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One-Year Outcomes of Intravitreal Faricimab Injection in Treatment-Naïve Patients With Neovascular Age-Related Macular Degeneration

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Abstract

Purpose: To investigate the 1-year functional and morphologic outcomes of intravitreal (IVT) faricimab in treatment-naïve Japanese patients with neovascular age-related macular degeneration (nAMD). **Methods:** A retrospective study was performed to examine the outcomes of patients with nAMD who received IVT faricimab using a treat-and-extend regimen. The best-corrected visual acuity (BCVA), central foveal thickness (CFT), central choroidal thickness, dry macular achievement, and treatment intervals at 48 weeks were evaluated. Furthermore, the presence of polypoidal lesions at 48 weeks, as indicated by indocyanine green angiography, was investigated in patients with polypoidal choroidal vasculopathy (PCV). **Results:** This study included 48 Japanese treatment-naïve patients with nAMD assessed at 1 year of follow-up. The BCVA was significantly improved 1 year after initial treatment ($P < .001$). CFT and central choroidal thickness were also significantly decreased after 1 year ($P < .001$ and $P < .001$, respectively). Dry macula was achieved in 42 eyes (87.5%), and the mean (±SD) treatment interval at 12 months was 14.5 ± 4.4 weeks. The 1-year polyp regression rate was 76.9% (10/13 eyes). **Conclusions:** IVT faricimab was well tolerated and appeared to improve both functional and anatomic outcomes in Japanese patients with nAMD. In addition, a high rate of polyp regression was seen in patients with PCV.

Keywords

neovascular age-related macular degeneration, faricimab, polypoidal choroidal vasculopathy, intravitreal injection, antivascular endothelial growth factor

Introduction

Age-related macular degeneration (AMD) is one of the leading causes of blindness in older adults,[1,2] and the number of patients with the disease is predicted to increase worldwide.[3] Intravitreal (IVT) antivascular endothelial growth factor (anti-VEGF) injections for neovascular AMD (nAMD) are the first-line treatment option.[4] However, frequent injections and consultations are a heavy burden for both patients and clinicians. Recently, faricimab, a targeted antibody that binds with high affinity both to VEGF-A and angiopoietin 2 (Ang2), was approved to treat nAMD.[5] The TENAYA and LUCERNE trials showed that faricimab maintained the best-corrected visual acuity (BCVA) and, compared with aflibercept, resulted in a greater reduction in central macular thickness (CMT) with fewer injections.[5] In these trials, about 80% of patients extended their injection intervals to beyond 12 to 16 weeks.[5] Twelve-week or 16-week dosing intervals of IVT faricimab were also effective for improving and maintaining VA for 96 weeks, which was not inferior to an 8-week dosing interval of IVT aflibercept.[6]

On the other hand, to reduce the frequency of clinic visits and control disease activity, a treat-and-extend regimen is now commonly used in the Asia-Pacific region to treat nAMD, including polypoidal choroidal vasculopathy (PCV).[7] Treatment with faricimab results in fewer clinic and injection visits, lessening the overall treatment burden and thus benefiting both patients with nAMD and clinicians.

We previously described the favorable outcomes during the loading phase of faricimab in patients with nAMD.[8] However, few reports have evaluated the 1-year outcomes in the clinical

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setting.[9] The purpose of our study was to investigate the 1-year functional and morphologic outcomes of IVT faricimab in patients with treatment-naïve nAMD. In addition, the 1-year rate of polyp regression in patients with PCV was assessed by indocyanin green angiography (ICGA).

Methods

This retrospective cross-sectional study included patients who were diagnosed with treatment-naïve nAMD at Yokohama City University Medical Center between June 2022 and March 2023. Patients received a treat-and-extend regimen of IVT faricimab injections and completed 1-year follow-up. All patients provided written informed consent before their medical record data were used in this research. The ethics committee of Yokohama City University Medical Center approved the study, which adhered to the tenets of the Declaration of Helsinki.

