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Real-World Evidence for Faricimab in Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema: A Scoping Review

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Purpose: Since faricimab (Vabysmo) was approved for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME), a growing body of real-world data has been reported, forming an important source of evidence for faricimab in a heterogeneous population. Scoping reviews are an effective approach to comprehensively assess the state of evidence on areas yet to be well characterized, allowing for the inclusion of a wide range of study designs and methodologies. This scoping review aimed to assess the current breadth and nature of real-world evidence (RWE) for faricimab and describe its safety and effectiveness in routine clinical practice.

Design: Scoping review of published articles and grey literature.

Participants: Eligible records included primary research reporting on any real-world data from ≥5 participants treated with faricimab in its licensed indications, published in English since 2022. This review did not involve novel data collection in human participants.

Methods: MEDLINE, Embase, and the Cochrane Database of Systematic Reviews were searched on February 16, 2024, and the results were reviewed by 2 independent reviewers. Manual searches of proceedings from major relevant conferences, ClinicalTrials.gov, and bibliographies of relevant systematic literature reviews were also conducted. Findings were summarized descriptively.

Main Outcome Measures: Data of interest included study design, population characteristics, treatment history, visual function and anatomic outcomes, patient-reported outcomes, safety, and economic outcomes.

Results: A total of 63 studies reporting RWE for faricimab in patients with nAMD or DME (n = 6–12 119 eyes) were identified, including a majority of studies in previously treated patients. Studies spanned 10 countries, with a predominance of retrospective observational studies. Results across the majority of studies suggested that faricimab was associated with improved visual acuity, reduced central choroidal/subfield macular thickness, and reduced/resolved retinal fluid and pigment epithelial detachment in both conditions, even over longer study periods (≥6 months). Adverse events reported were similar to the findings within the registration trials.

Conclusions: Outcomes of faricimab in routine practice align with reports from clinical trials, supporting the effectiveness and safety of faricimab in heterogeneous populations. Further high-quality studies using prospective, multicenter designs are required to provide a more comprehensive understanding of the long-term outcomes associated with faricimab.

Financial Disclosure(s): Proprietary or commercial disclosure may be found in the Footnotes and Disclosures at the end of this article.

Supplemental material available at www.ophthalmologyscience.org.

Intravitreal anti-VEGF monotherapies have been considered the standard of care for patients with neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). However, these treatments have historically required frequent injections, resulting in a marked treatment burden for patients, caregivers, and clinicians.[1–3] Long-term effectiveness results reported in clinical practice are heterogeneous, and while some studies have demonstrated successful maintenance of visual outcomes with anti-VEGFs, this is often contingent on sustained short treatment intervals (<8 weeks) throughout the treatment.[4–6] Long-term follow-up of patients treated with anti-VEGFs in clinical practice indicates that, in some cohorts, close to a third of the patients require injections at least every 8 weeks, and 40% of the patients discontinue treatment by 2 years.[2,7] Many patients on the maximum dosage regimens

https://doi.org/10.1016/j.xops.2025.100744
ISSN 2666-9145/25

(i.e., every 4–6 weeks) may show suboptimal or diminishing responses, while others may be refractory to anti-VEGF treatments or show persistent macular edema.[8,9]

Research has suggested that treatments that simultaneously target both the VEGF and angiopoietin-2 pathways may provide greater effectiveness and benefits to patients. Specifically, the additional inhibition of angiopoietin-2 may further stabilize blood vessels in the retina, leading to increased durability that potentially reduces the likelihood of undesirable effects and mitigates the high treatment burden placed on patients.[2,4,10] Faricimab (Vabysmo), developed by Roche (F. Hoffmann-La Roche AG), is the first bispecific antibody to simultaneously target both the VEGF and angiopoietin-2 pathways.[11] The efficacy of faricimab has been demonstrated across pivotal phase III randomized controlled trials,[12,13] including improved best-corrected visual acuity (VA) and reduced central subfield macular thickness (CST) in populations with nAMD (TENAYA and LUCERNE trials) and DME (YOSEMITE and RHINE trials).[14,15] Moreover, 59% to 63%/56% to 62% of DME patients treated with faricimab every 8 weeks achieved absence of intraretinal fluid (IRF) at weeks 92 to 100 (YOSEMITE and RHINE trials, respectively).[15] Faricimab further demonstrated strong durability, with the majority of patients achieving 16-week dosing intervals at week 112 in the TENAYA and LUCERNE (nAMD) trials and at week 96 in the YOSEMITE and RHINE (DME) trials.[14,15] Across these trials, >59% of patients were able to achieve a dosing interval of every 16 weeks while achieving and maintaining visual and anatomical improvements.[14,15] In addition to nAMD and DME, the effectiveness, safety, and durability of faricimab have also been demonstrated in patients with macular edema secondary to retinal vein occlusion (RVO) in the BALATON and COMINO phase III randomized controlled trials.[16,17]

