

Two-Year Real-World Outcomes of Faricimab for Diabetic Macular Edema in Japan

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Background: Diabetic macular edema (DME) is a leading cause of vision loss in working-age adults. Faricimab, a bispecific antibody targeting VEGF and Ang-2, has been shown to reduce treatment burden by enabling extended injection intervals. However, real-world, long-term data from Japanese populations are limited.

Purpose: To evaluate the two-year efficacy and safety of intravitreal faricimab for DME in a real-world clinical setting in Japan.

Methods: This retrospective observational study was conducted at the International Goodwill Hospital, Yokohama, Japan. Patients with DME who were followed for two years after initiating intravitreal faricimab. Outcome measures included central subfield thickness (CST), best-corrected visual acuity (BCVA), macular fluid resolution, and recurrence. Changes were evaluated using nonparametric tests and survival analysis.

Results: We analyzed 9 patients (16 eyes) with DME who were followed for two years after initiating intravitreal faricimab. A four-injection loading phase was omitted in all but one case, with a median of one initial injection. CST decreased from 332.3 μm to 267.0 μm ($p = 0.069$), and BCVA remained stable (0.49 to 0.55 logMAR, $p = 0.2081$). Complete macular fluid resolution occurred in 87.5% of eyes, with a median resolution time of 6 months. Recurrence occurred in 37.5% of eyes during follow-up, with a median time to recurrence of 9 months. Among eyes on fixed dosing ($n = 11$), 72.7% achieved a final injection interval of ≥ 12 weeks. Intraretinal fluid (IRF) significantly decreased ($p = 0.0078$), and chronic cystoid changes were associated with limited CST reduction ($p = 0.016$). No treatment-related adverse events were reported.

Conclusion: Faricimab demonstrated favorable anatomical outcomes and extended injection intervals over two years in a real-world setting, despite the omission of a loading phase in most cases. These findings support its practical utility of faricimab for DME management in Japan.

Keywords: diabetic macular edema, faricimab, real-world study, optical coherence tomography, injection interval

Introduction

Diabetic macular edema (DME), a major cause of visual impairment secondary to diabetic retinopathy (DR), significantly impairs visual function, particularly in working-age individuals, and adversely affects quality of life.¹

The pathophysiology of DME involves chronic inflammation and breakdown of the blood–retinal barrier, both of which are triggered by diabetes-induced hyperglycemia. Inflammatory mediators such as vascular endothelial growth factor (VEGF), tumor necrosis factor- α , and interleukins become upregulated, leading to increased retinal vascular permeability. These molecular changes lead to the accumulation of intraretinal and subretinal fluid.²

Anti-VEGF therapy remains the standard treatment for DME, with agents such as aflibercept and ranibizumab demonstrating proven clinical efficacy.³ However, some patients exhibit suboptimal responses to anti-VEGF therapy

and require frequent intravitreal injections (IVIs). Moreover, extending treatment intervals is often challenging with these agents, leading to increased treatment burden in real-world clinical settings. Faricimab, a bispecific antibody that simultaneously targets VEGF and angiopoietin-2 (Ang-2), has recently emerged as a novel therapeutic option for DME.⁴ Compared to conventional anti-VEGF agents such as aflibercept and ranibizumab, faricimab offers the potential for extended treatment intervals, reduced treatment burden, and sustained efficacy.⁵

In the Phase 2 BOULEVARD trial, faricimab demonstrated improvements in both visual acuity and anatomical outcomes in patients with DME, including those previously treated with anti-VEGF agents.⁶ Furthermore, the Phase 3 YOSEMITE and RHINE trials reported that personalized treatment intervals (PTI) enabled the extension of dosing intervals to 12 weeks or longer in a substantial proportion of patients.⁷ These findings highlight faricimab as a promising therapeutic option with sustained efficacy and reduced treatment burden.

Meanwhile, real-world evidence regarding the long-term efficacy and safety of faricimab remains limited. In particular, most studies focusing on Japanese patients with DME have only reported short-term outcomes, with few addressing longer-term treatment results. For instance, a study by Kusuvara et al demonstrated significant improvements in both visual acuity and anatomical parameters at six months after faricimab initiation,⁸ however, data on subsequent clinical courses remain scarce. In the YOSEMITE and RHINE trials, a head-to-head dosing period was implemented, in which all treatment arms received four consecutive injections at 4-week intervals (Q4W) after treatment initiation.⁹ However, in real-world clinical settings, financial and social constraints often make it difficult to ensure such initial Q4W loading regimens. Therefore, it is essential to accumulate real-world, mid-to-long-term data that reflect practical treatment environments to evaluate the actual efficacy and durability of faricimab therapy.