The inclusion criteria were the presence of nAMD determined by clinical findings, spectral-domain optical coherence tomography (SD-OCT) (version 5.3, Spectralis, Heidelberg Engineering), fluorescein angiography, and ICGA (version 5.3, Spectralis, Heidelberg Engineering). Patients with a history of previous treatment for nAMD (ie, laser photocoagulation, photodynamic therapy, other IVT anti-VEGF agents, or IVT steroids) were excluded from the study. Patients with a history of eye diseases such as uncontrolled glaucoma, macular hole, diabetic retinopathy, uveitis, retinal vein occlusion, and rhegmatogenous retinal detachment were also excluded.

In the loading phase, patients received faricimab 6.0 mg/0.05 mL 3 or 4 times a month. A treat-and-extend regimen was used in the maintenance phase and adjusted by 2 to 4 weeks based on the presence on OCT of exudative findings or new hemorrhage detected by fundoscopy, such as increased intraretinal fluid, subretinal fluid, and subretinal pigment epithelium (RPE) fluid. In the current study, the scheduled treatment interval at 1 year was shortened to a minimum of 8 weeks and extended to a maximum of 20 weeks. Patients were excluded if complications such as intraocular inflammation (IOI) developed. Patients who did not respond to treatment and were switched to other anti-VEGF agents were also excluded. Nonresponders were defined by physicians as patients for whom IVT faricimab was deemed ineffective even at a minimum interval at any time during the study.

The endpoints were best-corrected visual acuity (BCVA), CMT, central choroidal thickness, number of IVT injections, the rate of dry macula at 1 year, and the regression of polyps evaluated at 1 year by ICGA. These endpoints were retrospectively evaluated 48 weeks after the initial treatment. CMT, the distance from the internal limiting membrane to the RPE at the fovea, and central choroidal thickness, the thickness between Bruch membrane and the inner surface of the choroidal-scleral junction at the fovea, were measured with a function included on OCT B-scan, which passes through the fovea.

Statistical analysis was conducted using the statistical programming language R (version 3.4.3, The R Foundation for Statistical Computing). The dry macula rate of patients with and without PCV was compared with Fisher exact tests, and χ^2 test was used to compare treatment intervals between patients with and without PCV. Paired-intergroup comparisons of BCVA, CMT, and central choroidal thickness were performed using the linear mixed model and Dunnett multiple comparison test. BCVA was analyzed after converting VA to logMAR units. $P < .05$ was considered statistically significant.

Table 1. Clinical Characteristics of Patients With Neovascular AMD.

Characteristic	Value
Patients (n)	46
Eyes (n)	48
Mean age (y) ± SD	76.8 ± 7.5
Sex, n (%)	
Male	24 (52.2)
Female	22 (47.8)
Lens status, n (%)	
Phakic	39 (81.3)
Pseudophakic	9 (18.7)
AMD subtype, n (%)	
Without PCV	35 (72.9)
With PCV	13 (27.1)
Mean baseline logMAR BCVA ± SD	0.39 ± 0.32
Mean baseline central foveal thickness (μm) ± SD	445 ± 233
Mean baseline central choroidal thickness (μm) ± SD	205 ± 98

Abbreviations: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PCV, polypoidal choroidal vasculopathy.

Results

Patient Characteristics

Of 54 patients enrolled in this study, 8 were excluded. One patient developed suspected IOI, 3 patients did not complete the follow-up period, and 4 patients (3 without PCV and 1 with PCV) were nonresponders and switched to other IVT injection medications within 1 year. Therefore, the 1-year follow-up was completed in 48 eyes of 46 patients (24 men, 22 women). The mean age was 76.8 ± 7.5 years (range, 55-89). Thirty-five patients (72.9%) did not have PCV while the remaining 13 patients (27.1%) did. Table 1 illustrates the demographics and baseline characteristics. Table 2 provides the exclusion details of the patients. Figure 1 describes the findings of the patient identified as a nonresponder to faricimab therapy.

