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Review Article

Consensus of Expert Recommendations for the Safe Administration of Brolucizumab in Neovascular Age-related Macular Degeneration

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Brolucizumab offers improved anatomical outcomes and extended dosing intervals compared to aflibercept, reducing treatment burden. However, postmarketing surveillance and real-world studies have highlighted safety concerns, including intraocular inflammation (IOI), retinal vasculitis, and retinal vascular occlusion, necessitating risk management strategies. To address these concerns, a comprehensive review of clinical trials, real-world data, and safety reports were conducted by an expert panel. This consensus report offers practical, evidence-based recommendations to ensure the safe administration of brolucizumab in patients with neovascular age-related macular degeneration (nAMD). The safety management of brolucizumab in patients with nAMD starts with selecting suitable patient profiles through thorough risk assessments. Educating patients about the risk of inflammation and its symptoms is important, as prompt recognition and early medical attention may help improve outcomes. Close monitoring with frequent follow-ups and the use of widefield fundus imaging or peripheral fundus examination are also necessary for early detection and management of complications. Effective management of IOI includes considering discontinuation of brolucizumab, alternative anti–vascular endothelial growth factor therapies, and

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corticosteroid treatments based on anatomical location and severity of IOI. Differentiating noninfectious IOI from infectious endophthalmitis is essential to ensure appropriate intervention and safeguard vision. In conclusion, this consensus recommendations emphasized the importance of the evidence-based and patient-centered stepwise approaches that should be considered when prescribing brolucizumab to patients with nAMD. This is not an absolute guideline, and the management should be adapted according to the ophthalmic conditions and the patients' opinions after thorough discussions.

Key Words: Age-related macular degeneration, Brolucizumab, Intraocular inflammation, Retinal vasculitis, Uveitis

Introduction

Neovascular age-related macular degeneration (nAMD) is a leading cause of vision loss, with a chronic nature that demands frequent treatment [1]. Conventional therapies, involving regular intravitreal injections, often lead to poor patient adherence, which increases the risk of undertreatment and further vision loss. Studies have shown that a significant portion of patients discontinue treatment or fail to follow the injection schedule, emphasizing the burden of current treatment regimens [2,3].

In phase 3 trials, HAWK and HARRIER, brolucizumab, an anti–vascular endothelial growth factor (anti-VEGF) therapy introduced in 2019, has demonstrated superior anatomical outcomes, including reductions in central subfield thickness and fluid resolution compared to other treatments, while enabling longer dosing intervals of up to 12 weeks [4–7]. Despite its efficacy, concerns regarding safety emerged following postmarketing surveillance, particularly related to intraocular inflammation (IOI), retinal vasculitis (RV), and retinal vascular occlusion (RO). These complications highlight the importance of vigilant patient selection, monitoring, and early intervention [5,8–16].

This recommendation presents evidence-based recommendations for the safe use of brolucizumab in nAMD patients, focusing on patient selection, monitoring protocols, and early treatment strategies to minimize risks and enhance therapeutic outcomes.

Materials and Methods

Expert panel discussions were held twice in 2021 and 2022, involving 15 experts from multiple centers in South Korea (Supplementary Table 1). To develop these recommendations, a comprehensive review of clinical trials, real-world data, and postmarketing safety reports was conducted. These discussions, which included input from practicing ophthalmologists and retina specialists, provided practical perspectives on brolucizumab's use in clinical settings and helped refine the recommendations. This collaborative approach ensures that the recommendations are based on both evidence and clinical expertise. A concise overview of the author's recommendations, informed by expert opinion, is presented in Fig. 1.

Consensus Recommendations for Safety Management of Brolucizumab

Select suitable patient profiles

1) Risk assessment

The decision to use brolucizumab in patients with nAMD should be based on a careful risk-benefit evaluation. While the drug offers anatomical advantages and the potential for longer treatment intervals, it is associated with risks such as IOI, RV, and RO [6,7,9,17,18]. Previous research has indicated that female sex, older age, a history of diabetes, and Japanese ethnicity could be potential risk factors for developing brolucizumab-related IOI [13,14,19,20]. However, recent real-world data from South Korea did not identify these factors associated with the risk of IOI [21]. Additional studies are needed to determine the factors contributing to IOI following brolucizumab injections. Moreover, a personalized risk assessment is recommended, particularly in patients with poor vision in the fellow eye to avoid bilateral vision loss [9].

