Original Article

Efficacy and Safety of Biosimilar Ranibizumab (Razumab) versus Innovator Ranibizumab (Lucentis) in BRVO: A Retrospective Study from Eastern India

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Abstract

Background: To compare the efficacy and safety of intravitreal Razumab and Lucentis in the management of macular edema secondary to branch retinal vein occlusion (BRVO). **Material and Methods:** In this comparative study, 92 eyes of 92 patients with BRVO-associated macular edema were included, with 47 eyes receiving intravitreal Razumab and 45 eyes receiving Lucentis. Baseline demographic and clinical characteristics, including age, gender, best-corrected visual acuity (BCVA), and central retinal thickness (CRT), were comparable between groups. Patients were followed for 6 months. Primary outcomes included changes in BCVA and CRT, while secondary outcomes assessed safety and injection burden. **Results:** Both groups demonstrated significant improvement in visual and anatomical outcomes at 6 months. Mean BCVA improved from 46.6 ± 10.1 to 64.3 ± 9.5 letters in the Razumab group and from 45.9 ± 9.1 to 65.2 ± 8.9 letters in the Lucentis group ($p < 0.001$ for both), with no significant difference in mean visual gain between groups (16.3 ± 6.7 vs. 17.0 ± 7.2 letters; $p = 0.63$). Similarly, CRT decreased significantly in both groups, with reductions of 184.7 ± 81.4 µm in the Razumab group and 189.6 ± 78.3 µm in the Lucentis group ($p < 0.001$ for both), without significant intergroup difference ($p = 0.77$). Safety outcomes were comparable, with no serious ocular or systemic adverse events reported. Minor adverse events, including Subconjunctival hemorrhage and transient intraocular pressure elevation, were infrequent and similar between groups. The mean number of injections was also comparable (4.3 ± 0.8 vs 4.2 ± 0.9; $p = 0.58$). **Conclusion:** Intravitreal Razumab and Lucentis demonstrate comparable efficacy and safety in the treatment of BRVO-related macular edema, with significant improvements in visual acuity and retinal thickness over 6 months. These findings support Razumab as a cost-effective alternative to Lucentis without compromising clinical outcomes.

Keywords: BRVO, macular edema, Razumab, Lucentis, Ranibizumab, anti-VEGF, biosimilar.

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Introduction

Branch retinal vein occlusion (BRVO) is the second most prevalent retinal vascular disorder after diabetic retinopathy and significantly contributes to visual impairment worldwide. Population-based data from India, including insights from the Central India Eye Study, revealed a prevalence of retinal vein occlusion of approximately 0.77%, with BRVO constituting the majority of these cases.[1] The principal cause of vision loss in BRVO is macular edema, which arises from increased vascular permeability, primarily driven by the vascular endothelial growth factor (VEGF) and inflammatory mediators.[2]

Intravitreal anti-VEGF therapy is the standard treatment for macular edema associated with BRVO. Lucentis (Ranibizumab), a recombinant humanized monoclonal antibody fragment targeting VEGF-A, has demonstrated significant visual and anatomical benefits in randomized clinical trials.[3] Notably, the BRAVO study reported substantial improvements in best-corrected visual acuity (BCVA) and reductions in central retinal thickness (CRT) in patients with BRVO.[4]

Despite its proven efficacy, the high cost of innovator Ranibizumab limits its accessibility and long-term use in developing countries, such as India, where out-of-pocket healthcare expenses remain substantial. Consequently, there has been an increasing reliance on biosimilars, such as Razumab, the first biosimilar of Ranibizumab approved in India.[5] Real-world Indian studies, including the RE-ENACT and RE-ENACT 2 studies, have shown that Razumab significantly improves visual acuity and retinal thickness, with a safety profile comparable to that of the innovator molecule across various retinal vascular disorders.[6,7]

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Despite the growing body of evidence supporting the use of Razumab, there is a paucity of direct comparative studies between Razumab and Lucentis for macular edema associated with BRVO, particularly in the real-world Indian context, where economic factors, treatment adherence, and accessibility significantly impact outcomes.