Given the accumulating body of real-world evidence (RWE) reported since its approval in different geographies, synthesizing these results in a scoping review is important to evaluate the safety and effectiveness of faricimab in clinical practice for a more heterogeneous patient population. Scoping reviews are an effective methodology to assess the state of evidence on a particular evidence gap[18] and have grown in volume and popularity in recent years across a number of research topics and indications in ophthalmology.[19–22] Unlike systematic literature reviews, which are designed to answer precisely designed research questions, scoping reviews are broader and more flexible in nature, allowing for the inclusion of a wide range of study designs and methodologies, thus providing a comprehensive overview of available evidence.[23] The purpose of this scoping review was to assess the volume and nature of all RWE for faricimab and to describe the safety and effectiveness of faricimab in the clinical setting.

Methods

The current scoping review was performed according to a prespecified protocol (see Supplementary Material 1, available at www.ophthalmologyscience.org) and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Scoping Reviews reporting guidelines,[24] as well as the methodological recommendations for the design and conduct of scoping reviews as described by Arksey and O'Malley and the Joanna Briggs Institute.[18,25] Eligibility criteria to guide the screening and selection of relevant studies were designed around the "Population, Concept, Context" approach recommended for scoping reviews, wherein the population, interventions and outcomes (concepts), and clinical settings (contexts) of interest were clearly identified in order to guide the extraction of data in alignment with the objectives of the scoping review.[25] Full details of the search methodology are provided in the Supplementary Material 1.

Eligibility Criteria

Eligibility criteria for the scoping review are provided in Table S1 (available at www.ophthalmologyscience.org). Briefly, eligible records included primary research in peer-reviewed journals or grey literature that reported RWE on ≥5 participants treated with faricimab for nAMD, DME, or macular edema, after RVO. All searches were restricted to articles published in English, and the date was limited to January 2022 onward, reflecting the year in which faricimab was first approved for medical use in the United States and European Union, as no relevant studies of real-world data were expected to be present before this date.[26,27]

Search Methods and Study Selection

The following electronic databases were searched on February 16, 2024, to identify relevant published literature: MEDLINE (including MEDLINE In-Process, MEDLINE Daily, and MEDLINE Epub Ahead of Print), Embase, and the Cochrane Database of Systematic Reviews (searched via the Cochrane Library). Search terms included combinations of free text and medical subject headings/Emtree terms for faricimab, including trade names and other product terms. Full search terms used in the MEDLINE, Embase, and Cochrane Database of Systematic Reviews electronic databases are provided in Tables S2 and S3 (available at www.ophthalmologyscience.org). MEDLINE and Embase were searched simultaneously via the OVID SP platform, and the in-built deduplication functionality was used to identify unique references, with further manual exclusion of any remaining duplicates across the 3 databases. Records identified in the electronic database searches were then reviewed against the eligibility criteria by 2 independent reviewers.

Additional manual searches included reviewing of the bibliographies of all relevant systematic literature reviews and meta-analyses identified from the electronic database searches described above, as well as searches of proceedings from 5 relevant major conferences held in 2022 and 2023 (Table S4, available at www.ophthalmologyscience.org). ClinicalTrials.gov was additionally searched for any observational studies or patient registries involving patients treated with faricimab (Table S5, available at www.ophthalmologyscience.org).

