International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Efficacy of Intravitreal Razumab in Patients with Diabetic Macular Edema: A Retrospective Observational Study from a Tertiary Care Hospital

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Received: 25-02-2026
Accepted: 15-04-2026
Available online: 30-04-2026

ABSTRACT

Background: Diabetic macular edema (DME) is a major cause of visual impairment in patients with diabetic retinopathy. Intravitreal anti-vascular endothelial growth factor therapy has become a mainstay of treatment, and Razumab, a biosimilar ranibizumab, is increasingly used in routine clinical practice.

Objective: To evaluate the efficacy and short-term safety of intravitreal Razumab in patients with DME treated at a tertiary care hospital.

Methods: This retrospective observational study included 113 patient with DME treated with intravitreal Razumab from a period of January 2024 to July 2025. Baseline demographic, systemic, and ocular characteristics were recorded. Primary outcomes were changes in best-corrected visual acuity (BCVA) and central macular thickness (CMT) from baseline to follow-up. BCVA was recorded in logarithm of the minimum angle of resolution (logMAR) units, while CMT was measured in micrometers. Assessments were conducted at baseline, 1 month, 3 months, and at the final follow-up visit. Safety was evaluated by documenting any injection-related adverse events.

Results: The study comprised of 63 females (55.8%) and 50 males (44.2%), with a mean age of 61.58 ± 7.42 years. Most patients had center-involving DME (79.6%), and the mean HbA1c was 8.63 ± 1.21%. The average number of Razumab injections was 2.91 ± 1.04, with a mean follow-up duration of 5.03 ± 1.11 months. Mean BCVA improved significantly from 0.71 ± 0.26 log MAR at baseline to 0.42 ± 0.19 log MAR at final follow-up ($p < 0.001$). Mean CMT decreased significantly from 468.06 ± 67.19 µm to 339.64 ± 76.28 µm ($p < 0.001$). A visual response of at least 0.1 logMAR was achieved in 104 patients (92.0%), while an anatomical response of at least 50 µm reduction in CMT was observed in 108 patients (95.6%). Patients with centre-involving DME showed greater BCVA improvement ($p = 0.035$) and greater CMT reduction ($p = 0.002$) than those with non-center-involving DME. Intravitreal Razumab was generally well tolerated; transient intraocular pressure rise occurred in 5 patients (4.4%), subconjunctival hemorrhage in 8 (7.1%), and mild anterior inflammation in 1 (0.9%), with no case of endophthalmitis.

Conclusion: Intravitreal Razumab was associated with significant short-term improvement in both visual acuity and macular thickness in patients with DME, with an acceptable safety profile. These findings support its usefulness as an effective treatment option in routine tertiary-care practice.

Keywords*: diabetic macular oedema, Razumab, intravitreal injection, visual acuity, central macular thickness.*

INTRODUCTION

Diabetic macular oedema (DME) is one of the leading causes of visual impairment in people with diabetic retinopathy and remains a major public health challenge because of the rising global burden of diabetes mellitus.[1] The pathogenesis of DME is multifactorial, but vascular endothelial growth factor (VEGF)-mediated disruption of the blood-retinal barrier plays a central role in increasing vascular permeability and promoting retinal thickening, which provides the biological basis for anti-VEGF therapy.[2]

Over the past decade, intravitreal anti-VEGF agents have become the standard first-line treatment for center-involving DME because they produce superior visual and anatomical outcomes compared with older laser-based approaches in appropriately selected eyes.[3] Among these agents, ranibizumab has been supported by robust randomized clinical trial evidence. In the RISE and RIDE studies, ranibizumab produced significant and sustained improvements in best-corrected visual acuity (BCVA) and central retinal thickness in eyes with DME.[4,5] Comparative effectiveness data from Protocol T further established anti-VEGF therapy as a central component of DME management in routine practice, while also highlighting that visual gains may vary according to baseline vision and treatment strategy.[6]

Despite the efficacy of innovator ranibizumab, treatment affordability and access remain important barriers in low- and middle-income settings, where the need for repeated injections may limit adherence and long-term disease control.[7] Razumab, the first biosimilar of ranibizumab approved in India, was introduced to address this gap by providing a lower-cost anti-VEGF option for retinal vascular diseases, including DME[7]. Emerging real-world studies from India have suggested that biosimilar ranibizumab can achieve meaningful improvements in visual acuity and central macular thickness with an acceptable short-term safety profile, and comparative analyses have reported outcomes broadly similar to those of innovator ranibizumab in DME.[7,8]