This study aimed to evaluate the two-year efficacy and safety of faricimab treatment for DME in a real-world setting using a retrospective observational design. We assessed both anatomical and functional outcomes over the two-year treatment period to examine the therapeutic effects and their durability.

Materials and Methods

Study Design

This retrospective observational study evaluated the two-year efficacy of faricimab treatment in patients with DME. Patient data were collected from the initiation of treatment through a two-year follow-up period from the initiation of treatment, and both anatomical and functional outcomes, including best-corrected visual acuity (BCVA) and central subfield thickness (CST), were assessed.

Study Population

Patients who initiated faricimab treatment for diabetic macular edema between July and December 2022 at the International Goodwill Hospital, Yokohama, Japan, were retrospectively reviewed. The inclusion criteria were a diagnosis of DME secondary to diabetic retinopathy (DR), age ≥ 18 years, and availability of follow-up data for at least two years, and continuous faricimab treatment throughout the two-year period. The exclusion criteria included a history of other retinal disorders such as retinal detachment or retinal vein occlusion, as well as cases that underwent ocular surgery such as cataract surgery or vitrectomy, or retinal laser treatment during the follow-up period.

Data Collection

Data were collected from electronic medical records and imaging systems. Baseline demographic and clinical information included patient age, sex, and the severity of DR. The severity of DR was classified according to the International Clinical Diabetic Retinopathy Disease Severity Scale as mild to moderate non-proliferative DR (mNPDR), severe non-proliferative DR (sNPDR), or proliferative DR (PDR).¹⁰ Treatment history was reviewed, including the use of anti-VEGF agents such as intravitreal aflibercept and ranibizumab, and the total number of injections administered. Additional data were collected on prior panretinal photocoagulation (PRP), lens status (phakic or pseudophakic), and prior vitrectomy. The number of IVIs, treatment intervals, and the use of fixed or pro re nata (PRN) regimens were also recorded over the two-year follow-up period.

Best-corrected visual acuity (BCVA) and central subfield thickness (CST) were assessed based on measurements obtained within one month before treatment initiation and then at six-month intervals throughout the two-year follow-up period. BCVA was measured using a standard Landolt C chart and converted to logMAR values for analysis. CST was measured using a swept-source optical coherence tomography device (DRI OCT Triton or Triton Plus; Topcon Corporation, Tokyo, Japan).

The following OCT biomarkers were also evaluated: the presence or absence of subretinal fluid (SRF) and intraretinal fluid (IRF), chronic cystoid changes, hyperreflective foci (HRF), disorganization of the retinal inner layers (DRILs), vitreomacular adhesion or traction (VMA/VMT), epiretinal membrane (ERM), and irregularities in the external limiting membrane (ELM) and ellipsoid zone (EZ).

Resolution of macular fluid and recurrence of edema were evaluated using OCT images obtained during follow-up visits. Recurrence was defined as the reappearance of IRF or SRF after a period of complete resolution.

Outcome Measures

The primary outcomes were changes in CST and BCVA. Secondary outcomes included the resolution of macular fluid, injection frequency and intervals, recurrence, changes in OCT biomarkers, and associations with baseline characteristics.

Statistical Analysis

CST and BCVA were compared using the paired *t*-test or Wilcoxon signed-rank test, depending on data distribution. Time to macular fluid resolution and recurrence was analyzed using Kaplan–Meier curves.

Pre- and post-treatment changes in OCT biomarkers were assessed using McNemar’s exact test. Associations between baseline biomarkers and outcomes (CST, BCVA, resolution, recurrence) were evaluated using Mann–Whitney U and Fisher’s exact tests. Univariate analyses examined relationships between treatment outcomes and baseline clinical factors (DR severity, IOL status, prior vitrectomy, PRP history, loading injections, previous anti-VEGF treatments). ANOVA, Welch’s *t*-test, or Spearman’s rank correlation were used as appropriate.

All tests were two-sided, with $p < 0.05$ considered statistically significant. Analyses were conducted using Python (v3.11; SciPy v1.9.3, pandas v1.5.3).

Safety Assessment

The safety of faricimab treatment was evaluated by recording the presence and severity of all adverse events during the treatment period. Adverse events were assessed based on a review of medical records and findings from routine ophthalmic examinations. Particular attention was given to known anti-VEGF-related complications, such as intraocular inflammation, elevated intraocular pressure, vitreous opacity, retinal detachment, and vascular occlusion.

