, while Ranibizumab, though beneficial, may require more frequent dosing to maintain similar outcomes. Tailoring anti-VEGF therapy based on individual patient characteristics, response pattern, and access to follow-up remains a key strategy for achieving optimal results [20-22].

However, several limitations should be acknowledged. The follow-up duration of six months, while adequate for early outcome assessment, may not fully capture long-term efficacy and recurrence patterns. Real-world adherence factors, variations in disease chronicity, and systemic metabolic control could also influence visual and anatomical outcomes. Moreover, the study did not include cost-effectiveness analysis, which would provide a more comprehensive evaluation of treatment sustainability in low- and middle-income healthcare settings. Future research with larger multicenter trials, extended follow-up, and inclusion of quality-of-life and economic parameters would further validate the present findings and guide evidence-based treatment guidelines.

5. CONCLUSION

It is concluded that all three anti-VEGF agents Ranibizumab, Aflibercept, and Faricimab are effective in improving visual acuity and reducing central retinal thickness in patients with diabetic macular edema. However, among these, Faricimab demonstrated superior functional and anatomical outcomes along with a significantly reduced injection burden. Its dual inhibition of VEGF-A and Angiopoietin-2 pathways likely contributes to its enhanced efficacy and longer durability of action. Aflibercept also produced strong results and remains a dependable choice, while Ranibizumab showed modest improvement but required more frequent injections to sustain therapeutic benefit. The reduced number of injections observed with Faricimab indicates better patient compliance and lower treatment fatigue, which are important factors for real-world applicability, particularly in healthcare systems where long-term follow-up and cost-effectiveness are key considerations..

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