However, evidence remains particularly valuable in DME because treatment outcomes in routine clinical practice may differ from those reported in clinical trials owing to variations in baseline metabolic status, retinopathy severity, follow-up adherence, injection frequency, and health-system constraints.[3,6] Additional center-specific data are therefore important to understand how intravitreal Razumab performs in everyday practice, especially in Indian tertiary-care settings where patient profiles and treatment patterns may differ from those in controlled trials.[7,8]

In this context, the present study was designed to evaluate the efficacy and short-term safety of intravitreal Razumab in patients with DME at a tertiary care hospital, with particular emphasis on changes in BCVA and central macular thickness over follow-up, as well as the association of baseline demographic and ocular characteristics with treatment outcomes.

Materials and Methods

Study design and setting

This was a retrospective observational study conducted at the Department of Ophthalmology, Sir Thutop Namgyal Memorial hospital, Gangtok, Sikkim over a period from January 2024 to July 2025. The study evaluated the efficacy and short-term safety of intravitreal Razumab in patients with diabetic macular edema (DME) treated during routine clinical practice.

Study population

A total of 113 patient records with DME treated with intravitreal Razumab during the study period were included in the analysis. The dataset comprised both unilateral and bilateral disease presentations, as documented in the medical records. Demographic characteristics systemic profile, and ocular features were recorded.

Eligibility criteria

Records were included if the patient had a diagnosis of DME, had received intravitreal Razumab during the study period, and had available baseline and follow-up documentation for visual and anatomical assessment. Records with incomplete key outcome data or inadequate follow-up information were excluded from analysis.

Data collection

Data were collected retrospectively from hospital case records. Baseline demographic and systemic variables included age, sex, duration of diabetes, glycated hemoglobin (HbA1c), hypertension, dyslipidemia, and insulin use. Ocular variables included eye laterality, type of DME (center-involving or non-center-involving), severity of diabetic retinopathy, and lens status. The number of Razumab injections administered and total follow-up duration were also recorded.

In patients with bilateral disease, the ocular status was documented as bilateral involvement at baseline, while treatment outcome assessment was based on the treated eye data available in the record.

Treatment protocol
All patients received intravitreal Razumab as part of routine institutional management for diabetic macular edema (DME). Decisions regarding initiation of therapy, need for repeat injections, and follow-up intervals were made by the treating ophthalmologist based on clinical findings and optical coherence tomography (OCT) assessments. The total number of Razumab injections administered during the observation period was recorded for each patient.

Outcome measures
The primary outcome measures were change in best-corrected visual acuity (BCVA) and change in central macular thickness (CMT) following treatment. BCVA was recorded in logarithm of the minimum angle of resolution (logMAR) units, and CMT was recorded in micrometers on optical coherence tomography.

Assessments were noted at baseline, 1 month, 3 months, and final follow-up. A visual responder was defined as a case showing an improvement of at least 0.1 logMAR from baseline to final follow-up. An anatomical responder was defined as a case showing a reduction of at least 50 µm in CMT over the same interval.

For overall response assessment, treatment outcome was categorized as good or partial response. A good response was defined as clinically meaningful improvement in both functional and anatomical parameters, namely an improvement of at least 0.1 logMAR in BCVA together with a reduction of at least 50 µm in CMT from baseline to final follow-up. A partial response was defined as improvement in only one of these domains or improvement in both domains without meeting both predefined thresholds.

Safety assessment
Injection-related adverse events documented during follow-up were recorded. These included transient rise in intraocular pressure, subconjunctival haemorrhage, mild anterior inflammation, and endophthalmitis.

Statistical analysis
Data were analysed using SPSS Statistics for Windows, version 26.0. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequency and percentage. Changes in BCVA and CMT across follow-up visits were analysed using repeated-measures analysis. Comparisons of follow-up values with baseline were performed using appropriate paired statistical tests. A p-value <0.05 was considered statistically significant.