Changes in BCVA

The mean logMAR BCVAs at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 0.39 ± 0.32, 0.34 ± 0.31, 0.32 ± 0.32, 0.32 ± 0.34, 0.32 ± 0.37, and 0.30 ± 0.37, respectively. Throughout the 12-month period, the BCVA improved significantly at 2, 4, 6, and 12 months after injection compared with the baseline but not at 1 month ($P = .125$, $P = .020$, $P = .024$, $P = .027$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 2).

Table 2. Details of the Excluded Patients.

Case	Age (y)	Sex	AMD Subtype	Reason for Exclusion	Details
1	87	Female	Without PCV	IOI	Floaters and vitreous opacity in the fundus after 2nd faricimab injection; suspicious for IOI
2	67	Male	With PCV	Nonresponder	Fluid persisted and CFT increased after 2nd faricimab injection; patient switched to brolucizimab
3	82	Female	Without PCV	Nonresponder	New SMH noted at week 30 after 5th injection; patient switched to brolucizimab
4	75	Male	Without PCV	Nonresponder	Decreased VA, increased fluid at week 29 after 5th injection; patient switched to brolucizimab
5	65	Male	Without PCV	Nonresponder	Fluid increased at week 26 after 4th injection; patient switched to aflibercept

Abbreviations: AMD, age-related macular degeneration; CFT, central foveal thickness; IOI, intraocular inflammation; PCV, polypoidal choroidal vasculopathy; SMH, submacular hemorrhage; VA, visual acuity.

The clinical courses of each disease subtype are shown in Figure 2. In patients without PCV, the mean logMAR BCVAs at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 0.42 ± 0.32, 0.37 ± 0.32, 0.35 ± 0.32, 0.36 ± 0.35, 0.37 ± 0.38, and 0.34 ± 0.38, respectively. The BCVA improved significantly after injection at 12 months compared with the baseline value but not at 1, 2, 4, and 6 months ($P = .384$, $P = .119$, $P = .255$, $P = .326$, and $P = .035$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 2). In patients with PCV, the mean logMAR BCVAs at baseline and 1, 2, 4, 6, and 12 months after initial treatment were 0.31 ± 0.35, 0.25 ± 0.27, 0.23 ± 0.30, 0.21 ± 0.32, 0.20 ± 0.32, and 0.19 ± 0.33, respectively. Throughout the follow-up period, the BCVA improved significantly after injection at 2, 4, 6, and 12 months, but not at 1 month, compared with the baseline ($P = .125$, $P = .020$, $P = .024$, $P = .027$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 2).

Changes in CFT and Central Choroidal Thickness

The mean CFTs of all patients at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 445 ± 233, 280 ± 123, 239 ± 103, 224 ± 98, 238 ± 114, and 232 ± 103 μm, respectively. The mean CFTs at 1, 2, 4, 6, and 12 months decreased significantly compared with the baseline ($P < .001$ for all) (Figure 3A). In patients without PCV, the mean CFTs at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 477 ± 259, 295 ± 136, 252 ± 115, 237 ± 110, 254 ± 128, and 242 ± 117 μm, respectively. The mean CFTs at 1, 2, 4, 6, and 12 months decreased significantly compared with baseline ($P < .001$ for all) (Figure 3A). In patients with PCV, the mean CFTs at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 359 ± 104, 240 ± 69, 203 ± 47, 187 ± 35, 196 ± 48, and 204 ± 45 μm, respectively. The mean CFTs through the follow-up period decreased significantly compared with baseline ($P < .001$ for all) (Figure 3A).

For all patients, the mean central choroidal thicknesses at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 205 ± 98, 193 ± 97, 185 ± 90, 176 ± 89, 183 ± 90, and 178 ± 91 μm, respectively. The mean central choroidal thickness decreased significantly at all subsequent timepoints compared with the baseline ($P = .001$, $P < .001$, $P < .001$, $P < .001$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 3B). In patients without PCV, the mean central choroidal thicknesses at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 196 ± 98, 183 ± 99, 175 ± 92, 166 ± 90, 173 ± 93, and 172 ± 93 μm, respectively. The mean central choroidal thicknesses decreased significantly at 1, 2, 4, 6, and 12 months compared with the baseline ($P = .006$, $P < .001$, $P < .001$, $P < .001$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 3B). In patients with PCV, the mean central choroidal thicknesses at baseline and 1, 2, 4, 6, and 12 months after the initial injection were 230 ± 96, 219 ± 92, 211 ± 84, 205 ± 80, 208 ± 79, and 196 ± 86 μm, respectively. The mean central choroidal thicknesses decreased significantly at 2, 4, 6, and 12 months, but not at 1 month, compared with the baseline ($P = .269$, $P = .017$, $P < .001$, $P = .004$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively) (Figure 3B).