Therefore, the present study aimed to compare the efficacy and safety of intravitreal Razumab versus Lucentis in patients with macular edema secondary to BRVO in a retrospective real-world clinical setting.

Materials and Methods

This retrospective, interventional, comparative study was conducted at the Department of Ophthalmology, Calcutta National Medical College, Kolkata, West Bengal, India. This study adhered to the principles of the Declaration of Helsinki and was approved by the Institutional Ethics Committee. Owing to the retrospective nature of the study, a waiver of informed consent was granted.

The medical records of patients diagnosed with branch retinal vein occlusion (BRVO) associated with macular edema and treated between January 2022 and December 2025 were reviewed.

Inclusion Criteria

Patients were included if they met the following criteria.

- Age ≥ 18 years
- Clinical and optical coherence tomography (OCT)-confirmed diagnosis of BRVO with macular edema
- Receipt of at least three intravitreal injections of either Razumab (biosimilar ranibizumab) or Lucentis (ranibizumab)
- Minimum follow-up duration of 6 months

Exclusion Criteria

Patients were excluded if they had:

- Central retinal vein occlusion or hemi-retinal vein occlusion
- Prior intravitreal anti-VEGF or steroid therapy within 3 months before presentation
- Coexisting retinal diseases likely to affect visual acuity
- History of intraocular surgery (except uncomplicated cataract surgery) within the preceding 3 months

Treatment Protocol

All intravitreal injections were administered under strict aseptic conditions in an operating room. Patients received either Razumab or Lucentis at a dose of 0.5 mg/0.05 mL.

A loading phase of three consecutive monthly injections was followed by a pro re nata (PRN) regimen based on best-corrected visual acuity (BCVA) and OCT findings at the discretion of the treating physician.

Outcome Measures and Data Collection

The following parameters were recorded at baseline and 6 months:

- Best-corrected visual acuity (BCVA), measured using Early Treatment Diabetic Retinopathy Study (ETDRS) charts and expressed in letters
- Central retinal thickness (CRT), measured using spectral-domain OCT
- Number of intravitreal injections administered
- Ocular and systemic adverse events

Statistical Analysis: Data were recorded in a standardized pro forma and entered into Microsoft Excel (Microsoft Corp., Redmond, WA, USA) for management.

Statistical analysis was performed using SPSS software (version 31, IBM Corp., Armonk, NY, USA) and Graphpad Prism (version 10.6.1). Continuous variables are expressed as mean± standard deviation (SD), and categorical variables are presented as frequencies and percentages.

A paired t-test was used to assess within-group changes from baseline, and an independent t-test was used for between-group comparisons (Razumab vs. Lucentis). Statistical significance was set at $P < 0.05$.

Results

A total of 92 eyes from 92 patients diagnosed with branch retinal vein occlusion (BRVO) with macular edema were included. Of these, 47 eyes received intravitreal Razumab and 45 eyes received intravitreal Lucentis. The mean age (table 1) was 58.4 ± 9.6 years in the Razumab group and 59.1 ± 10.2 years in the Lucentis group, with no statistically significant difference (unpaired Student's t-test, p = 0.74). The mean difference was −0.7 years (95% CI:−4.7 to 3.3), with a negligible effect size (Cohen's d = 0.07). Gender distribution was comparable between groups (Razumab: 30 males, 17 females; Lucentis: 29 males, 16 females), with no significant difference (Chi-square test, p = 0.82). The effect size was minimal (Phi = 0.02). Baseline BCVA was 46.6 ± 10.1 letters in the Razumab group and 45.9± 9.1 letters in the Lucentis group, with no significant difference (unpaired Student's t-test, p= 0.76). The mean difference was 0.7 letters (95% CI: −3.2 to 4.6), with a trivial effect size (Cohen's d = 0.07). Baseline CRT was 481.3 ± 91.7 µm in the Razumab group and 471.6 ±91.4 µm in the Lucentis group, with no significant difference (unpaired Student's t-test, p = 0.63). The mean difference was 9.7 µm (95% CI: −28.4 to 47.8), with a small effect size (Cohen's d = 0.11). Overall, baseline demographic and clinical characteristics were well balanced between the two groups.