Associations between baseline demographic or ocular characteristics and treatment outcomes were explored using subgroup analysis. Differences in continuous outcome measures such as BCVA improvement and CMT reduction were assessed using appropriate comparative tests, while categorical treatment response was analyzed using chi-square test or Fisher's exact test as applicable

This was a retrospective record-based observational study. No additional intervention was performed for research purposes. Patient confidentiality was maintained throughout data collection and analysis, and all data were handled in a de-identified manner.

Results
A total of 113 patient records of diabetic macular oedema treated with intravitreal Razumab during the study period were analyzed. The cohort comprised 63 females (55.8%) and 50 males (44.2%). Right-eye involvement was documented in 65 patients (57.5%), left-eye involvement in 41 patients (36.3%), and bilateral DME in 7 patients (6.2%). The baseline profile indicated a predominantly middle-aged to elderly diabetic population with a substantial burden of systemic comorbidity. Most cases had center-involving DME, and moderate and severe non-proliferative diabetic retinopathy constituted the largest subgroups. The mean HbA1c was elevated, consistent with a metabolically high-risk cohort. The average number of Razumab injections administered was 2.91 ± 1.04, with a mean follow-up duration of 5.03 ± 1.11 months (Table 1).

Table 1. Baseline demographic, systemic, and ocular characteristics of the study cohort

Characteristic	Value
Age (years)	61.58 ± 7.42
Female	63 (55.8)
Male	50 (44.2)
Right-eye	65 (57.5)
Left-eye	41 (36.3)
Bilateral DME	7 (6.2)

Center-involving DME	90 (79.6)
Non-center-involving DME	23 (20.4)
Moderate NPDR	49 (43.4)
Severe NPDR	49 (43.4)
PDR	15 (13.3)
Phakic lens	69 (61.1)
Pseudophakic lens	44 (38.9)
Duration of diabetes (years)	10.76 ± 3.71
HbA1c (%)	8.63 ± 1.21
Number of Razumab injections	2.91 ± 1.04
Follow-up duration (months)	5.03 ± 1.11
Hypertension	76 (67.3)
Dyslipidemia	54 (47.8)
On insulin	65 (57.5)

Change in best-corrected visual acuity after treatment

Best-corrected visual acuity improved progressively after treatment. The mean BCVA improved from 0.71 ± 0.26 logMAR at baseline to 0.42 ± 0.19 logMAR at final follow-up. The improvement was significant as early as 1 month and remained significant at 3 months and final follow-up (all $p < 0.001$). Repeated-measures analysis demonstrated a significant overall time effect on BCVA ($p < 0.001$). A visual response of at least 0.1 logMAR was achieved in 104 patients (92.0%) (Table 2, Figure 1).

Table 2. Best-corrected visual acuity over follow-up after intravitreal Razumab

Time point	Mean BCVA (logMAR) ± SD	95% CI	p value vs baseline
Baseline	0.71 ± 0.26	0.66 to 0.76	
1 month	0.59 ± 0.22	0.55 to 0.63	<0.001
3 months	0.48 ± 0.20	0.44 to 0.52	<0.001
Final follow-up	0.42 ± 0.19	0.38 to 0.45	<0.001

Additional visual outcome summary.

Outcome	Value
Mean BCVA improvement from baseline to final follow-up (logMAR)	0.29 ± 0.14
Visual responder (≥0.1 logMAR improvement)	104 (92.0)
Overall response: Good	99 (87.6)
Overall response: Partial	14 (12.4)