Treatment Intervals and Polyp Regression at 1 Year

During the 1-year follow-up, the mean number of injections administered was 6.5 ± 1.0. Dry macula was achieved in 42 eyes (87.5%), and the mean treatment interval at 12 months was 14.5 ± 4.4 weeks. Thirty of 35 eyes (85.7%) in patients without PCV and 12 of 13 eyes (92.3%) in patients with PCV had dry macula, with no significant difference ($P = .999$). At 1 year, 9 patients (18.8%) were able to extend treatment intervals to 20 weeks or longer. Seventeen patients (35.4%) received injections in 16- to 19-week intervals. Seven patients (14.6%) continued injections every 12 to 15 weeks, 7 patients (14.6%) continued injections every 9 to 11 weeks, and the remaining 8 patients (16.7%) received injections every 8 weeks (Figure 4). There was no significant difference in the proportion of treatment intervals between patients without PCV and patients with PCV ($P = .580$). The proportion of patients with PCV who showed complete polyp regression on ICGA after 1 year was 76.9% (10/13 eyes).

Conclusions

In this study, we evaluated the functional and morphologic outcomes of IVT faricimab using a treat-and-extend regimen in

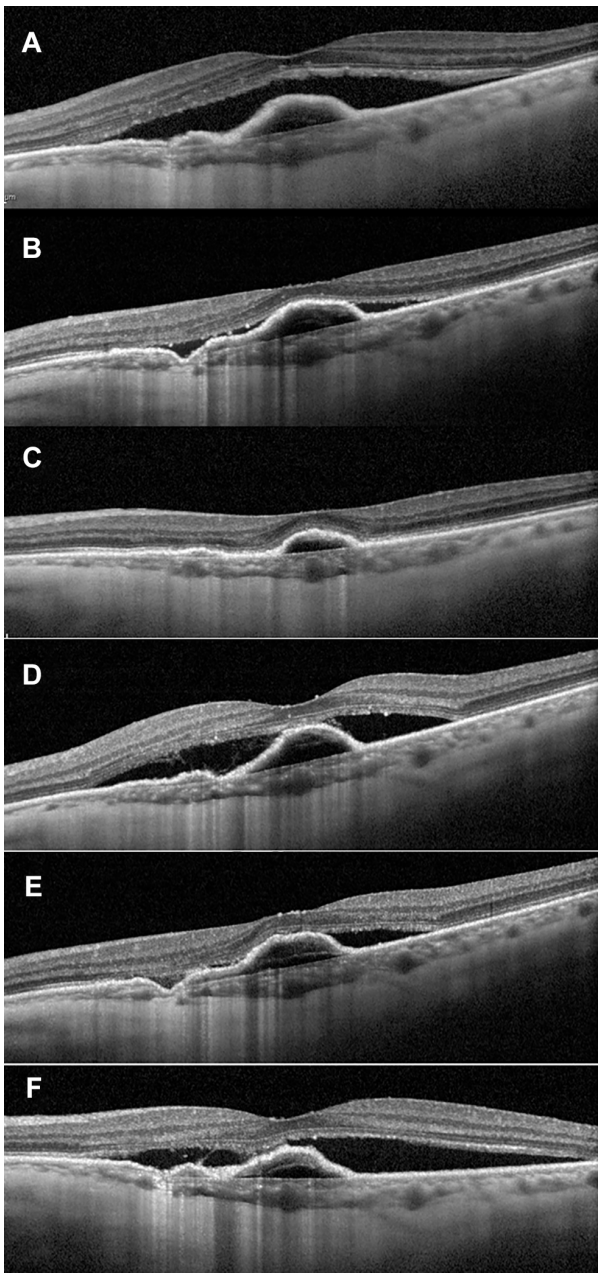

Figure 1. Optical coherence tomography (OCT) of a patient nonresponsive to faricimab therapy (Case 4 in Table 2). (A) Baseline OCT shows subretinal fluid (SRF) with type 1 macular neovascularization. The visual acuity (VA) was 20/32 OS when the initial faricimab injection was given. (B) Four weeks after the initial treatment, a decrease in SRF is seen, and a second faricimab injection is performed. (C) Eight weeks after the initial treatment, OCT shows regression of SRF, and a third injection is given. (D) SRF recurrence is seen 13 weeks after the initial treatment. The VA was still good at 20/20, and a fourth faricimab injection was performed with a treat-and-extend regimen. (E) At 21 weeks after the initial treatment, SRF appeared to improve, and a fifth faricimab injection is administered. (F) Twenty-nine weeks after the initial treatment, there is an increase in SRF and a decrease in VA to 20/32. At this time, the patient was switched to another antivascular endothelial growth factor agent.