Table 1: Baseline demographic and clinical characteristics of both groups

Parameter	Razumab (n=47)	Lucentis (n= 45)	Mean Difference(95%CI)	Effect Size	p-value
Age (years), mean ± SD	58.4 ± 9.6	59.1 ± 10.2	−0.7 (−4.7 to 3.3)	Cohen's d = 0.07	0.74†
Gender (M/F)	30 / 17	29 / 16	—	Phi = 0.02	0.82‡
Baseline BCVA (letters), mean ± SD	46.6 ± 10.1	45.9 ± 9.1	0.7 (−3.2 to 4.6)	Cohen's d = 0.07	0.76†
Baseline CRT (µm), mean ± SD	481.3 ± 91.7	471.6 ± 91.4	9.7 (−28.4 to 47.8)	Cohen's d = 0.11	0.63†

Visual Acuity Outcomes: At baseline [Table 2], the mean best-corrected visual acuity (BCVA) was 46.6 ± 10.1 letters in the Razumab group and 45.9 ± 9.1 letters in the Lucentis group, with no statistically significant difference between the groups (unpaired Student's t-test, p = 0.72). At 6 months, BCVA improved significantly in both groups. The mean

BCVA increased to 64.3 ± 9.5 letters in the Razumab group and 65.2 ± 8.9 letters in the Lucentis group. Within-group improvement from baseline was statistically significant for both groups (paired t-test, $p < 0.001$ for both). The mean BCVA gain was 16.3 ± 6.7 letters in the Razumab group and 17.0± 7.2 letters in the Lucentis group. The between-group difference in visual gain was not statistically significant (unpaired Student's t-test, $p = 0.63$). The mean difference in BCVA gain was −0.7 letters (95% CI: −3.5 to 2.1), with a small effect size (Cohen's $d = 0.10$).

Table 2: comparision of Visual acuity outcome between two groups.

Parameter	Razumab(n= 47)	Lucentis (n= 45)	Mean Difference (95% CI)	Effect Size	p-value
Baseline BCVA (letters), mean ± SD	46.6 ± 10.1	45.9 ± 9.1	0.7 (−3.3 to 4.7)	Cohen's d = 0.07	0.72
6-month BCVA (letters), mean ± SD	64.3 ± 9.5	65.2 ± 8.9	−0.9 (−4.6 to 2.8)	Cohen's d = 0.10	0.64
Mean BCVA gain (letters), mean ± SD	16.3 ± 6.7	17.0 ± 7.2	−0.7 (−3.5 to 2.1)	Cohen's d = 0.10	0.63
p-value (within group)	<0.001	<0.001	—	—	—

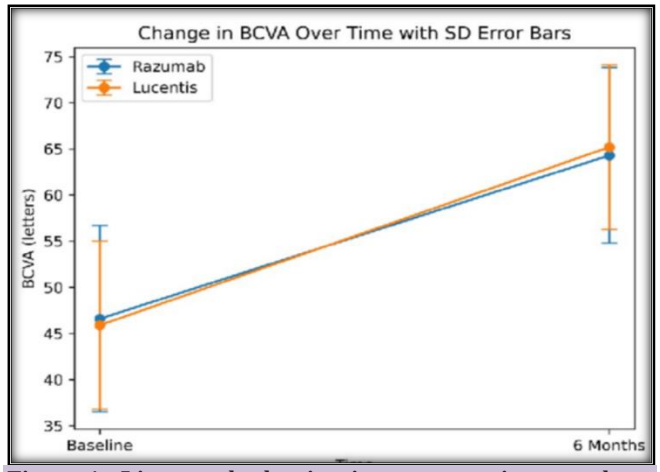

Figure 1: Line graph showing improvement in mean best-corrected visual acuity (BCVA) from baseline to 6 months in Razumab and Lucentis groups. Both groups demonstrated significant visual gains with comparable outcomes.

