Journal of Clinical and Nursing Research, 2026, Volume 10, Issue 1
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Comparative Study on the Efficacy and Safety of Faricimab and Conbercept in the Treatment of Diabetic Macular Edema

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Abstract: *Objective*: To compare the clinical efficacy and safety of intravitreal injection of faricimab and conbercept in the treatment of diabetic macular edema (DME). *Methods*: A total of 50 patients diagnosed with DME in our hospital from January 2023 to May 2025 were selected and randomly divided into an observation group and a control group, with 25 cases in each group, using a random number table method. The observation group received intravitreal injection of faricimab, while the control group received intravitreal injection of conbercept. Both groups adopted a loading phase plus maintenance phase treatment regimen. The best-corrected visual acuity (BCVA, expressed in logMAR) and central subfield thickness (CST) of the two groups were compared before treatment and at 1, 3, and 6 months after treatment, and the incidence of adverse events during treatment was recorded. *Results:* The logMAR BCVA in the observation group was lower than that in the control group at 3 and 6 months after treatment (both $p < 0.05$). The CST in the observation group was smaller than that in the control group at 1, 3, and 6 months after treatment (all $p < 0.05$). There was no statistically significant difference in the overall incidence of adverse events between the two groups ($\chi^2 = 0.189$, $p = 0.663$). *Conclusion:* Both intravitreal injections of faricimab and conbercept are effective in improving visual acuity and reducing macular edema in patients with DME, with good safety profiles. However, faricimab demonstrates superior efficacy in the medium to long term (3 and 6 months) compared to conbercept, making it more suitable for long-term treatment of patients with DME.

Keywords: Diabetic macular edema; Faricimab; Conbercept; Intravitreal injection; Efficacy; Safety

Online publication: Feb 12, 2026

1. Introduction

Diabetic macular edema (DME) is one of the common microvascular complications of diabetes, characterized by the accumulation of fluid in the macular region and the disruption of the blood-retinal barrier as its core pathological features. It can lead to a sharp decline in central vision and metamorphopsia, posing a severe threat to the visual function of patients and being one of the primary causes of blindness in diabetic patients [1,2]. With the

clinical application of anti-vascular endothelial growth factor (anti-VEGF) drugs, breakthrough progress has been made in the treatment of DME, which has become a first-line treatment option [3]. Faricimab, as a novel dual-target anti-VEGF drug, can simultaneously inhibit VEGF-A and Ang-2, while Conbercept is a domestically produced anti-VEGF drug with widespread clinical application [4]. However, regarding the comparative efficacy, differences in the extent of visual improvement, and safety risks of these two drugs in the treatment of DME, the current clinical research evidence is insufficient, and there is still a lack of clear guidance for their clinical application selection. Based on this, this study aims to clarify the differences in clinical efficacy between Faricimab and Conbercept in the treatment of DME through prospective clinical comparative analysis, systematically evaluate their improvement effects on patients' best-corrected visual acuity and central macular thickness, and monitor and compare the types and incidence rates of adverse reactions, providing high-quality evidence-based medical evidence for clinically optimizing DME treatment plans and individualizing drug selection.

2. Materials and methods

2.1. General information

A total of 50 patients diagnosed with diabetic macular edema (DME) who visited the ophthalmology department of our hospital from January 2023 to May 2025 were selected as the study subjects.

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria for DME outlined in the 2024 edition of the "Clinical Practice Guideline for Diabetic Retinopathy" by the American Academy of Ophthalmology [5];
(2) Foveal-involving macular edema, with optical coherence tomography (OCT) showing a central subfield thickness (CST) ≥ 320 μm;
(3) Best-corrected visual acuity (BCVA) ranging from 0.3 to 0.8 (logMAR 0.1 to 0.5);
(4) A diabetes duration of ≥ 3 years with stable glycemic control (glycated hemoglobin < 7.5%);
(5) Informed consent obtained from the patients, who signed the informed consent form.

2.1.2. Exclusion criteria

(1) Coexistence of other retinal diseases (e.g., age-related macular degeneration, retinal vein occlusion);
(2) Previous history of intravitreal injections or ocular surgery;
(3) Presence of other ocular conditions affecting vision, such as ocular infections, glaucoma, or cataracts;
(4) Severe systemic organic diseases affecting the heart, liver, or kidneys;
(5) Allergy to any component of the study drug.

2.1.3. Study groups

Patients were randomly assigned to the observation group and the control group using a random number table method, with 25 patients in each group. In the observation group, there were 14 males and 11 females; ages ranged from 45 to 72 years, with a mean age of (58.6 ± 6.3) years; the duration of diabetes ranged from 3 to 15 years, with a mean duration of (8.2 ± 2.5) years; the logMAR BCVA before treatment was (0.32 ± 0.08), and the CST was (426.8 ± 35.2) μm. In the control group, there were 13 males and 12 females, aged between 46 and 73 years old, with an average age of (59.2 ± 6.5) years old. The duration of diabetes ranged from 3 to 16 years, with an average

of (8.5 ± 2.7) years. Before treatment, the logMAR BCVA was (0.33 ± 0.09), and the CST was (430.2 ± 36.5) μm. There were no statistically significant differences in general data such as gender, age, duration of diabetes, logMAR BCVA, and CST between the two groups before treatment ($p > 0.05$), indicating comparability.