Select suitable patient profiles	Early detection of adverse events	Early treatment for IOI
1. Check medical history • Previous IOI or retinal vascular occlusion • Previous uveitis 2. Check preexisting IOI • Conduct ocular examination including slit-lamp examination and/or widefield photography 3. Discuss incidence, symptoms and risk of complications with patients prior to prescribing brolucizumab • Educate on possible symptoms of IOI including floaters, eye pain/discomfort, impaired vision, eye redness, and light sensitivity • Guide the patient to visit immediately if suspicious symptoms occur (floaters, visual decline, pain, redness, etc.)	1. Careful monitoring for IOI • Prior to the next injection visit, additional monitoring within 1 mon can be considered • Consider additional monitoring up to 3–6 mon after the initial injection 2. In case of suspected signs of IOI, detailed ocular examinations including the peripheral retina is needed • Consider widefield fundus photography or fluorescein angiography with peripheral sweeps	1. Consider discontinuing the planned brolucizumab treatment 2. Immediate management based on the severity and location of inflammation to prevent progression • Immediate corticosteroid treatment for significant IOI (1) Topical corticosteroid (preferably high-potency steroids): usually for mild anterior or intermediate uveitis (2) Systemic corticosteroid (3) If necessary, an intravitreal or sub-Tenon steroid injection can be considered • Close observation without treatment can also be considered for minimal anterior chamber inflammation (trace cells in the anterior chamber) 3. Before the decision of intensive corticosteroid treatment, infectious endophthalmitis should be ruled out

Fig. 1. Recommendations for assessment, patient education, and management of intraocular inflammation (IOI) after brolucizumab treatment.

2) Assessment before injection

Active inflammation is a contraindication for brolucizumab, and its presence should prompt alternative treatment considerations [5]. It is advisable to perform a comprehensive ocular assessment that includes both anterior and posterior segment evaluations, along with widefield imaging, to detect any signs of current and past inflammation before initiating treatment [22]. This thorough evaluation is also essential to distinguish whether inflammation observed after brolucizumab treatment was preexisting.

3) Patient counseling and education

Educating patients about the potential risks associated with brolucizumab, including IOI, RV, and RO, is critical for ensuring safe treatment. Informed patients are better equipped to recognize early symptoms of inflammation, such as floaters, blurriness, pain, or redness, and to report these changes promptly. Based on real-world data from South Korean patients, blurriness (39.5%) and floaters (13.2%) were frequently reported, while 44.8% were asymptomatic. Similarly, a multicenter retrospective study from the United States reported floaters (53.3%) and blurred vision (46.7%) to be common[8,9,11,17,23]. This proactive approach can help in early intervention and improve overall treatment outcomes.

Monitoring protocols

1) Early detection of adverse events

Close monitoring during the first 6 months of brolucizumab treatment is advised, with follow-up visits ideally scheduled within the first month after injection. Additional monitoring up to 3 to 6 months after initial brolucizumab treatment can help detect and manage potential adverse events promptly [11]. Notably, a long-term study in South Korean patients indicated that the average onset of IOI occurred around 1 month after injection. While the risk is higher during the early phase, IOI can develop at any time within 1 year of treatment, emphasizing the need for vigilance throughout the entire treatment period [21].

2) Clinical evaluation of suspected inflammation

For patients exhibiting signs of inflammation, detailed ocular assessments should include slit-lamp examination, fundus examination or photography including peripheral retina, fluorescein angiography with peripheral sweeps and optical coherence tomography (OCT). Widefield fundus photography or fluorescein angiography may be particularly helpful for detecting peripheral inflammation, which has been frequently observed in previous studies [23]. OCT can also assist in detecting subtle increases in vitreous opacity or inflammatory cells, providing valuable insights for early diagnosis [24]. Comprehensive ocular examina-

tions to evaluate both anterior and posterior segment inflammation would be needed for detection of adverse effects [8,9]. Moreover, differential diagnosis to rule out infectious endophthalmitis is also essential, as this condition requires immediate antibiotic treatment rather than corticosteroids [8].

Early treatment of adverse events

1) Inflammation management

If any ocular inflammation occurs, especially RV or RO, it is important to address the issue promptly. The initial step is to consider discontinuation of the planned brolucizumab treatment and switching to other alternative anti-VEGF agents. A recent real-world study from South Korea found a high recurrence rate of IOI in patients who continued brolucizumab treatment after an initial event of brolucizumab-related IOI with a recurrence rate of 27.8% to 50.0% [21,25]. However, many of these patients had previously been refractory to other anti-VEGF therapies, leaving limited alternatives. Therefore, decisions about further treatment should be based on the risk-benefit considering the patient's condition and opinion.