Ethical Consideration

This retrospective observational study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the Institutional Review Board of Yokohama City University Hospital (approval number: F250300004). The study was conducted as a single-center protocol at Yokohama City University, with the International Goodwill Hospital participating as a cooperating facility. All patient data were anonymized prior to analysis, and the requirement for written informed consent was waived due to the retrospective nature of the study. This study has been registered with the University Hospital Medical Information Network (UMIN000057639).

Results

Patient Characteristics

This study included 9 patients (16 eyes) with DME. The mean patient age was 69.9 years (range: 51–87 years), with 75% of patients being male and 25% female. The severity of DR included mNPDR, sNPDR, and PDR, with sNPDR being the most common (56.2%). Most eyes (87.5%) were pseudophakic, while 12.5% were phakic. The mean number of previous

Table 1 Patient Characteristics and Medical History in Diabetic Macular Edema Patients

Characteristic	
Number of patients (eyes)	9 patients (16 eyes)
Age	Median 73.5 (range: 51–87 years), Mean 69.9 years
Gender distribution	75% male, 25% female
Diabetic Retinopathy severity	mNPDR: 18.8% (3 eyes), sNPDR: 56.2% (9 eyes), PDR: 25.0% (4 eyes)
Prior PRP	12 eyes (75.0%)
Lens status	Pseudophakic: 87.5% (14 eyes), Phakic: 12.5% (2 eyes)
Prior vitrectomy	3 eyes (18.8%)
Previous anti-VEGF treatments	Median 12.5, Average 10.7 (range: 0–20) •IVA: Median 10 (range: 0–20), Mean 9.94 •IVR: Median 0 (range: 0–4), Mean 0.75
Naive cases	1 eye

Abbreviations: mNPDR, mild to moderate non-proliferative diabetic retinopathy; sNPDR, severe non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; PRP, panretinal photocoagulation; VEGF, vascular endothelial growth factor; IVA, intravitreal aflibercept; IVR, intravitreal ranibizumab.

anti-VEGF injections was 10.7, with only one eye being treatment-naïve. Prior vitrectomy was present in 3 eyes (18.8%), and prior PRP was performed in 12 eyes (75.0%) (Table 1).

Anatomical and Functional Outcomes

CST decreased from 332.3 μm at baseline to 267.0 μm at 24 months; however, this change was not statistically significant (p=0.069) (Figure 1a). BCVA showed a slight, non-significant worsening from 0.49 logMAR at baseline to 0.55 logMAR at 24 months (p = 0.2081), indicating relative visual stability over the treatment period (Figure 1b). However, some individual cases showed an improvement of ≥0.3 logMAR.

An exploratory analysis was conducted to examine the relationship between baseline characteristics and treatment outcomes. Improvement in BCVA was significantly associated with DR severity (p = 0.0061), with a trend toward less improvement in eyes with more advanced DR. In contrast, no statistically significant associations were found between other background factors and changes in BCVA, changes in CST, the number of injections required to achieve dryness (p > 0.05 for all comparisons).