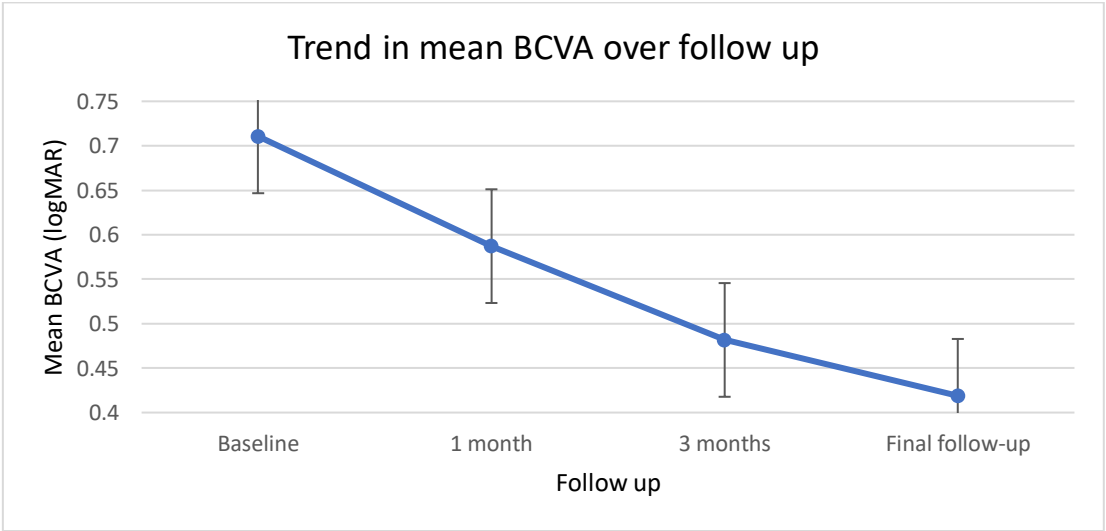

Figure 1. Trend in mean BCVA over follow-up

Error bars represent 95% confidence intervals.

Change in central macular thickness after treatment

Central macular thickness decreased steadily across follow-up visits, indicating a favorable anatomical response to treatment. The mean CMT declined from 468.06 ± 67.19 µm at baseline to 339.64 ± 76.28 µm at final follow-up. The

reduction was significant at 1 month, 3 months, and final follow-up compared with baseline (all $p < 0.001$). Repeated-measures analysis likewise confirmed a significant overall time effect on CMT ($p < 0.001$). An anatomical response of at least 50 µm reduction was observed in 108 patients (95.6%) (Table 3, Figure 2).

Table 3. Central macular thickness over follow-up after intravitreal Razumab

Time point	Mean CMT (µm) ± SD	95% CI	p value vs baseline
Baseline	468.06 ± 67.19	455.54 to 480.59	
1 month	408.39 ± 66.90	395.92 to 420.86	<0.001
3 months	367.40 ± 73.69	353.66 to 381.13	<0.001
Final follow-up	339.64 ± 76.28	325.42 to 353.86	<0.001

Additional anatomical outcome summary.

Outcome	Value
Mean CMT reduction from baseline to final follow-up (µm)	128.42 ± 49.04
Anatomical responder (≥50 µm reduction)	108 (95.6)

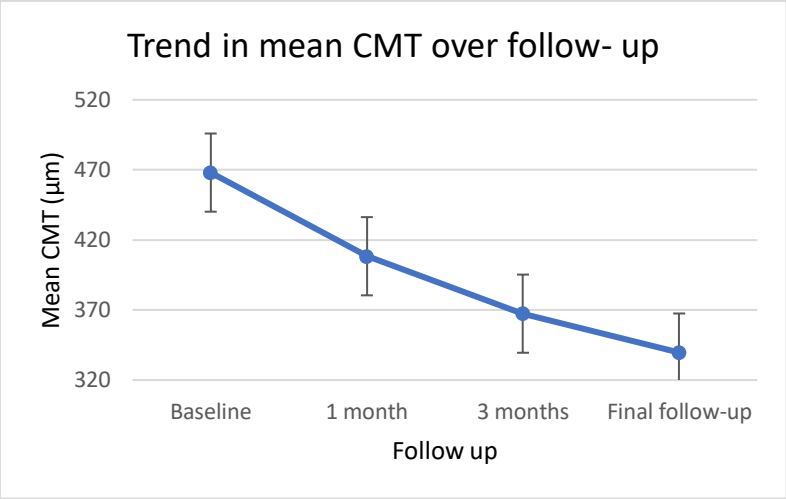

Figure 2. Trend in mean central macular thickness over follow-up

Error bars represent 95% confidence intervals.

Association of baseline demographic and ocular characteristics with treatment outcomes

Exploratory subgroup analysis showed that baseline diagnosis type was significantly associated with both visual and anatomical improvement. Patients with center-involving DME demonstrated greater improvement in BCVA than those with non-center-involving DME ($p = 0.035$) and also had a greater reduction in central macular thickness ($p = 0.002$). In contrast, sex, eye involvement, diabetic retinopathy severity, and lens status were not significantly associated with changes in BCVA or CMT. Good overall response was more frequent among females than males (93.7% vs 80.0%, $p = 0.043$), whereas eye involvement, diagnosis type, diabetic retinopathy severity, and lens status were not significantly associated with categorical response status (Table 4).