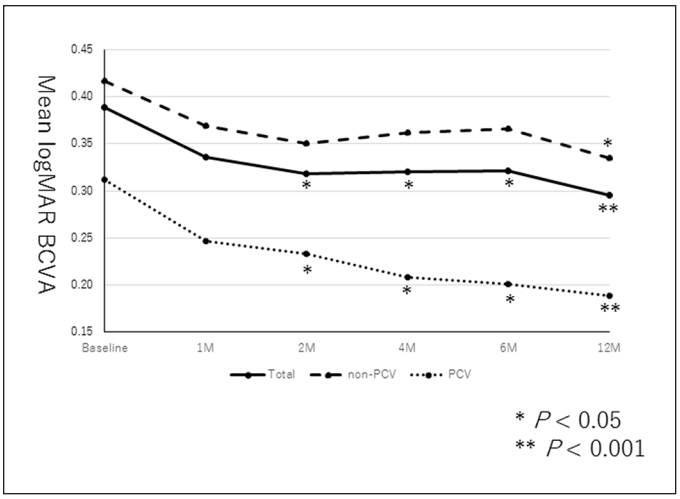

Figure 2. Changes in best-corrected visual acuity (BCVA) during the 12-month follow-up period. All cases show improvement in the mean BCVA at 2, 4, 6, and 12 months, but not at 1 month compared with the preoperative VA. In patients without polypoidal choroidal vasculopathy (PCV), the BCVA improved significantly after injection at 12 months compared with the baseline value but not at 1, 2, 4, and 6 months. In patients with PCV, the BCVA improved significantly after injection at 2, 4, 6, and 12 months, but not at 1 month, compared with the baseline.

patients with nAMD who completed 1 year of follow-up. The current results showed that the BCVA improved significantly during the 1-year follow-up period with a mean of 6.5 ± 1.0 injections. In addition, CFT and central choroidal thickness decreased significantly at 1 year. Our study confirmed that the treat-and-extend IVT faricimab regimen could be useful for the long-term treatment of nAMD.

Faricimab is a newly introduced anti-VEGF agent that was launched commercially after the TENAYA and LUCERNE studies, both of which were international phase 3 clinical trials.[5] The first bispecific antibody in the ophthalmology field, faricimab is an immunoglobulin G monoclonal antibody targeting both Ang2 and VEGF-A.[10] Overall, 46% of participants in TENAYA and 45% of participants in LUCERNE achieved 16-week dosing interval at 1 year. In addition, nearly 80% of participants treated in both studies were able to extend their treatment intervals at 1 year to beyond 12 weeks. In our study, 68.8% of patients could extend treatment intervals to 12 weeks, which was shorter than previous studies.[5] We speculate that the criteria to decide treatment intervals in our study might be stricter than TENAYA and LUCERNE, leading to this outcome. On the other hand, 54.2% of patients achieved intervals of more than 16 weeks with a high dry macula rate of 87.5%. Faricimab could help to extend treatment intervals and reduce the number of treatments, thereby decreasing the treatment burden for patients.