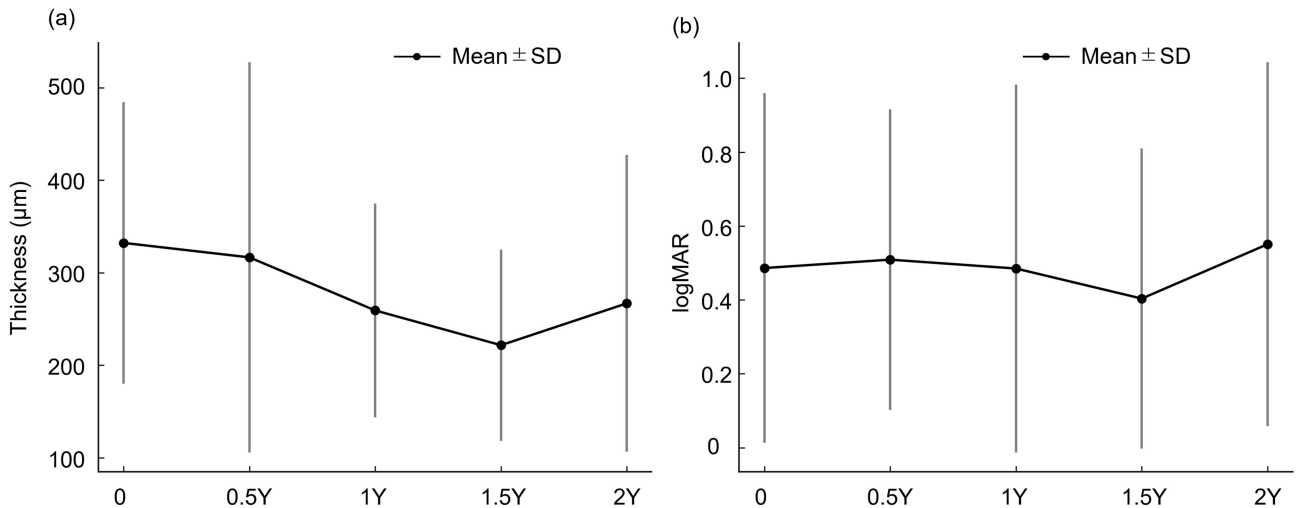


Figure 1 Longitudinal Changes in Central Subfield Thickness and Best-Corrected Visual Acuity Over Two Years. (a) Central subfield thickness (CST, μm) and (b) best-corrected visual acuity (BCVA, logMAR) were measured at baseline and at 6, 12, 18, and 24 months following the initiation of intravitreal faricimab treatment in patients with diabetic macular edema. Data are presented as mean ± standard deviation (SD).

Table 2 Summary of Treatment Outcomes for Diabetic Macular Edema

Number of Initial Loading Injections	Median 1 (range 1–4), Mean 1.3
Total Number of IVIs Over 2 Years	Median 5 (range 2–12), Mean 6.3
Final Injection Interval (weeks)	Median 12 (range 6–24), Mean 14.4
Proportion of Eyes with Final Injection Interval ≥ 12 Weeks	72.7% (8/11 eyes)
Proportion of Eyes with Final Injection Interval ≥ 16 Weeks	36.4% (4/11 eyes)
Number of Eyes Treated with PRN Regimen	5 eyes
Macular Fluid Resolution Rate at 2 Years	56.3% (9/16 eyes)
Number of Injections Until Complete Resolution	Median 2 (range 0–12), Mean 3.2
Time to Complete Resolution (months)	Median 6 (range 0–23), Mean 9.6
Number of Eyes with Unresolved Macular Edema	2 eyes
Recurrence Rate	37.5% (6/16 eyes)
Time to Recurrence (months)	Median 6.5 (range 2–20), Mean 8.2

Abbreviations: IVIs, intravitreal injections; PRN, pro re nata.

The median number of initial loading injections was one, and the median total number of IVIs over the two-year period was five. At two years after treatment initiation, complete resolution of retinal fluid was achieved in 56.3% of eyes (9/16). Among eyes in which resolution was achieved, the median time to complete resolution was six months, and the median number of injections required was two; the two eyes without resolution were excluded from these calculations. The median final injection interval was 12 weeks. Five eyes treated with a PRN regimen were excluded from the analysis of injection intervals due to the absence of fixed dosing schedules. Among eyes treated with a fixed dosing regimen ($n = 11$), 72.7% (8/11 eyes) reached a final injection interval of ≥ 12 weeks, and 36.4% (4/11 eyes) maintained an interval of ≥ 16 weeks. During the follow-up period, recurrence of DME occurred in 6 of 16 eyes (37.5%), with a median time to recurrence of 6.5 months (Table 2).

Kaplan–Meier Analysis of Macular Fluid Resolution and Recurrence

Kaplan–Meier analysis revealed that the median time to complete resolution of macular fluid was 6 months. Retinal fluid resolution was observed in 14 eyes (87.5%), while 2 eyes (12.5%) did not achieve resolution by the end of follow-up and were censored. The survival curve showed a steep decline immediately after treatment initiation, with a trend toward resolution in most cases within the first 6 months (Figure 2a). Regarding recurrence, the median time to recurrence was 9 months. Recurrence of edema was observed in 6 eyes (37.5%), whereas 10 eyes (62.5%) did not experience recurrence during the follow-up period and were considered censored. The survival curve remained stable initially but showed an increasing rate of recurrence after 6 months, particularly beyond the 9-month mark (Figure 2b).