Table 4. Association of demographic and eye-related characteristics with treatment outcomes

Variable	Category	n	BCVA improvement (logMAR) ± SD	CMT reduction (µm) ± SD	Good overall response, n (%)	p value for response
Sex	Female	63	0.30 ± 0.14	127.63 ± 47.85	59 (93.7)	
	Male	50	0.29 ± 0.14	129.42 ± 50.96	40 (80.0)	
	p value		0.697	0.850		0.043
Eye involvement	Bilateral DME	7	0.36 ± 0.13	141.43 ± 46.46	7 (100.0)	
	Left eye	41	0.27 ± 0.13	135.78 ± 51.65	36 (87.8)	
	Right eye	65	0.30 ± 0.14	122.38 ±	56 (86.2)	

				47.42		
	p value for		0.200	0.304		0.572
Diagnosis type	Center-involving DME	90	0.31 ± 0.14	134.29 ± 50.61	79 (87.8)	
	Non-center-involving DME	23	0.24 ± 0.13	105.48 ± 34.50	20 (87.0)	
	p-value		0.035	0.002		1.000
Diabetic retinopathy severity	Moderate NPDR	49	0.27 ± 0.14	135.69 ± 42.86	43 (87.8)	
	PDR	15	0.34 ± 0.11	122.00 ± 65.99	13 (86.7)	
	Severe NPDR	49	0.29 ± 0.14	123.12 ± 49.08	43 (87.8)	
	p value		0.224	0.389		0.993
Lens status	Phakic	69	0.30 ± 0.14	132.64 ± 52.52	59 (85.5)	
	Pseudophakic	44	0.28 ± 0.14	121.82 ± 42.77	40 (90.9)	
	p value		0.414	0.234		0.560

Safety profile

Intravitreal Razumab was generally well tolerated. Transient intraocular pressure rise occurred in 5 patients (4.4%), subconjunctival haemorrhage in 8 (7.1%), and mild anterior inflammation in 1 (0.9%). No case of endophthalmitis was recorded (Table 5).

Table 5. Injection-related adverse events

Adverse event	n (%)
Transient intraocular pressure rise	5 (4.4)
Subconjunctival hemorrhage	8 (7.1)
Mild anterior inflammation	1 (0.9)
Endophthalmitis	0 (0.0)

Discussion

In this retrospective observational study of 113 patient records with diabetic macular edema treated with intravitreal Razumab, we observed significant improvement in both functional and anatomical outcomes over follow-up. Mean BCVA improved from 0.71 ± 0.26 logMAR at baseline to 0.42 ± 0.19 logMAR at final follow-up, while mean CMT decreased from 468.06 ± 67.19 µm to 339.64 ± 76.28 µm. The proportion of eyes achieving a visual response of at least 0.1 logMAR was 92.0%, and an anatomical response of at least 50 µm reduction in CMT was seen in 95.6%. These findings suggest that intravitreal Razumab was associated with clinically meaningful short-term benefit in this tertiary-care DME cohort.

The visual and anatomical improvements observed in our cohort are broadly consistent with published early Indian experience with Razumab. Sameera et al. reported favorable short-term efficacy and acceptable tolerability with biosimilar ranibizumab in routine ophthalmic practice, supporting the clinical usefulness of Razumab outside controlled trial settings.[9] Our findings also align with larger Indian pooled real-world evidence from the RE-ENACT program, which found that Razumab was associated with improvement in visual and disease-related outcomes across retinal vascular disorders, including diabetic macular edema, without new safety concerns.[10]

Our results are also directionally similar to real-world ranibizumab outcomes reported outside India. Patrao et al., in a United Kingdom National Health Service cohort, found that ranibizumab treatment for DME was associated with improvement in visual acuity and retinal thickness in routine practice, although treatment exposure and follow-up patterns differed from those of pivotal trials.[11] The consistency of our findings with such real-world ranibizumab data is relevant because Razumab is a biosimilar ranibizumab and would be expected to show comparable class-related functional and anatomical benefits in everyday care rather than only under trial conditions.[10,11]

An important feature of the present study is that these gains were achieved with a mean of only 2.91 ± 1.04 injections over an average follow-up of 5.03 ± 1.11 months. This matters because real-world anti-VEGF treatment intensity in DME is often lower than that seen in randomized controlled trials. Ciulla et al. showed that, in routine practice, patients

with DME typically receive fewer anti-VEGF injections and tend to have less favorable visual outcomes than those reported in clinical trials.[12] Against that background, the statistically significant BCVA and CMT improvements seen in our study suggest that Razumab can still deliver meaningful benefit within the constraints of real-world treatment patterns.