Ohji et al[11] reported on the 1-year results of the ALTAIR study, in which 123 treatment-naïve patients with nAMD were given aflibercept using a treat-and-extend regimen (2-week arm and 4-week arm). The mean BCVA in the 2-week arm improved

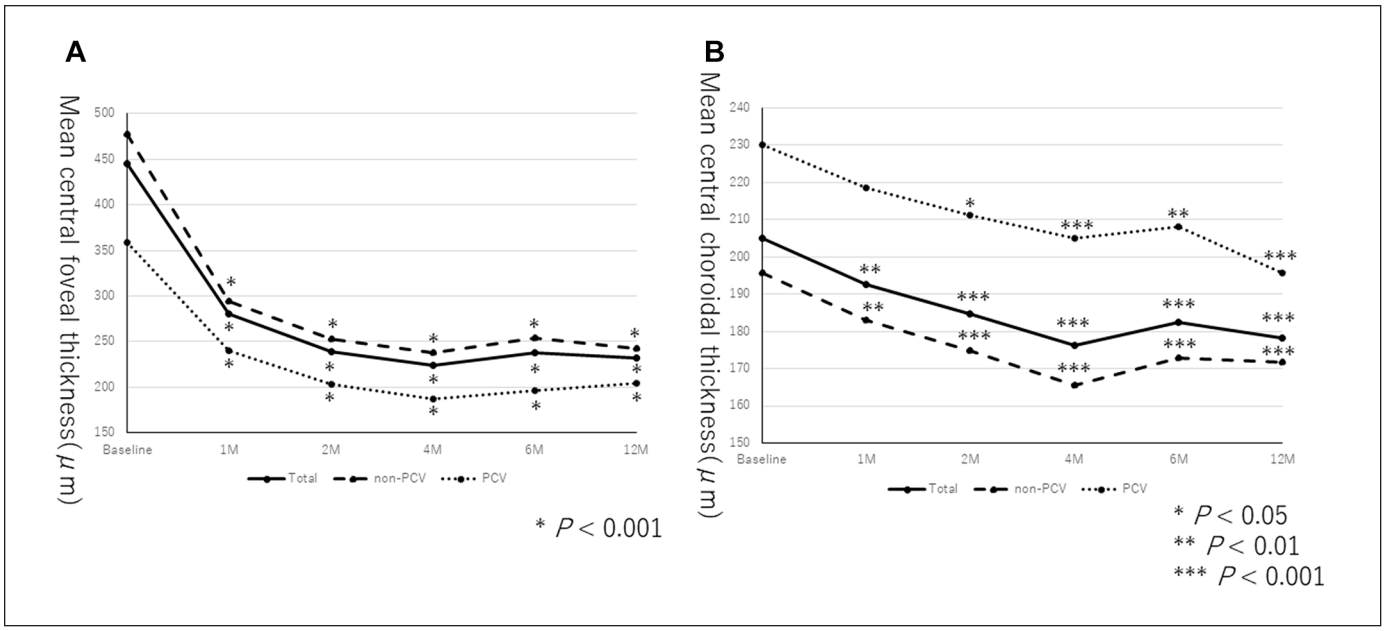

Figure 3. Changes in the central foveal thickness (CFT) and central choroidal thickness during the 12-month follow-up period. (A) In all cases and in each subtype of age-related macular degeneration, the mean CFT at 1, 2, 4, 6, and 12 months decreased significantly compared with those at baseline (all $P < .001$). (B) In all cases and in patients without polypoidal choroidal vasculopathy (PCV), the mean central choroidal thickness at 1, 2, 4, 6, and 12 months decreased significantly compared with baseline (all $P < .05$). In patients with PCV, central choroidal thickness decreased significantly compared with baseline 4, 6, and 12 months after injection but not at 1 and 2 months ($P = .999$, $P = .079$, $P = .004$, $P = .020$, and $P < .001$ at 1, 2, 4, 6, and 12 months, respectively).