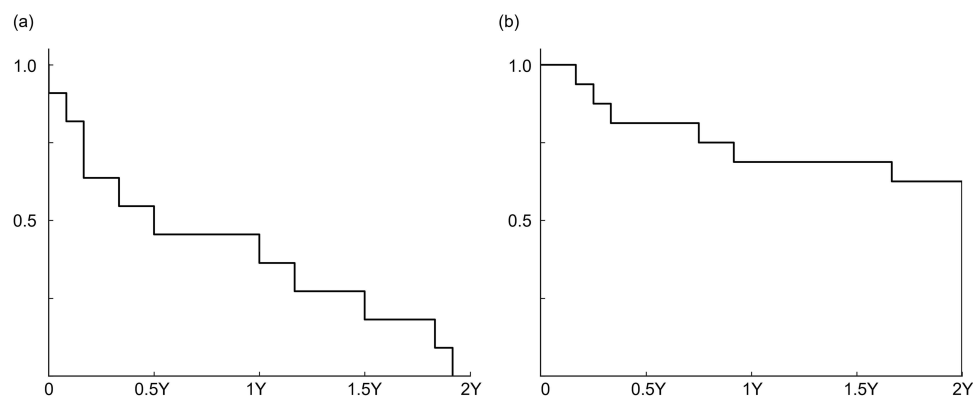


Figure 2 Kaplan–Meier Curves for Time to Macular Fluid Resolution and Recurrence. Kaplan–Meier survival curves showing (a) the time to complete resolution of macular fluid and (b) the time to recurrence after initial resolution. The Y-axis represents the event-free survival probability: remaining unresolved in (a) and free from recurrence in (b). Median times to resolution and recurrence were 6 and 9 months, respectively. Tick marks indicate censored observations.

Table 3 Summary of Biomarker Changes and Statistical Analysis (McNemar's Exact Test)

Biomarker	Pre-Treatment (n)	Pre-Treatment (%)	Post-Treatment (n)	Post-Treatment (%)	P-value
SRF	0	0.00%	0	0.00%	0.0078
IRF	15	93.80%	7	43.80%	
Chronic Cysts	9	56.20%	5	31.20%	0.125
HRF	7	43.80%	7	43.80%	1
DRILs	10	62.50%	12	75.00%	0.6875
VMA or VMT	2	12.50%	0	0.00%	1
ERM	5	31.20%	4	25.00%	
ELM Disruption	11	68.80%	9	56.20%	0.625
EZ Disruption	13	81.20%	8	50.00%	0.0625

Abbreviations: SRF, subretinal fluid; IRF, intraretinal fluid; HRF, hyperreflective foci; DRILs, disorganization of the retinal inner layers; VMA, vitreomacular adhesion; VMT, vitreomacular traction; ERM, epiretinal membrane; ELM, external limiting membrane; EZ, ellipsoid zone.

Biomarker Analysis

The baseline frequencies of IRF (93.8%), ELM disruption (68.8%), EZ disruption (81.3%), and DRILs (62.5%) changed to 43.8%, 56.3%, 50.0%, and 75.0%, respectively, at two years.

According to McNemar's exact test, only IRF showed a statistically significant reduction ($p = 0.0078$). No significant changes were observed for chronic cystoid changes ($p = 0.125$), HRF ($p = 1.000$), or DRILs ($p = 0.6875$). SRF and VMA/VMT were not subjected to statistical analysis due to the absence of discordant pairs or the presence of unidirectional changes (Table 3).

Among baseline biomarkers, the presence of chronic cystoid changes was significantly associated with a smaller reduction in CST ($p = 0.016$). No other biomarkers demonstrated statistically significant associations with CST or BCVA changes (all $p > 0.05$); however, DRILs ($p = 0.057$) and ERM ($p = 0.088$) showed trends toward association with less visual improvement. No significant associations were found between baseline biomarkers and either macular fluid resolution or recurrence (all $p > 0.05$).

Adverse Events and Safety Profile

No adverse events related to faricimab treatment were observed during the study period. There were no reports of serious ocular adverse events, such as intraocular inflammation, elevated intraocular pressure, vitreous opacity, retinal detachment, or vascular occlusion. In addition, no systemic adverse events were observed.

Discussion

This retrospective study demonstrated that faricimab provided sustained anatomical benefits over two years in patients with DME, despite the omission of a loading phase in most cases. The treatment response appeared to be influenced by chronic cystoid changes and the severity of diabetic retinopathy.