Data Collection and Synthesis

Included publications that reported on the same study were linked to avoid double counting and to ensure that the latest available follow-up timepoints were captured. For each study, key information was extracted into a prespecified data grid by a single individual and independently verified by a second individual. A full list of extracted information is presented in the Supplementary Material 1. Given the exploratory and descriptive nature of the scoping review, no quality or risk of bias assessments were carried out, and pooled synthesis of treatment outcomes or data

dispersion patterns were not conducted.[25] As studies differed in their reported point estimates (i.e., mean, median, change from baseline value) for each outcome, pooled point estimates are reported in text with the corresponding study-specific point estimate reported in Tables S6 – S10 (available at www.ophthalmologyscience.org).

Ethics Statement

Only aggregate data from published literature were analyzed; therefore, ethics approval or informed consent was not necessary, in adherence to the Declaration of Helsinki.

Results

Searches and Screening

After duplicate results were removed, 274 unique records were identified through electronic database searches, of which 37 were found to fulfill the eligibility criteria. An additional 39 records were included from the supplementary searches, yielding a total of 76 articles reporting on 63 unique studies eligible for inclusion in the scoping review (Fig 1).[28–50,51–89] A list of records excluded at the full-text review stage of the database searches, including a brief rationale for exclusion, is detailed in Table S11 (available at www.ophthalmologyscience.org).

Of the 76 articles identified, 22 (29%) were peer-reviewed journal articles and 54 (71%) were conference abstracts (30 presented at the European Society of Retina Specialists, 14 at the Association for Research in Vision and Ophthalmology, 6 at the Asia-Pacific Vitreo-retina Society, 2 at the American Academy of Ophthalmology, 1 at the American Society of Retina Specialists, and 1 at the European Association for Diabetic Eye Complications). Five records (7%) were published or presented in 2022, 65 (85%) in 2023, and 6 (8%) in 2024 (at the time of searches in February 2024). A description of the study and population characteristics for the included studies is presented in Table S12 (available at www.ophthalmologyscience.org).

Overview of Included Studies

The geographic distribution of the studies included in this scoping review is displayed in Figure 2A. Studies captured in the scoping review were primarily conducted in the United Kingdom (n = 22 studies, 35%), United States (n = 16, 26%), Japan (n = 13, 21%), Switzerland (n = 3, 5%), United Arab Emirates (n = 2, 3%), and Germany (n = 2, 3%), as well as Taiwan, Singapore, Malaysia, and Australia (n = 1 study each, 2%). One multicountry study was included.[65]

Most of the included studies used a retrospective design, including 53 studies (84%) of patient health records and 3 studies (5%) conducted using patient registries (IRIS Registry [Intelligent Research in Sight] and Fight Retinal Blindness! Registry). Seven studies (11%) involved investigator-led prospective data collection. Single-site studies comprised the majority of evidence (n = 50 studies, 79%); there were 11 multicenter studies (17%) and 2 studies (3%) where the site setting was unclear. Sample sizes ranged from 6 to 12 119 eyes and from 5 to 10 551 patients; 38 studies (60%) reported on populations of ≤100 eyes (Fig 2B). Duration of follow-up was reported by time (days/weeks/months), ranging between 1 and 12 months (n = 48 studies); or by number of injections, with an average of 1 to 5 injections (n = 17 studies) (Figure S3, (available at www.ophthalmologyscience.org). Seven studies (11%) used a comparative design, of which 5 (8%) and 2 (3%) studies included comparator groups receiving aflibercept and brolucizumab, respectively, and 1 study (2%) provided a comparison against untreated eyes.[37,38,48,49,54,59,83]

Of the 63 studies included in the scoping review, 41 (65%) were conducted specifically in patients with nAMD, 13 (21%) in patients with DME, and 9 (14%) included a mixed population of patients with nAMD and DME (Fig 2C). No studies were identified for faricimab use in clinical practice in patients with macular edema secondary to RVO.

Population baseline characteristics and treatment outcomes, stratified by indication, are summarized below, highlighting key data from studies presenting long-term follow-up of ≥6 months. Full details of data extracted from each of the included studies, including those that did not report outcome data separately for nAMD and DME subgroups, are available in Tables S6–S10, S12, and S13 and Figures S4 to S10 (available at www.ophthalmologyscience.org).