Similarly, the difference in BCVA at 6 months between the two groups was not statistically significant (mean difference: −0.9 letters; 95% CI: −4.6 to 2.8; Cohen's $d = 0.10$; $p = 0.64$). Overall, both treatments resulted in significant visual improvement, with no clinically or statistically significant difference between groups [Figure 1].

Central retinal Thickness Outcomes: At baseline [Table 3], the mean central retinal thickness (CRT) was 503.4 ± 101.8 µm in the Razumab group and 497.3 ± 98.7 µm in the Lucentis group, with no statistically significant difference between groups (unpaired Student's t-test, $p = 0.77$). The mean difference was 6.1 µm (95% CI: −35.9 to 48.1), with a trivial effect size (Cohen's $d = 0.06$). At 6 months, CRT decreased significantly in both groups. The mean CRT reduced to 288.4 ± 75.2 µm in the Razumab group and 272.7 ± 65.9 µm in the Lucentis group. The reduction from baseline was statistically significant within both groups (paired t-test, $p < 0.001$ for both).

Table 3: Comparision of Central retinal thickness outcomes between two groups

Parameter	Razumab (n= 47)	Lucentis (n= 45)	Mean Difference (95%CI)	Effect Size	p-value
Baseline CRT (µm), mean ± SD	503.4 ± 101.8	497.3 ± 98.7	6.1 (−35.9 to 48.1)	Cohen's d = 0.06	0.77
6-month CRT (µm), mean ± SD	288.4 ± 75.2	272.7 ± 65.9	15.7 (−13.5 to44.9)	Cohen's d = 0.22	0.29
Mean CRT reduction (µm), mean ± SD	184.7 ± 81.4	189.6 ± 78.3	−4.9 (−37.8 to28.0)	Cohen's d = 0.06	0.77
p-value (within group)	<0.001	<0.001	—	—	—

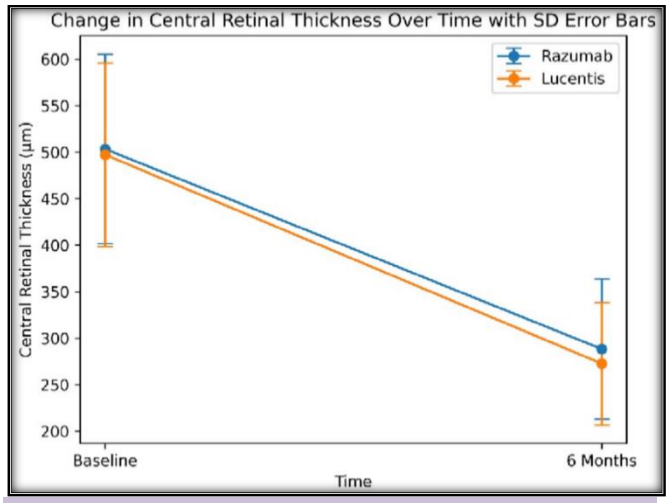

Figure 2: Change in central retinal thickness (CRT) over 6 months in Razumab and Lucentis groups. Error bars represent standard deviation (SD). Both groups showed significant reduction in CRT with comparable outcomes.

The mean reduction in CRT was 184.7 ± 81.4 µm in the Razumab group and 189.6 ± 78.3 µm in the Lucentis group. The difference in CRT reduction between the groups was not statistically significant (unpaired Student's t-test, $p = 0.77$). The mean difference was −4.9 µm (95% CI: −37.8 to 28.0), with a negligible effect size (Cohen's $d = 0.06$). Similarly, the difference in CRT at 6 months between groups was not statistically significant (mean difference: 15.7 µm; 95% CI: −13.5 to 44.9; Cohen's $d = 0.22$; $p = 0.29$). Overall, both treatments resulted in significant anatomical improvement, with comparable efficacy between the two groups [Figure 2].