In the YOSEMITE and RHINE trials, the faricimab groups demonstrated approximately a 200 μm reduction in CST and a gain of +10 to +11 ETDRS letters over two years, indicating both anatomical and functional efficacy.^{7,9} Similarly, in the Japanese subgroup of the YOSEMITE trial, a 200–255 μm reduction in CST and a gain of +9 to +12 ETDRS letters were reported, showing trends consistent with the global data.¹¹ In contrast, in the present study, anatomical improvement was modest and visual acuity was largely maintained. This limited treatment effect may be attributable to several background factors. Wong et al reported that switching to faricimab should be considered early in cases with suboptimal response to prior anti-VEGF therapy, and that an initial loading phase of four injections followed by cautious interval extension is preferable.¹² In this study, the loading phase was omitted, and most eyes had been switched to faricimab after a long history of anti-VEGF treatment. A short-term report by Ohara et al, in which faricimab was administered on a PRN basis without a loading phase in treatment-resistant DME, similarly showed no statistically significant improvement in CST or visual acuity, with the primary benefit being the extension of treatment intervals.⁵ These findings support the limited treatment effect observed in the present study.

Furthermore, no eyes presented with SRF at baseline in this study, and all cases were characterized by IRF-dominant DME. SRF is considered relatively uncommon in DME, but cases with SRF have been reported to show significantly greater improvements in both visual acuity and CST.¹³ Therefore, the absence of SRF in the present cohort is considered a contributing factor to the limited anatomical and functional improvements observed.

Regarding IRF, the YOSEMITE and RHINE trials reported that 98.7% to 99.0% of eyes had IRF at baseline, and after two years, IRF resolution was achieved in 58–63% of eyes in the Q8W group and 44–49% in the T&E group.⁹ In the Japanese subgroup of the YOSEMITE trial, IRF resolution rates were 55.7–70.8% in the Q8W group and 17.3–29.0% in the T&E group, suggesting a higher tendency for recurrence in the T&E group.¹¹ In this study, IRF was present in 93.8% of eyes at baseline and decreased to 43.8% at two years, resulting in an overall resolution rate of 56.2%, which is notably better than the 17.3–29.0% reported in the Japanese T&E group. However, recurrence occurred in a substantial proportion of eyes even during ongoing treatment. With respect to treatment intervals, the global YOSEMITE and RHINE cohorts reported Q16W achievement rates of 62.3% and Q12W or longer in 78.1% of eyes at two years,⁷ whereas in the Japanese subgroup, these rates were lower, at 38.9% and 61.1%, respectively.¹¹ In this study, the achievement rates for extended intervals were similar to those reported in the Japanese RCT subgroup. These findings suggest the importance of optimizing treatment intervals and the need for careful monitoring within individualized treatment strategies.

This study also evaluated the associations between baseline OCT biomarkers and complete macular fluid resolution or recurrence. No statistically significant associations were found for any of the examined biomarkers. This finding is consistent with the report by Giancipoli et al, who similarly identified no significant associations between fluid resolution and OCT biomarkers other than large juxtafoveal microaneurysms (MAs). IRF, DRILs, EZ disruption, and other structural markers were not significantly associated with fluid resolution in their study.¹⁴ Because assessment of MAs typically requires fluorescein angiography (FA), which was not routinely performed in this study, thereby precluding analysis of MA-related effects. These results suggest that most OCT biomarkers likely have limited predictive value for fluid resolution. Conversely, this study also conducted exploratory analyses to assess the relationships between OCT biomarkers and changes in CST and BCVA. Chronic cystoid changes were significantly associated with less CST reduction, while the presence of DRILs and ERM showed trends toward associations with smaller visual gains. Previous research also found that DRILs were also associated with difficulty in extending treatment intervals,⁵ which may suggest some relevance even though the follow-up periods differed. These findings suggest that certain OCT biomarkers appear to influence treatment responsiveness and complement existing reports, including that of Giancipoli et al, by providing more detailed insights into anatomical and functional outcomes.

During the two-year observation period, no cases of intraocular inflammation or other adverse events were observed in our cohort (16 eyes). This is consistent with previous real-world data reporting a low incidence of mild intraocular inflammation with faricimab treatment.¹⁵

Limitations

This study has several limitations. First, the sample size was relatively small, which may limit the statistical power to detect differences and associations. Second, its retrospective, single-center design may introduce selection bias and limit the generalizability of the findings. Finally, treatment regimens were not standardized, which may have influenced the outcomes.

Conclusion

In real-world clinical settings, early initiation of faricimab with loading may improve outcomes, although practical constraints often limit this approach. Despite the omission of loading in most cases, favorable results were achieved, including IRF resolution and extended injection intervals. These findings support the clinical utility of faricimab and warrant prospective studies to determine its optimal use.

Author Contributions

Yuki Mizuki and Soichiro Inokuchi contributed equally to this work and are co-first authors. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition

of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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