2.2. Treatment methods

Before treatment, both groups of patients underwent comprehensive routine ocular examinations (including visual acuity, intraocular pressure, slit-lamp examination, fundus ophthalmoscopy, OCT, etc.) and general physical examinations to assess the feasibility of treatment. All injection procedures were performed by the same experienced ophthalmologist, strictly adhering to aseptic techniques. Three days before injection, levofloxacin eye drops were administered four times a day to prevent infection. During the injection, surface anesthesia was applied, and the eyelids were held open with a speculum. The needle was inserted 3.5 mm posterior to the inferotemporal corneal limbus, and the drug was slowly injected before withdrawing the needle. The puncture site was then pressed for 3 to 5 minutes, and the procedure was concluded after observing no abnormalities.

The observation group received an intravitreal injection of Faricimab at a dose of 6 mg each time, while the control group received an intravitreal injection of Conbercept at a dose of 0.5 mg each time. Both groups adopted a loading phase + maintenance phase treatment regimen: during the loading phase, injections were administered once a month for three consecutive times; the maintenance phase commenced in the fourth month, during which the resolution of macular edema was evaluated based on OCT examination results. If the central subfield thickness (CST) was < 320 μm and visual acuity remained stable, injections were given once every three months; if CST was ≥ 320 μm, injections were administered once every two months. The total follow-up period was six months.

2.3. Observation indicators

(1) Best-corrected visual acuity (BCVA)

Assessed using a standard logarithmic visual acuity chart, with visual acuity converted to logMAR values for statistical analysis. Lower logMAR values indicate better visual acuity. Measurements were taken before treatment and at 1, 3, and 6 months post-treatment.

(2) Central subfield thickness (CST)

Measured using spectral-domain OCT by scanning a 5 mm area of the macular region and averaging three measurements of retinal thickness at the fovea. Measurements were taken before treatment and at 1, 3, and 6 months post-treatment.

(3) Safety indicators

Adverse events occurring in patients in both groups during treatment were recorded, including ocular adverse events (conjunctival hemorrhage, ocular pain, increased intraocular pressure, vitreous opacity, etc.) and systemic adverse events (headache, nausea, fluctuations in blood pressure, etc.). The incidence of adverse events was calculated.

2.4. Statistical methods

Data analysis was performed using SPSS 26.0 statistical software. Measurement data were expressed as mean ± standard deviation ($\overline{x} \pm s$). Paired *t*-tests were used for comparisons within groups before and after treatment, while independent sample *t*-tests were used for comparisons between groups. Categorical data were expressed as rates (%), and comparisons were made using the χ^2 test. A *p*-value of less than 0.05 was considered statistically significant.

3. Results

3.1. Comparison of logMAR BCVA between the two groups before and after treatment

The logMAR BCVA in the observation group was lower than that in the control group at 3 and 6 months after treatment (both $p < 0.05$). See **Table 1**.

Table 1. Comparison of logMAR BCVA between the two groups before and after treatment

Group	Before treatment	1 month of treatment	3 months of treatment	6 months of treatment
Observation group (n = 25)	0.32 ± 0.08	0.24 ± 0.07	0.18 ± 0.06	0.13 ± 0.05
Control group (n = 25)	0.33 ± 0.09	0.25 ± 0.08	0.22 ± 0.07	0.18 ± 0.06
t-value (vs. control)	0.415	0.470	2.169	3.201
p-value (vs. control)	0.680	0.640	0.035	0.002

3.2. Comparison of CST between the two groups before and after treatment

The CST in the observation group was smaller than that in the control group at 1, 3, and 6 months after treatment (all $p < 0.05$). See **Table 2**.

Table 2. Comparison of CST between the two groups before and after treatment

Group	Before treatment	1 month of treatment	3 months of treatment	6 months of treatment
Observation group (n = 25)	426.82 ± 35.21	358.63 ± 28.55	312.44 ± 22.36	298.63 ± 18.54
Control group (n = 25)	430.22 ± 36.51	375.45 ± 29.86	338.64 ± 25.77	324.84 ± 21.62
t-value (vs. control)	0.335	2.036	3.840	4.601
p-value (vs. control)	0.739	0.047	< 0.001	< 0.001

3.3. Comparison of adverse events between the two groups

During the treatment period, a small number of adverse events occurred in both groups, all of which were mild to moderate in severity. These events were relieved after symptomatic treatment, and no serious adverse events (such as endophthalmitis, retinal detachment, or severe systemic allergic reactions) occurred. There was no statistically significant difference in the overall incidence of adverse events between the two groups ($\chi^2 = 0.189$, $p = 0.663$). See **Table 3**.