Populations and Outcomes in Studies of Patients with nAMD

Study Population and Baseline Characteristics. Of the 41 studies conducted specifically in patients with nAMD, 26 (63%) reported results from previously treated patients, 7 (17%) on treatment-naïve patients, and 8 (20%) on both treatment-naïve and previously treated patients (Fig 2C). The mean age of patients ranged between 65 and 83 years (n = 37 studies), and the proportion of females ranged between 32% and 63% (n = 32 studies). Baseline characteristics for the 9 other studies that included patients with nAMD as part of a wider mixed population are described in Table S12.

Treatment Patterns. Patients with nAMD switching to faricimab had most frequently been treated with aflibercept (n = 26 studies, 63%) and ranibizumab (n = 18 studies, 44%). Sixteen studies reported on treatment patterns with faricimab (Table S13), including 9 studies that provided data on the number of faricimab injections and 12 studies that provided data on the treatment interval. Comparative data prior to and after switching to faricimab were reported in 7 studies on previously treated patients, all of which reported numerical increases in the mean injection interval after initiation of faricimab, with mean faricimab injection intervals ranging between 6.1 and 10.4 weeks.

Treatment Outcomes. *VA Outcomes.* The majority of studies (n = 33, 89%) reported numerical improvements in VA between the initiation of faricimab and follow-up (Table S6). In 3 studies assessing outcomes over the long term (≥6 months), all in previously treated patients, mean