Safety Outcomes: No serious ocular or systemic adverse events were reported in either group during the study period. Minor ocular adverse events were infrequent and comparable between groups. Subconjunctival hemorrhage occurred in 5 eyes (10.6%) in the Razumab group and 3 eyes (6.6%) in the Lucentis group, with no statistically significant difference (Fisher's exact test, p= 0.47). The odds ratio (OR) was 1.66 (95% CI: 0.37–7.39), indicating no increased risk. Transient intraocular pressure (IOP) elevation was observed in 3 eyes

(6.3%) in the Razumab group and 2 eyes (4.4%) in the Lucentis group. This difference was not statistically significant (Fisher's exact test, p = 0.65), with an OR of 1.44 (95% CI: 0.23–9.13). All cases were transient and managed successfully with topical antiglaucoma medications. There were no cases of endophthalmitis, retinal detachment, or systemic thromboembolic events in either group [Table 4].

Table 4: Safety outcomes and injection burden

Parameter	Razumab (n = 47)	Lucentis (n = 45)	p-value
Number of injections (mean ± SD)	4.3 ± 0.8	4.2 ± 0.9	0.58
Subconjunctival hemorrhage, n (%)	5 (10.6%)	3 (6.6%)	0.47
Transient IOP elevation, n (%)	3 (6.3%)	2 (4.4%)	0.65
Serious adverse events	0	0	—

The mean number of injections administered was 4.3 ± 0.8 in the Razumab group and 4.2 ±0.9 in the Lucentis group, with no statistically significant difference (unpaired Student's t-test, p = 0.58). The mean difference was 0.1 injections (95% CI: −0.3 to 0.5), with a trivial effect size (Cohen's d = 0.12). Overall, both treatments demonstrated comparable safety profiles with no significant differences in adverse events or treatment burden [Figure 3].

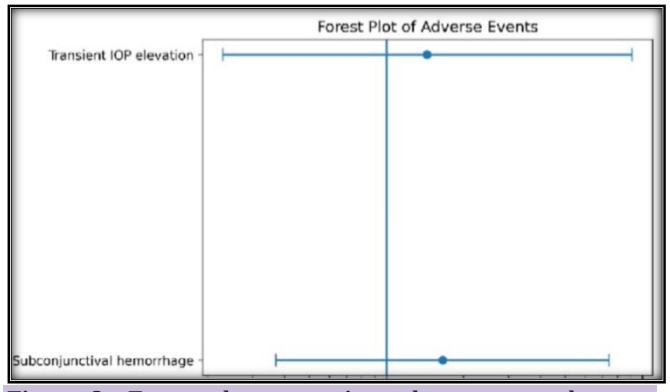

Figure 3: Forest plot comparing adverse events between Razumab and Lucentis groups. Squares represent odds ratios, and horizontal lines indicate 95% confidence intervals. The vertical line at odds ratio = 1 represents no difference between groups. No statistically significant differences were observed for any adverse event.

Discussion

The present study demonstrates that intravitreal Razumab and Lucentis provide comparable functional and anatomical outcomes in patients with branch retinal vein occlusion (BRVO) associated with macular edema. Both groups exhibited significant improvement in best-corrected visual acuity (BCVA) and substantial reduction in central retinal thickness (CRT) over 6-month period, with no statistically or clinically significant differences between the two treatment arms.