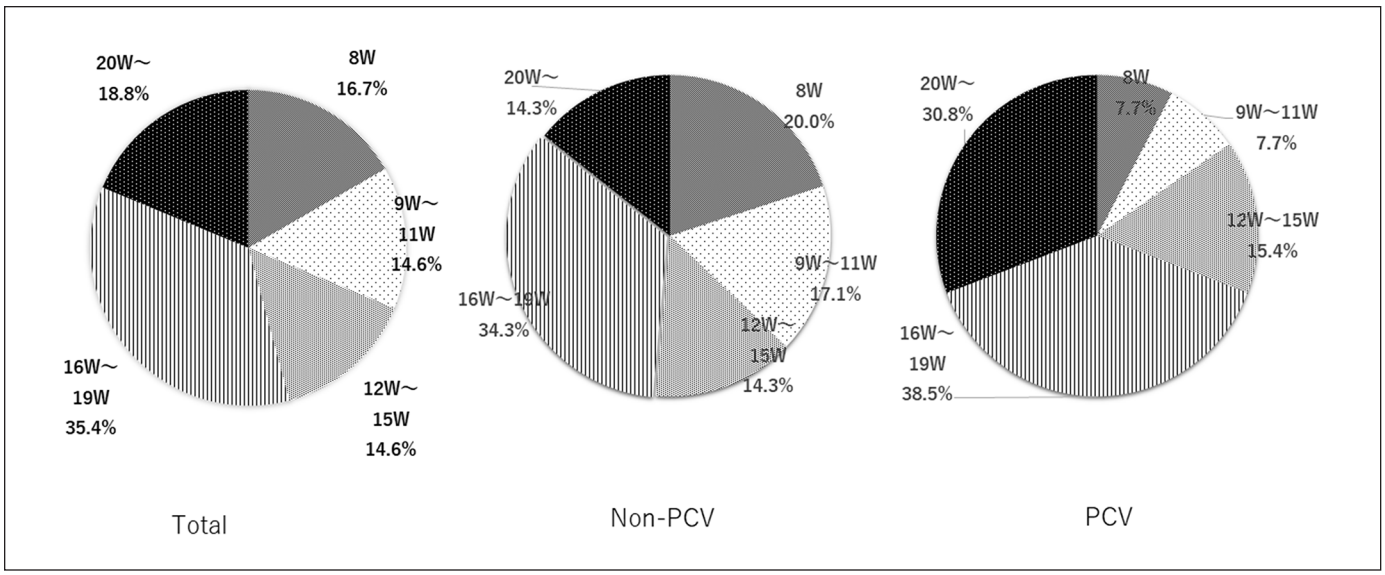

Figure 4. Proportion of treatment interval at 1 year. About 70% of patients could extend their treatment interval to more than 12 weeks. Five patients (14.3%) without polypoidal choroidal vasculopathy (PCV) were able to extend treatment intervals to 20 weeks or more. Twelve patients (34.3%) had treatment in 16- to 19-week intervals. Five patients (14.3%) received injections in 12- to 15-week intervals, 6 patients (17.1%) received injections in 9- to 11-week intervals, and the remaining 7 patients (20.0%) received injections every 8 weeks. Four patients (7.7%) with PCV were able to extend treatment intervals to 20 weeks or longer. Five patients (38.5%) received injections in 16- to 19-week intervals. Two patients (15.4%) received injections in 12- to 15-week intervals, 1 patient (7.7%) received injections in 9- to 11-week intervals, and the remaining patient (7.7%) received injections every 8 weeks.