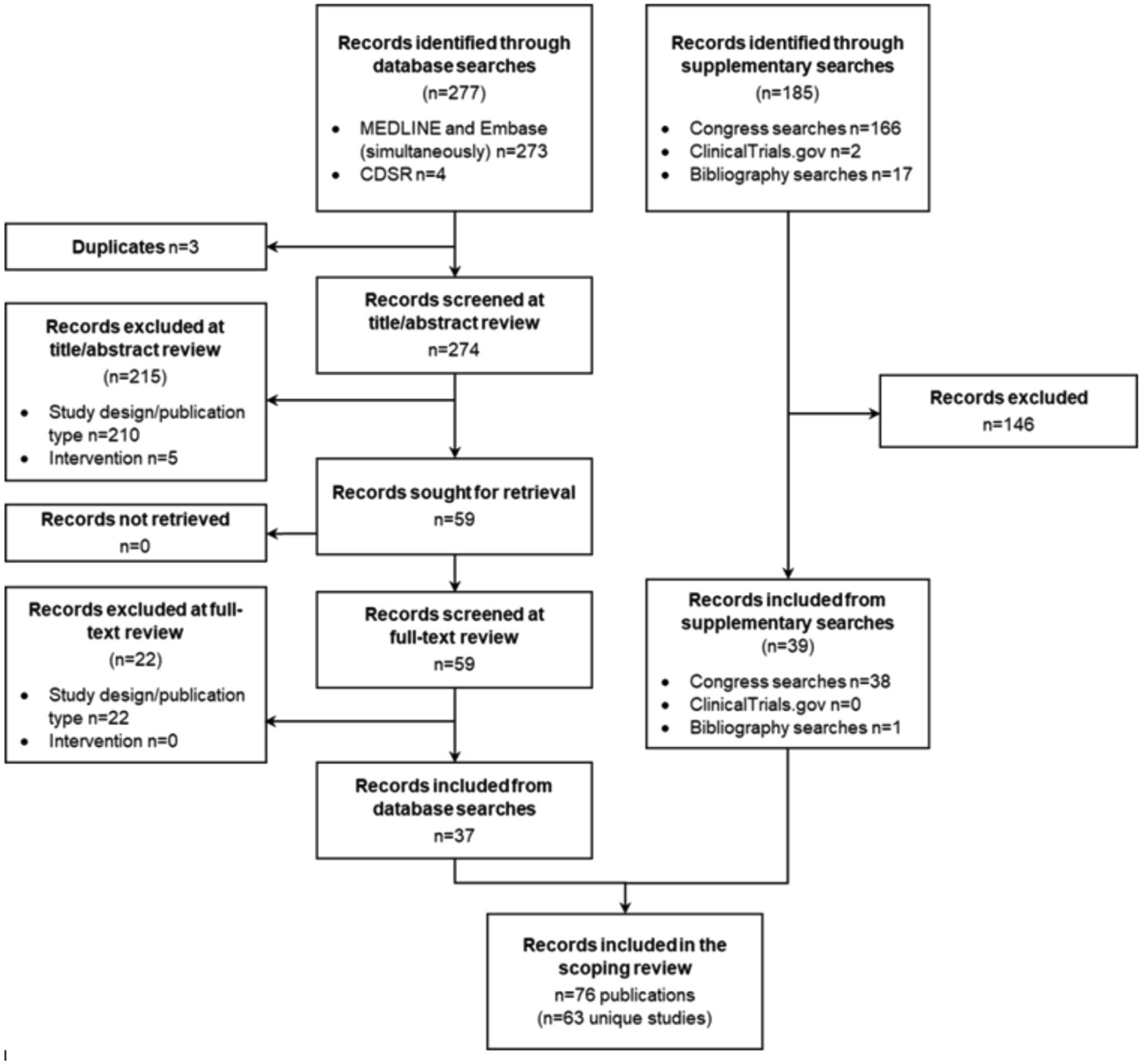

Figure 1. PRISMA diagram. CDSR = Cochrane Database of Systematic Reviews; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

best-corrected VA improved in the range of 0.06 to 0.07 logarithm of the minimum angle of resolution[35,36] and 2.87 letters.[33]

Central Subfield Macular Thickness Outcomes. A total of 16 studies (89%) reported numerical reductions in CST after initiation of treatment with faricimab (Table S7). In 2 studies that presented long-term outcomes, mean CST improved by 25 μm over 6 months in a population of previously treated patients,[36] and by 63.6 μm after the sixth faricimab injection in patients with a mixed treatment history.[33]

Retinal Fluid Outcomes. A total of 25 studies in nAMD populations reported findings on retinal fluid presence/absence or levels, of which 23 (92%) studies reported reductions in IRF, subretinal fluid, and subretinal pigment epithelium fluid in patients, after treatment with faricimab (Table S8). In 2 studies of previously treated patients who reported outcomes at 6 months post-faricimab intervention, IRF reduced in the range of 33.3% to 69.2% and subretinal fluid reduced in the range of 33.4% to 58.3%.[36,60]

Pigment Epithelial Detachment Outcomes. Baseline data for pigment epithelial detachment (PED) were provided in 13 studies of patients with nAMD, all of which reported reduced PED height or PED resolution in patients post-faricimab treatment (Table S9). The percentage of eyes with reduced PED ranged from 4.2% to 57.4% after faricimab treatment. In studies assessing long-term outcomes (≥6 months), 1 study of previously treated patients reported the percentage of eyes with PED to be reduced by