When we compared the baseline demographic characteristics of patients with branch retinal vein occlusion (BRVO) associated with macular edema receiving intravitreal Razumab or Lucentis, the findings demonstrated that both treatment groups were well balanced in terms of age and gender distribution, with no statistically significant differences observed. This comparability is essential to minimize confounding factors and ensure that any differences in clinical outcomes can be more reliably attributed to therapeutic interventions rather than baseline disparities. The mean age of patients in both groups was approximately 58–59 years, which is consistent with the known epidemiology of BRVO. Previous studies have reported that retinal vein occlusion predominantly affects individuals over 50 years of age, with an increasing incidence in older populations owing to systemic vascular risk factors such as hypertension, diabetes mellitus, and atherosclerosis.[8,9] The negligible effect size (Cohen's d= 0.07) and wide confidence interval further confirmed that the age distribution between the two groups was clinically comparable and unlikely to bias the outcomes. Similarly, gender distribution was nearly identical between the Razumab and Lucentis groups, with a slight male predominance in both. This aligns with prior epidemiological data suggesting either a balanced or marginal male predominance in BRVO cases.[10] The absence of a statistically significant difference (p = 0.82) and the very small effect size (Phi = 0.02) indicate that gender is unlikely to act as a confounding variable in this cohort. In the present study, both Razumab and Lucentis demonstrated significant improvement in best-corrected visual acuity (BCVA) over a 6-month period in patients with branch retinal vein occlusion (BRVO) associated with macular edema. Importantly, the baseline BCVA was comparable between the two groups, indicating an equitable starting point for evaluating the treatment outcomes. The absence of a statistically significant difference at baseline (p = 0.72) minimized potential bias and strengthened the validity of the comparative efficacy analysis. At 6 months, both groups exhibited substantial visual gains, with mean BCVA improving to 64.3 ± 9.5 letters in the Razumab group and 65.2 ± 8.9 letters in the Lucentis group. The within-group improvements were highly significant (p < 0.001), underscoring the effectiveness of anti-vascular endothelial growth factor (anti-VEGF) therapy in improving visual outcomes in patients with BRVO. These findings are consistent with the results of the BRAVO trial,[4] which demonstrated significant visual acuity gains with Ranibizumab in patients with BRVO, with mean improvements of approximately 16–18 letters at 6 months. The magnitude of visual gain observed in our study (16.3 letters for Razumab and 17.0 letters for Lucentis) closely parallels those reported in pivotal clinical trials and real-world studies of Ranibizumab. This similarity suggests that Razumab, a biosimilar of Ranibizumab, provides comparable therapeutic benefits in terms of visual acuity improvement. Previous studies evaluating Razumab in retinal vascular diseases have also reported significant BCVA gains comparable to those of the innovator molecule, supporting its clinical effectiveness.[6-11] Importantly, the between-group comparison revealed no

statistically significant difference in BCVA gain (p = 0.63), with a minimal mean difference of −0.7 letters and a small effect size (Cohen's d = 0.10). The confidence interval (−3.5 to 2.1 letters) further indicates that any true difference between the two treatments is likely clinically insignificant. These findings reinforce the concept of therapeutic equivalence between Razumab and Lucentis in the management of BRVO-related macular edema. The comparable efficacy observed in this study has important clinical and economic implications. While Lucentis has been widely validated through large randomized controlled trials, its high cost can limit its accessibility, particularly in low- and middle-income countries. Razumab, a more affordable biosimilar, offers a cost-effective alternative without compromising efficacy. This is particularly relevant in the Indian healthcare setting, where treatment affordability significantly influences patient compliance and the long-term outcomes. Overall, the results of this study support the use of both Razumab and Lucentis as effective treatment options for improving visual acuity in BRVO. The absence of significant differences in visual gain between the two groups highlights the potential of Razumab as a viable and economically advantageous alternative to the reference biologic.