Second step is the administration of anti-inflammatory medication, and the corticosteroid is the mainstay of treatment. Based on findings from clinical trials and real-world studies, we recommend determining the route of the corticosteroid therapy based on the anatomical location and severity of the IOI. In cases of mild inflammation, topical corticosteroids are often sufficient to resolve the issue. [12,21]. In moderate to severe cases, especially involving the vitreous or retina, systemic corticosteroids should be considered to achieve adequate control of inflammation. Additionally, intravitreal or sub-Tenon corticosteroid injections may be employed when deemed necessary. However, the efficacy of adding local corticosteroid injection in suppressing inflammation has not yet been fully validated compared to the administration of oral corticosteroid alone. The choice of treatment should be guided by the clinical response, with adjustments made as needed to ensure the resolution of inflammation.

2) Exclusion of infectious causes

Distinguishing noninfectious inflammation from infectious endophthalmitis is critical. While both conditions may share some clinical features they differ significantly in timing and presentation [26,27]. Infectious endophthalmitis typically develops within 3 to 7 days of an intravitreal injection and is characterized by acute symptoms, including pain, hypopyon, and significant anterior segment inflammation [27,28]. In contrast, IOI after brolucizumab usually appears in a delayed fashion, around 1 month after injection, and often lacks acute signs like hypopyon [21,25]. Given the overlapping features, clinicians can use diagnostic tools such as vitreous and aqueous sampling to confirm infectious causes, enabling prompt treatment with antibiotics if necessary [29]. Systemic diseases that may trigger RV should also be considered in the differential diagnosis. Once infectious causes are ruled out, corticosteroid therapy can be initiated for noninfectious inflammation.

Discussion

This study aligns with existing recommendations by emphasizing the importance of patient selection, monitoring protocol and early treatment of adverse events. [8,9]. Pretreatment evaluations and patient education remain central to ensuring safety. As symptoms were mild in most cases of IOI, the early recognition and timely presentation by patients may play a crucial role in detecting and managing the adverse events early [21,25]. Moreover, this paper underscores the value of widefield imaging techniques, such as ultra-widefield fundus photography and fluorescein angiography with peripheral sweeps, to identify inflammation that might otherwise go undetected. Advanced imaging modalities like widefield fluorescein angiography would enhance the detection of peripheral inflammation. By integrating this approach, the recommendation aims to improve early detection and management of complications associated with brolucizumab.

Recent real-world studies from South Korea have provided updated insights into the incidence of brolucizumab-associated IOI. A nationwide cohort study of 60,966 patients reported significantly higher IOI rates in brolucizumab-treated patients (3.47%–3.69%) compared to ranibizumab (0.36%) or aflibercept (0.49%) [30]. Phase 3 trials of brolucizumab in patients with diabetic macular edema (KESTREL and KITE) [31] showed lower incidence rates of RV and RO—2.1% and 0.6%, respectively—compared to 3.3% reported in the nAMD trials (HAWK and HARRIER) [6]. South Korean multicenter studies found

IOI rates of 9.4% to 13.9% in real-world settings, with most cases being mild and responsive to steroids [21,25,32–34]. Notably, treatment-naive patients showed lower IOI rates (3.7%) than switch patients (9.9%), and while IOI recurrence occurred in 23.7% of re-dosed patients, most maintained good visual outcomes [32–34]. These findings emphasize the importance of individualized risk assessment and suggest potential disease-specific susceptibility to brolucizumab-associated inflammation.

The mechanisms underlying IOI following brolucizumab injections are not yet fully elucidated. However, immunogenicity is considered a major contributing factor, as brolucizumab has shown the highest rate of antidrug antibody formation among anti-VEGF agents, potentially leading to inflammation in susceptible individuals [16,35]. In addition, a recent biomarker analysis indicated that increased P-selectin, tumor necrosis factor α, interleukin 1α, and matrix metalloproteinase-9, along with a decrease in Th2 cell populations, may contribute to the pathogenesis of IOI, supporting a delayed-type hypersensitivity mechanism [36]. Although these studies suggest several possible immunologic mechanisms, the exact pathophysiology of brolucizumab-associated IOI remains unclear, and further investigation is needed.