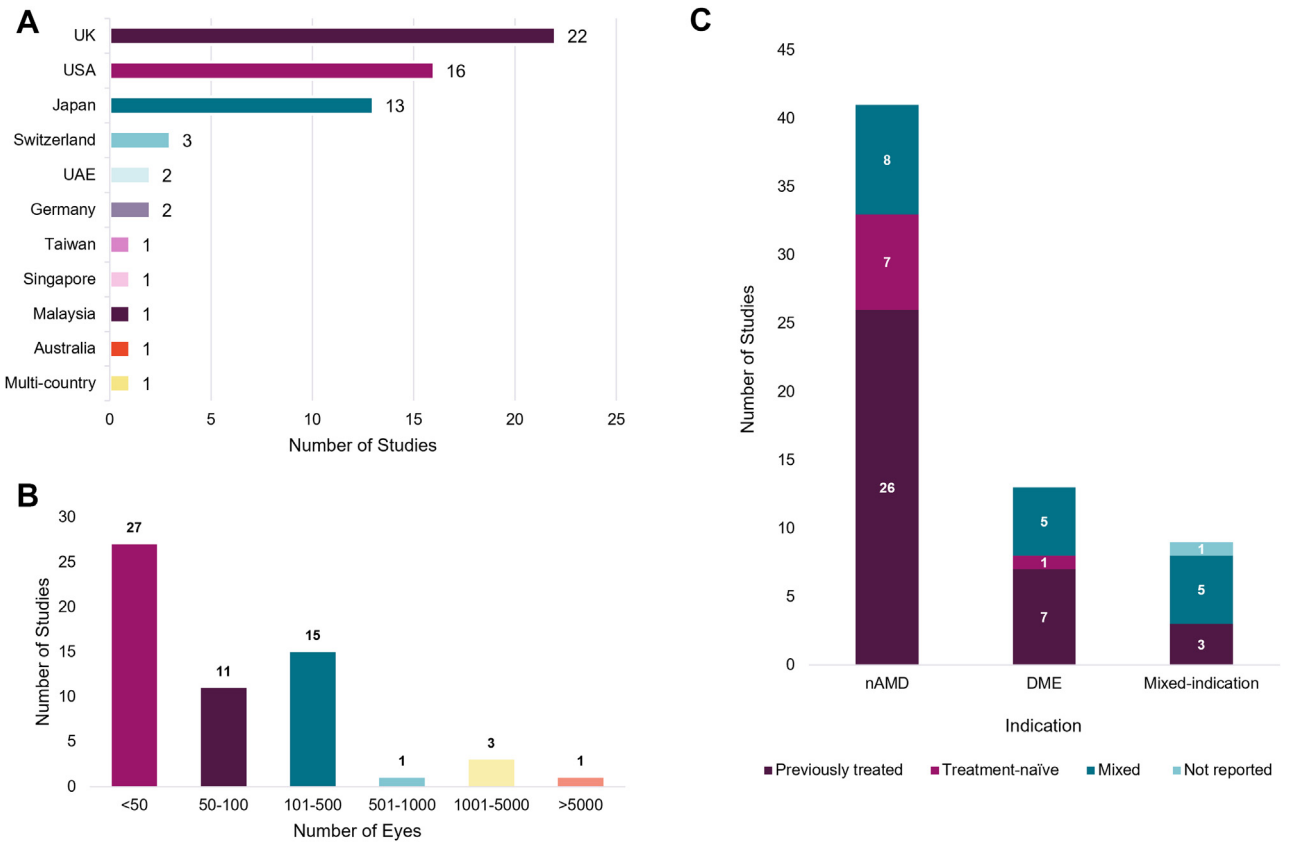

Figure 2. Distribution of studies included in the scoping review by **(A)** geography, **(B)** sample size, and **(C)** indication and treatment history. UAE = United Arab Emirates; UK = United Kingdom; USA = United States of America.

6.2% at 6 months post-faricimab intervention,[60] while 2 other studies of previously treated and mixed treatment history patients found reductions in mean PED height in the range of 73.8 to 74.4 μm at 6 months after faricimab intervention.[33,43]

Populations and Outcomes in Studies of Patients with DME

Study Population and Baseline Characteristics. Of the 63 studies included in the scoping review, 13 (21%) included solely patients with DME, of which 6 studies reported results from previously treated patients, 1 study reported results in treatment-naïve patients, and 6 studies reported populations with mixed treatment history. The mean age of patients ranged between 60 and 70 years (n = 13 studies) and the proportion of women ranged between 33% and 58% (n = 10 studies).

Baseline characteristics for the other 9 studies that included patients with DME as part of a wider population are described in Table S12.

Treatment Patterns. Among patients with DME switching to faricimab, the most commonly used prior treatments were aflibercept (n = 10 studies, 77%) and ranibizumab (n = 5 studies, 38%). Seven studies reported treatment patterns after initiation of faricimab, of which 1 reported on the length of the injection intervals (Table S13). In this study of previously treated eyes, an injection interval of ≥8 weeks was achieved in 4.3% versus 23% of participants prior to and after initiation of faricimab, respectively.[58]

Treatment Outcomes. *VA Outcomes.* Of the 10 studies reporting VA outcomes in patients with DME treated with faricimab, the majority (n = 8, 80%) reported numerical improvements in VA between baseline and follow-up assessments after initiation of faricimab (Table S6). In studies assessing outcomes over the long term (≥6 months), 1 study in a cohort with a mixed treatment history reported best-corrected VA logarithm of the minimum angle of resolution to improve by 0.01 at 6 months after faricimab intervention.[35]

Central Subfield Macular Thickness Outcomes. Of the 5 studies reporting CST in DME patients, 4 (80%) reported numerical reductions in CST after faricimab intervention (Table S7).