In the present study, both Razumab and Lucentis demonstrated significant anatomical improvement, as evidenced by a marked reduction in central retinal thickness (CRT) over a 6-month follow-up period. At baseline, CRT values were comparable between the two groups, with no statistically significant difference (p = 0.77) and a trivial effect size (Cohen's d = 0.06). This baseline equivalence is important because it ensures that subsequent differences in anatomical outcomes are attributable to treatment effects rather than initial disparities in disease severity. At 6 months, both groups showed substantial reductions in CRT, with mean values decreasing to 288.4 ± 75.2 µm in the Razumab group and 272.7 ±65.9 µm in the Lucentis group. The reductions from the baseline were highly statistically significant in both groups (p < 0.001), confirming the effectiveness of anti-vascular endothelial growth factor (anti-VEGF) therapy in resolving macular edema associated with BRVO. These findings are consistent with those of the BRAVO study, which reported significant reductions in retinal thickness following Ranibizumab therapy, paralleling improvements in visual acuity.[4] The magnitude of CRT reduction observed in our study (approximately 185–190 µm) is comparable to that reported in both randomized controlled trials and real-world studies of Ranibizumab. This suggests that Razumab, a biosimilar to Ranibizumab, achieves a similar degree of anatomical response. Previous studies evaluating Razumab have also demonstrated significant reductions in CRT across retinal vascular disorders, supporting its efficacy in reducing macular edema.[6,12] Importantly, there was no statistically significant difference between the two groups in terms of CRT reduction (p = 0.77), with a negligible effect size (Cohen's d = 0.06) and mean difference of −4.9 µm. Additionally, the CRT values at 6 months were not significantly different between the groups (p = 0.29), further reinforcing the comparable anatomical efficacy of the two agents. The confidence intervals for these comparisons were wide and crossed zero, indicating that any observed differences were likely due to chance and were not clinically meaningful. The concordance between the anatomical and functional outcomes in this study, namely, significant CRT reduction alongside improved BCVA, aligns with the established relationship between macular edema resolution and visual recovery in BRVO. However, it is important to note that the correlation between CRT reduction and visual gain is not always linear, as other factors, such as photoreceptor integrity and duration of edema, may influence visual outcomes.[13] From a clinical perspective, the comparable efficacy of Razumab and Lucentis in reducing CRT has important implications, particularly in resource-constrained settings. Given the lower cost of Razumab, its similar anatomical performance supports its role as a cost-effective alternative to reference biologics without compromising treatment outcomes. Overall, the findings of this study demonstrate that both Razumab and Lucentis are highly effective in reducing macular edema in BRVO, with no significant differences in the anatomical outcomes between the two groups. This further supports the therapeutic equivalence of biosimilars and innovator molecules in real-world clinical practice.

In the present study, both Razumab and Lucentis demonstrated a favorable safety profile over the 6-month follow-up period, with no serious ocular or systemic adverse events reported in either group. This finding is consistent with the well-established safety of intravitreal anti-vascular endothelial growth factor (anti-VEGF) agents in the management of retinal vascular disorders. Minor ocular adverse events were infrequent and comparable between the two groups. Subconjunctival hemorrhage was the most commonly observed complication, occurring in 10.6% of eyes in the Razumab group and 6.6% in the Lucentis group, with no statistically significant difference (p = 0.47). This is a known benign and self-limiting complication of intravitreal injections, typically related to needle entry and conjunctival vessel injury rather than the pharmacologic agent itself.[14] The observed rates in our study were comparable to those reported in previous clinical trials and real-world studies. Transient intraocular pressure (IOP) elevation was observed in a small proportion of eyes in both groups (6.3% in Razumab vs. 4.4% in Lucentis), with no significant difference between them (p = 0.65). All cases were mild and responded well to topical antiglaucoma medications without long-term sequelae. Transient IOP spikes following intravitreal injections are well documented and are generally attributed to an immediate increase in intraocular volume rather than drug-specific effects.[3] Importantly, no cases of endophthalmitis, retinal detachment, or systemic thromboembolic events were reported in either group of patients. These findings are reassuring, as such complications, although rare, represent the most serious risks associated with intravitreal anti-VEGF therapy in patients with DME. Large clinical trials, such as the BRAVO and CRUISE studies, have similarly reported low rates of serious ocular and systemic adverse events with ranibizumab.[15] The comparable safety outcomes between Razumab and Lucentis observed in this study further support the safety profile of the biosimilar. Previous studies evaluating Razumab have also demonstrated no increase in adverse events compared to the reference molecule, reinforcing its clinical reliability.[6,12] Concerns regarding the immunogenicity and