The baseline profile of our cohort further supports the real-world nature of the study population. The mean HbA1c was 8.63 ± 1.21%, hypertension was present in 67.3%, dyslipidemia in 47.8%, and insulin use in 57.5%, indicating a metabolically high-risk group. In addition, most cases had center-involving DME (79.6%), and moderate or severe NPDR accounted for the majority of retinopathy severity categories. This pattern is comparable to Indian clinical-practice data reported by Kulkarni et al., who likewise highlighted that DME outcomes in everyday care are influenced by systemic comorbidity burden, treatment adherence, and pragmatic treatment delivery rather than idealized trial conditions.[13] Our findings therefore add to the growing body of evidence that meaningful visual and anatomical gains are achievable even in metabolically complex patients seen in routine tertiary practice.

One of the more relevant findings of our subgroup analysis was that center-involving DME was associated with greater improvement in BCVA ($p = 0.035$) and greater reduction in CMT ($p = 0.002$) compared with non-center-involving DME. This is clinically plausible, because eyes with fovea-involving edema generally have greater baseline central thickening and may therefore demonstrate more measurable anatomical reduction after anti-VEGF therapy. Real-world comparative treatment data, such as those reported by Koç et al., support the view that functional and structural improvement in DME is influenced by baseline disease characteristics and treatment selection in routine care.[14] In contrast, sex, eye involvement, retinopathy severity, and lens status were not significantly associated with continuous changes in BCVA or CMT in our cohort, although females showed a higher proportion of good overall response than males (93.7% vs 80.0%, $p = 0.043$). Given the exploratory nature of these subgroup comparisons and the limited sample size within some categories, these findings should be interpreted cautiously.

The short duration of follow-up in the present study should also be considered when interpreting the results. Our data reflect early treatment response over approximately five months rather than long-term durability. However, longer-term real-world ranibizumab evidence suggests that improvement can be sustained in routine practice despite fewer injections than recommended in label-based regimens. In the ETOILE study, Kodjikian et al. found that real-world ranibizumab treatment in DME improved visual acuity over 24 months, even though injection frequency remained below protocol-driven trial intensity.[15] Thus, while our study cannot comment on long-term maintenance, the early direction of benefit is consistent with longer-term observational anti-VEGF literature.

The safety findings in our cohort were reassuring. Transient intraocular pressure rise occurred in 4.4%, subconjunctival hemorrhage in 7.1%, and mild anterior inflammation in 0.9% of cases, while no case of endophthalmitis was recorded. These adverse events are in keeping with the expected safety profile of intravitreal anti-VEGF therapy and are broadly consistent with published Indian real-world experience with Razumab, in which no major unexpected safety signals were observed.[9,10] Although the sample size and follow-up duration limit inference regarding rare adverse events, the absence of serious injection-related complications in this series is clinically encouraging.

This study has several strengths. It reflects routine tertiary-care practice, includes both functional and anatomical endpoints, reports responder analyses, and evaluates baseline factors associated with outcome. At the same time, it has important limitations. Its retrospective record-based design makes it vulnerable to missing data and selection bias. The study was conducted at a single center, the follow-up period was relatively short, and there was no parallel comparator arm using another anti-VEGF agent or treatment strategy. Retreatments were delivered according to real-world clinician judgment rather than a fixed protocol, which may also have influenced outcome variability. In addition, the use of patient-record-level reporting rather than a strict protocolized study-eye framework should be recognized as a methodological limitation.

Conclusion

Intravitreal Razumab was associated with significant short-term improvement in both BCVA and CMT in patients with diabetic macular edema in this tertiary-care observational cohort. The magnitude and direction of benefit were broadly consistent with published real-world evidence on Razumab and ranibizumab therapy[9-15] Razumab therefore appears to be an effective and well-tolerated treatment option for DME in routine clinical practice. Larger prospective studies with standardized retreatment criteria and longer follow-up are needed to better define long-term visual durability, anatomical outcomes, and predictors of response

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