This study highlights the need for careful monitoring, especially during the early phases of treatment, as the average onset of IOI was reported to be 28.5 ± 1.4 days, with most cases (92.2%) occurring after the first to third injections in long-term real-world data in South Korea. However, continuous monitoring throughout the treatment course is also important as IOI can still occur up to 1 year after any injection [21]. Furthermore, management strategies focus on early detection and intervention using corticosteroids tailored to the severity of inflammation, while distinguishing IOI from infectious endophthalmitis to guide appropriate treatment. Treatment options include topical corticosteroids for mild cases, intravitreal corticosteroid injection for moderate inflammation, and posterior sub-Tenon triamcinolone injection for selected cases, while the evidence for topical steroids as the single therapy remains uncertain [8,21,37–39]. For severe cases, particularly those involving occlusive vasculitis, systemic corticosteroids may be required to prevent serious vision loss. Moreover, continuous monitoring throughout the treatment course remains essential as IOI can occur up to one year after any injection. Most IOI cases show favorable outcomes with appropriate corticosteroid management, emphasizing the importance of early recognition and prompt intervention in optimizing brolucizumab therapy safety.

Integrating recent findings, we emphasize a structured, evidence-based approach to balance efficacy and safety in brolucizumab therapy. A real-world South Korean study showed that 82.7% of refractory nAMD patients achieved anatomical improvement or extended injection intervals, despite a 9.9% of IOI incidence [32]. Treat-and-extend regimens demonstrated favorable long-term outcomes with a low IOI incidence in treatment-naive patients [40]. Additionally, brolucizumab led to complete polyp regression in 74.2% of treatment-naive polypoidal choroidal vasculopathy patients, significantly improving outcomes with careful IOI management [41]. These data highlight the importance of appropriate patient selection and close monitoring to optimize therapeutic benefits and minimize risks.

This recommendation highlights the current consensus but has notable limitations. Clear risk factors for complications like IOI and RV are not definitively established, and evidence supporting the prophylactic use of topical corticosteroids with brolucizumab is currently lacking. The recommendations are based on expert consensus from multicenter meetings held in South Korea in 2021 and 2022 and should be viewed as guidance rather than strict mandates and further modifications can be made on them as more evidence appears in the future. Clinicians are encouraged to consider individual patient circumstances and evolving evidence when applying these strategies.

Conclusion

This report offers guidance on the use of brolucizumab for treating nAMD, based on expert opinion and current evidence. Its administration requires a careful risk-benefit assessment, especially in patients with a history of IOI. Comprehensive ocular examinations should be conducted before each injection, and patients must be educated to recognize and report potential complications. Close monitoring is crucial for early detection of adverse effects, with detailed evaluations of the peripheral retina when inflammation is suspected. Prompt, tailored interventions, such as corticosteroid treatment, are key to managing complications and preserving vision.

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Supplementary Materials

Supplementary Table 1. Expert panel members and affiliated centers participating in 2021 and 2022 consensus meetings

Supplementary materials are available from https://doi.org/10.3341/kjo.2025.0010.

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Supplementary Table 1. Expert panel members and affiliated centers participating in 2021 and 2022 consensus meetings

Expert panel member	Affiliation
2021	
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Sang Jin Kim	Samsung Medical Center, Seoul, Korea
Ji Eun Lee	Pusan National University Hospital, Busan, Korea
Sun Taek Lim	Parangsae Eye Hospital, Seoul, Korea
2022	
June-Gone Kim	Asan Medical Center, Seoul, Korea
Chang Ryong Kim	Parangsae Eye Hospital, Seoul, Korea
Kyu Hyung Park*	Seoul National University Hospital, Seoul, Korea
Young-Hoon Park*	Seoul St. Mary's Hospital, Seoul, Korea
Min Sagong	Yeungnam University Medical Center, Daegu, Korea
Hyun Sub Oh	Nune Eye Hospital, Seoul, Korea
Se Joon Woo	Seoul National Bundang Hospital, Seongnam, Korea
Seung Young Yu*	Kyung Hee University Medical Center, Seoul, Korea
Christopher Seungkyu Lee	Severance Eye Hospital, Seoul, Korea

*Kyu Hyung Park, Seung Young Yu, and Young-Hoon Park attended both 2021 and 2022 meetings.