Retinal Fluid Outcomes. One study of previously treated patients that reported retinal fluid results at baseline and at follow-up after 3 injections of faricimab reported a reduced proportion of eyes with IRF and no change in the proportion with subretinal fluid (Table S8).[58]

Safety Outcomes

The safety outcomes reported are summarized in Table S10. Overall, 36 studies reported safety outcomes after injection

of faricimab across both nAMD and DME populations, of which 24 (66%) reported on patients with nAMD, 7 (19%) reported on patients with DME, and 5 (14%) reported on mixed population cohorts (n = 5−1222 patients, n = 11−1537 eyes). Six studies (17%) reported on the long-term safety follow-up at ≥6 months.[32,35,36,43,60,67]

Of the 36 studies, 21 (58%) reported no adverse events over the course of follow-up, including 3 studies that had a specific focus on reporting serious adverse events. In the remaining 15 studies, adverse events were infrequent, with the highest reported overall rate of 3% of the total cohort.[85] The most commonly reported ocular adverse events included intraocular inflammation, hemorrhagic events, retinal pigment epithelium tears, and endophthalmitis/presumed endophthalmitis. Systemic adverse events were rare.[35,59]

Discussion

The current scoping review identified rapidly growing RWE for faricimab, with 63 studies (n = 6−12 119 eyes) published since 2022 across Asia, Europe, North America, and Australia. The majority of RWE included congress abstracts presented in 2023, the year after the approval of faricimab for nAMD and DME. The vast majority of studies were single-center chart reviews of patient health records, with a small number of multicenter investigator-led data collection and patient registry studies. There were twice as many studies on faricimab in nAMD than in DME. In both indications, a majority of previously treated patients switching from aflibercept or ranibizumab were included.

Across both populations, studies reported VA, CST, retinal fluid, and PED endpoints most frequently, in that order. Of the studies recording multiple follow-ups, improvements in visual and anatomical endpoints were reported as early as 1 month after initiation of faricimab. In studies of previously treated individuals who switched to faricimab, increased durability was reported for up to the first year of faricimab treatment. Most studies reported no adverse or serious adverse events associated with faricimab over the study period.

Results from this scoping review support the safety and effectiveness of faricimab in nAMD and DME across heterogeneous patient populations. The results also add to the overall body of evidence for faricimab and are aligned with the efficacy and safety results of the phase III clinical trial program for faricimab.[90,91] Findings from clinical practice further support the effectiveness, durability, and safety of faricimab in clinical practice by synthesizing evidence (1) from heterogeneous populations across various countries; (2) employing broader inclusion and exclusion criteria compared to randomized controlled trials; (3) including a greater proportion of previously treated patients; and (4) measuring endpoints at different treatment lengths and follow-up times.

As is common across RWE, heterogeneity in clinical populations can impact study findings; therefore, documenting and accounting for confounding variables is integral to RWE study designs. The variability in study endpoints and relatively short follow-up time (typically <6 months) affected the comparability of effects in this review. Most studies did not report the presence of comorbidities, full treatment history, or disease duration.[31,44,54,58] Additional effects of prolonged disease, single-clinician managed cohorts, concomitant medications, and variable treatment histories could further impact the effects of faricimab and differences in the management of cases reported across studies. Although no RWE studies were identified in patients with macular edema secondary to RVO, due to the more recent approval of faricimab in this population, it is expected that the literature on this indication will increase as real-world data are collected and analyzed.

Strengths and Limitations of the Review

Scoping reviews, by nature, form an important methodology for evidence synthesis and are highly suitable to identify key gaps in the evidence.[18] In the field of ophthalmology, scoping reviews are commonly used to collect and synthesize evidence on a broad range of topics, from understanding ophthalmic disease mechanisms[92] and drug-associated adverse events[19] to informing decision and policymaking[20,21] and models of care.[22] The scoping review methodology, given its flexibility, can be used to evaluate a broad range of topics, populations, and reproducible methodological approaches in the study search, selection, and extraction. Moreover, the broad coverage of published and grey literature, with no restrictions on study outcomes, allowed for the capture of a large number of relevant studies regarding clinical and patient-reported outcomes from RWE for faricimab across multiple populations and follow-up timepoints.