Table 3. Comparison of adverse events between the two groups

Group	Conjunctival hemorrhage	Eye pain	Elevated intraocular pressure	Overall incidence rate (%)
Observation group (n = 25)	1	1	0	2 (8.0)
Control group (n = 25)	2	1	1	4 (16.0)
χ^2-value	-	-	-	0.189
p-value	-	-	-	0.663

4. Discussion

DME (Diabetic Macular Edema) is a common complication of diabetic retinopathy with a complex pathogenesis.

It is primarily associated with the overexpression of VEGF (Vascular Endothelial Growth Factor) and the accumulation of fluid in the macular region due to the disruption of the blood-retina barrier. If left untreated, it can lead to a severe decline in vision or even blindness, significantly affecting the patient's quality of life [6]. Currently, intravitreal injection of anti-VEGF drugs is the first-line treatment for DME, aiming to alleviate macular edema and improve visual acuity by inhibiting VEGF activity [7].

Conbercept is an anti-VEGF drug independently developed in China, belonging to the class of fusion proteins. It can specifically bind to multiple subtypes of VEGF-A, inhibiting angiogenesis and vascular leakage. Conbercept has been widely used in the treatment of DME with proven efficacy [8]. Faricimab is a novel bispecific antibody that not only inhibits VEGF-A but also inhibits angiopoietin-2 (Ang-2). Ang-2 can exacerbate macular edema by disrupting vascular stability, so faricimab can exert its effects through a dual pathway, more effectively stabilizing the blood-retina barrier and reducing macular edema [9]. This study compared the efficacy of the two drugs in treating DME. The results showed that after 1, 3, and 6 months of treatment, the logMAR BCVA (Best Corrected Visual Acuity) of both groups significantly decreased compared to before treatment, and the CST (Central Subfield Thickness) significantly decreased compared to before treatment. This indicates that both drugs can effectively improve visual acuity and macular edema in patients with DME, consistent with previous research findings.

Further analysis revealed that at 3 and 6 months of treatment, the logMAR BCVA in the observation group was lower than that in the control group, and the CST was smaller than that in the control group, with statistically significant differences. However, there were no statistically significant differences in these indicators between the two groups at 1 month of treatment. This suggests that the short-term efficacy of faricimab is generally comparable to that of conbercept, but faricimab demonstrates superior medium- to long-term efficacy. The reason for this may be related to the dual mechanism of action of faricimab: on the one hand, by specifically inhibiting the VEGF-A signaling pathway, it effectively reduces leakage from retinal choroidal neovascularization, thereby alleviating fluid accumulation in the macular region from the source [9]. On the other hand, its inhibitory effect on Ang-2 stabilizes the morphology and function of vascular endothelial cells, reduces vascular permeability, and subsequently decreases the recurrence of macular edema, ultimately achieving a more sustained therapeutic effect [10]. Additionally, pharmacokinetic analysis shows that faricimab has a relatively longer half-life, enabling it to maintain stable and effective drug concentrations in ocular tissues, significantly prolonging its duration of action. This may also be one of the key factors contributing to its superior medium- to long-term efficacy compared to conbercept.

In terms of safety, there was no statistically significant difference in the incidence of adverse events between the two groups in this study, and all adverse events were mild to moderate in severity. They were alleviated after symptomatic treatment, with no serious adverse events such as endophthalmitis or severe hemorrhage occurring. The two most common ocular adverse events were conjunctival hemorrhage. Based on the analysis of clinical operation records, this symptom was primarily associated with injection procedures and constituted a transient reaction that resolved spontaneously without the need for special intervention. In the control group, one case of transient intraocular pressure elevation occurred, which rapidly returned to the normal range after treatment with topical antihypertensive eye drops, without causing adverse effects on the patient's visual function. The aforementioned safety data fully demonstrate that both Faricimab and Conbercept exhibit good safety profiles for the treatment of diabetic macular edema (DME), with controllable clinical application risks.

Although this study clarified the differences in short-term and mid-term efficacy between the two drugs

in treating DME, it still has certain limitations and requires an objective assessment of the applicability of the research findings. Firstly, the sample size was relatively small, and the follow-up period was short, which limited the ability to evaluate the long-term durability and safety of the two drugs. Additionally, as this was a single-center study, the results may have geographical limitations, potentially leading to insufficient representativeness and difficulty in fully extrapolating the findings to DME patient populations with different regional and clinical characteristics, thereby introducing potential geographical and selection biases. Future research should involve large-sample, multicenter studies with long-term follow-up to further validate the efficacy and safety of the two drugs, providing more comprehensive and reliable evidence-based medical support for optimizing individualized treatment plans for DME.

5. Conclusion

In conclusion, both Faricimab and Conbercept administered via intravitreal injection are effective in improving visual acuity and reducing macular edema in patients with DME, with good safety profiles. However, Faricimab demonstrates superior mid- to long-term (3- and 6-month) efficacy compared to Conbercept, making it more suitable for long-term treatment in patients with DME.

Disclosure statement

The authors declare no conflict of interest.

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