by 9.0 letters and by 8.4 letters in the 4-week arm. The mean number of injections in the first year was 7.2 ± 6.9 and the mean last injection interval was 10.7 ± 11.8 weeks, respectively. Matsumoto et al[12] also reported 1-year results in 68 treatment-naïve patients with type 1 macular neovascularization treated with IVT brolucizumab using a treat-and-extend regimen, showing the mean number of injections of 6.4 ± 0.6 and the mean last injection interval of 14.0 ± 2.9 weeks.[12] In our current study, the mean number of injections administered was 6.5 ± 1.0 and the mean last interval was 14.5 ± 4.4 weeks. Although a direct comparison between our study and previous studies is difficult, favorable visual outcomes were found with faricimab, with longer intervals than aflibercept. The number of injections and treatment intervals for faricimab and brolucizumab were almost the same. However, there is a concern that treatment with brolucizumab carries the risk of developing IOI.[13]

Central choroidal thickness significantly decreased in the current study from 205 µm to 178 µm (13.2% decrease from baseline) at 1 year. We previously reported 1-year results in treatment-naïve patients with PCV given IVT brolucizumab, showing a mean central choroidal thickness decrease from 226 µm to 181 µm (19.9% decrease from baseline).[14] We also reported the comparison of faricimab and brolucizumab in the loading phase and described that greater changes in central choroidal thickness after IVT brolucizumab injection were seen at 1 year than those of faricimab for patients with nAMD, showing that faricimab might have less influence on central choroidal thickness than brolucizumab.[8] Choi et al[15] studied 88 patients with PCV who received anti-VEGF injections and reported that faster chorioretinal atrophy growth was significantly related to a thin choroid. Thinning of the choroid could influence chorioretinal atrophy in the longer term and might be related to adverse functional outcomes, especially if the fovea is involved. Therefore, it is necessary to consider whether choroidal thinning due to IVT faricimab may affect VA outcomes over a longer follow-up period.

In the current study, the rate of complete polyp regression at 12 months was 76.9%. In our previous study, bimonthly IVT injections of aflibercept monotherapy as treatment for PCV resulted in a 48.0% rate of complete polyp regression; patients prescribed an as-needed regimen reported a rate of 52.9%.[16] The rate of polyp regression in patients who received IVT brolucizumab, however, was between 73.9% and 93.3%.[12,14] The rate of polyp regression with IVT faricimab was higher than aflibercept monotherapy and comparable to brolucizumab. An Ang2 inhibitor, faricimab may potentially restore the weak vessel polyp walls, resulting in patients with PCV having higher rates of regression and better functional outcomes with less frequency compared with patients without PCV. Therefore, faricimab could be an optimal treatment option in patients with nAMD both with and without PCV.

In this study, vitritis was observed in 1 of 56 eyes (1.8%), which could have been a case of suspected IOI. Brolucizumab-related IOI is one of the major adverse events of IVT treatment according to the HAWK and HARRIER study (4.6%).[17] According to the TENAYA and LUCERNE[18] data, however, the incidence of IOI in faricimab-treated patients was 1.6% in the subgroup of Asian patients and 2.0% in the subgroup of non-Asian patients, which is consistent with our study. Although IOI after treatment with IVT faricimab is rare, the occurrence is possible, and prompt treatment is required. In addition, 4 of 56 eyes (7.1%), 3 without PCV and 1 with PCV, had no response to IVT faricimab and were switched to other anti-VEGF agents, raising the awareness that not all patients respond well to faricimab.

This study has some limitations, including its retrospective design and small sample. A large-scale randomized study with a longer follow-up period is needed to confirm our results, as the long-term outcomes beyond 1 year are unknown. In addition, 4 patients who were nonresponders were excluded and switched to other IVT agents within 1 year. There is a possibility that the mean interval dosing would have been reduced if these 4 eyes were treated with faricimab.

In conclusion, IVT faricimab effectively improved the functional and morphologic outcomes in patients with nAMD over a 1-year follow-up period, in addition to a high rate of resolution of polypoidal lesions as seen on ICGA. These results suggest that faricimab could be useful for the treatment of nAMD, including PCV, but with less treatment burden.

Ethical Approval

The ethics committee of Yokohama City University Medical Center approved the study.

Statement of Informed Consent

All patients provided written informed consent.

Conflict of Interest

All authors declare no conflict of interest.

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