safety of biosimilars have been a topic of discussion; however, accumulating evidence suggests that Razumab maintains a safety profile similar to that of innovator Ranibizumab. Overall, the absence of serious adverse events and the low incidence of minor complications in both groups indicate that intravitreal administration of Razumab and Lucentis was safe and well tolerated. The lack of significant differences in safety outcomes between the two treatments further supports the use of Razumab as a safe alternative to Lucentis for managing BRVO-associated macular edema.

The mean number of injections was similar between the groups (4.3 vs. 4.2), indicating a comparable treatment burden. This is clinically relevant because injection frequency directly affects patient compliance, healthcare resource utilization, and overall cost-effectiveness. In the present study, the mean number of intravitreal injections administered over the 6-month follow-up period was comparable between the two groups, with 4.3 ± 0.8 injections in the Razumab group and 4.2 ± 0.9 injections in the Lucentis group. The difference was not statistically significant ($p = 0.58$), with a minimal mean difference of 0.1 injections and a trivial effect size (Cohen's $d = 0.12$). These findings indicate that both treatments require a similar frequency to achieve comparable functional and anatomical outcomes. The injection burden observed in this study is consistent with previously reported anti-VEGF treatment regimens for BRVO, particularly those employing pro re nata (PRN) or individualized dosing strategies. In the BRAVO trial, patients receiving Ranibizumab required frequent injections during the initial phase, followed by as-needed dosing based on disease activity.[4] Real-world studies have similarly reported a mean of 3–5 injections over a 6-month period, depending on the treatment protocols and patient response.[16] The comparable injection frequency between Razumab and Lucentis further supports the therapeutic equivalence of the biosimilar and reference biologic. This suggests that Razumab does not require increased dosing frequency to achieve similar clinical outcomes, alleviating concerns regarding potential differences in durability or efficacy. Previous studies evaluating Razumab in retinal vascular diseases have also reported similar retreatment requirements compared to those of Ranibizumab, reinforcing its role as a viable alternative.[12] From a clinical standpoint, the injection burden is a critical consideration, as it directly impacts patient compliance, healthcare resource utilization, and overall treatment costs. The finding that Razumab achieves comparable outcomes with a similar number of injections, combined with its lower cost, enhances its value proposition, particularly in resource-limited settings.

Overall, the results of this study demonstrate that both Razumab and Lucentis have similar treatment durability, as reflected by their comparable injection requirements. This further strengthens the evidence supporting the use of Razumab as an effective and practical alternative to Lucentis in the management of BRVO-associated macular edema. Given the equivalent efficacy and safety demonstrated in this study, the choice between Razumab and Lucentis may be guided by economic considerations. Razumab, as a biosimilar, is significantly more cost-effective, particularly in resource-limited settings. This has important implications for improving access to anti-VEGF therapy in developing countries, where treatment affordability is a major barrier. These findings support the growing role of biosimilars in ophthalmology, offering a viable alternative without compromising clinical outcomes.

Limitations: Despite its strengths, this study had certain limitations. The relatively short follow-up duration (6 months) may not capture the long-term outcomes or recurrence rates. Additionally, the sample size, although adequate for detecting moderate differences, may be underpowered to identify very small effect sizes. The study design may also limit generalizability, as it was conducted at a single center. Future multicenter randomized controlled trials with longer follow-ups are warranted to confirm these findings and evaluate the long-term efficacy and safety.

Conclusion

In conclusion, both Razumab and Lucentis provide significant and comparable improvements in visual acuity and macular edema in patients with BRVO. With similar safety profiles and treatment burdens, Razumab represents a cost-effective alternative to Lucentis without compromising clinical efficacy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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