A number of limitations inherent to the nature and aims of the scoping review methodology should be acknowledged. First, since the objective of this study was to assess the state of evidence on faricimab in routine practice, studies were not prioritized or stratified by quality or strength of evidence using standard risk of bias assessment tools. Second, pooled synthesis of data, dispersion and spread of data, and analyses of statistical significance were beyond the scope of the review and, as such, only numerical trends and point estimates could be described. Finally, an important limitation remains that the data from conference abstracts that were included may not have undergone peer review to the level of published studies, may be incomplete, or present only a partial picture of the characteristics and outcomes of faricimab in nAMD and DME.

Future Perspectives

The results of this scoping review complement recent reviews showcasing the growing body of RWE characterizing the use of faricimab in clinical practice and the consistency of results supporting the safety, durability, and effectiveness of faricimab across published studies.[93−96] The current scoping review echoes findings from these reviews for stable visual outcomes and reduced treatment burden after faricimab intervention in nAMD and DME, based on findings from a larger evidence base. It is expected that studies

recruiting a larger number of patients over longer durations will emerge in the coming years as patients are maintained on faricimab; these will be critical in characterizing the long-term effectiveness and durability of faricimab.

Retrospective medical chart reviews largely contributed to the initial body of RWE for faricimab. It is important for future studies to examine a variety of real-world data sources, such as claims and electronic health record data, to provide convergent evidence from large samples for the safety and effectiveness of faricimab in nAMD and DME. It is also important that future RWE studies leverage prospective designs to further profile the safety and effectiveness of faricimab in clinical settings.

Acknowledgments

The authors wish to acknowledge Manya Mirchandani, Siddharth Ramanan, and Declan Summers of Costello Medical (Cambridge, United Kingdom), who assisted with study design, data collection, interpretation and analysis, and manuscript development.

Footnotes and Disclosures

Originally received: August 26, 2024.
Final revision: February 13, 2025.
Accepted: February 14, 2025.
Available online: February 21, 2025. Manuscript no. XOPS-D-24-00325.

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Disclosure(s):

All authors have completed and submitted the ICMJE disclosures form.

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R.G.: Advisory board member − Apellis, Roche, Genentech, Bayer, Novartis, Belite Bio, Ocular Therapeutix, Complement Therapeutics, Boehringer Ingelheim Pharmaceuticals, Character Bioscience, Janssen, AbbVie, Astellas; Consultant − Apellis, Roche, Genentech, Bayer, Novartis, Belite Bio, Janssen, AbbVie, Astellas (payment to author); Honoraria − Apellis, Roche (payment to author); Travel expenses − Bayer.

A.A.: Employee − Costello Medical Ltd.

R.P.S.: Grants − Jannsen; Consultant − Apellis, Iveric Bio, An Astellas Company, Ocular Therapeutix, Eyepoint, Regenxbio, Genentech, Bausch and Lomb, Zeiss, Alcon, Regeneron.

A.D.: Employee − F. Hoffmann-La Roche Ltd.

V.C.: Advisory board member − Alcon, Roche, Bayer, Novartis, Apellis, Boehringer Ingelheim; Grants − Bayer, Novartis, Roche.

This study was supported by F. Hoffmann-La Roche AG. F. Hoffmann-La Roche AG participated in the study design, review, and approval of the manuscript.

Support for Open Access publication was provided by F. Hoffmann-La Roche AG.

HUMAN SUBJECTS: No human subjects were included in this study. Only aggregate data from published literature were analyzed; therefore, ethics approval or informed consent was not necessary, in adherence to the Declaration of Helsinki.

No animal subjects were included in this study.

Author Contributions:

Conception and design: Chaudhary, Guymer, Artignan, Downey, Singh

Data collection: Artignan

Analysis and interpretation: Chaudhary, Guymer, Artignan, Downey, Singh

Obtained funding: Downey

Overall responsibility: Chaudhary, Guymer, Artignan, Downey, Singh

Abbreviations and Acronyms:
CST = central subfield macular thickness; **DME** = diabetic macular edema; **IRF** = intraretinal fluid; **nAMD** = neovascular age-related macular degeneration; **PED** = pigment epithelial detachment; **RVO** = retinal vein occlusion; **RWE** = real-world evidence; **VA** = visual acuity.

Keywords:
Faricimab, Age-related macular degeneration, Diabetic retinopathy, Real-world data.

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