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Comparative Evaluation of Razumab and Accentrix in Diabetic Macular Edema: Effects on Visual Acuity and Central Macular Thickness

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ABSTRACT

Background: Diabetic retinopathy is a microvascular disorder occurring as a long-term effect of diabetes mellitus. It may lead to vision-threatening damage to the retina that will eventually lead to blindness. It is the most common cause of severe vision loss in adults of working age groups in India and the Western world. Early detection and timely intervention are crucial in preventing blindness caused by diabetic retinopathy. Currently, anti-VEGF agents are the first-line treatment for central macular edema. Ranibizumab has beneficial effects in patients with baseline good visual acuity. This study aimed to find out the differences between the effects of Biosimilar and cost-effective Razumab and the Innovator brand Accentrix in terms of improving Visual Acuity and reducing Central Macular Thickness.

Materials and Methods: This randomised comparative study was done at Krishna Netralaya from March 2024 to December 2024. A total of 38 eyes were taken having Diabetes and were diagnosed with Diabetic Macular Edema. They were randomly given anti-VEGF injections, Razumab and Accentrix. They were divided into Group R (Razumab)= 14 and Group A (Accentrix)= 24.

Result: Improvement was comparable between two groups, Group A and group R in terms of Visual Acuity ($p<0.05$) whereas CMT showed statistically significant differences with Accentrix injection ($p<0.05$), but showed

no statistically significant differences with Razumab injection ($p>0.05$) with Wilcoxon W test.

Conclusion: Anti VEGF injection is a safe and effective treatment in case of Diabetic Macular Edema irrespective of age at the time of treatment. While both agents are effective in improving visual outcomes, Accentrix offer superior anatomical benefits. Further studies with larger sample sizes and longer follow-up are warranted to confirm these results and guide clinical decision-making.

Keywords: *Razumab, Accentrix, Diabetic Macular Edema (DME), Best Corrected Visual Acuity (BCVA), Central Macular Thickness (CMT), Optical Coherence Tomography (OCT), Intravitreal injection, Intra Ocular Pressure (IOP), Vascular Endothelial Growth Factor (VEGF)*

1. INTRODUCTION

Anti-VEGF, such as Ranibizumab, is a major treatment option for various retinal disorders such as DME [1], where VEGF plays a primary role in the disease pathogenesis [2]. DME is one of the leading causes of visual impairment in the working-age population in many countries. Innovator ranibizumab (IR) received the United States Food and Drug Administration (US-FDA) approval in 2006 [3]. However, the higher cost of the drug led to the development of a market for biosimilars known by the brand name Razumab (Intas Pharmaceuticals). It is the first ophthalmic biosimilar developed in India, which was approved by the Drug Controller General of India in 2015 [4]. Since then, Razumab has been widely implemented in India as a cost-effective treatment option [4]. There are multiple studies that have compared the pre- and post-treatment efficacy and safety of Razumab. However, comparative data on Razumab vs Accentrix are meagre. The innovator brand Accentrix and the cost-effective biosimilar Razumab [5][6] are compared for their effects on improving visual acuity and reducing macular thickness.

Objective: To evaluate and compare the effects of Razumab (R) and Accentrix (A) on visual acuity and central macular thickness in patients with DME.

2. MATERIALS AND METHODS

Study Design:

This was a prospective, randomised, single-centre trial conducted over 1 year. Patients were enrolled from March 2024 to December 2024 and randomised to receive either Razumab (R) or Accentrix (A). All procedure adhered to the tenets of the declaration of Helsinki, and patient confidentiality was strictly maintained throughout the study. Informed consent was obtained from all participants after explaining the purpose, procedures, and potential outcomes of the study.

Inclusion Criteria**:** Known case of DME, aged between 45 to 86 years of age, with controlled diabetes.

Exclusion Criteria: History of intra-vitreal injections given in past, history of any other systemic illness, history of pregnant and lactating women and history of any other ocular surgery which could hamper their vision.

Treatment Protocol: Patients in the Razumab (R) group received 14 intravitreal injections of Razumab, while the Accentrix (A) group received 24 injections of Accentrix. Patients in both groups received 3 injections at an interval of one month. Follow-ups were done after 1 month of each injection.

Procedure: All patients gone through a detailed ophthalmic evaluation prior to receiving intravitreal anti-VEGF injections. The evaluation included BCVA assessment using Snellen chart, slit-lamp biomicroscopy, IOP measurement, and dilated fundus examination. OCT was performed to assess CMT. Following a thorough explanation of the procedure, risks, and benefits, written informed consent was obtained from all patients. Systemic medical history was reviewed to rule out contraindications or active ocular infection. Both Accentrix (Ranibizumab) or Razumab (biosimilar Ranibizumab) were administered via intravitreal injection under aseptic conditions in a minor operating room.

Outcome Measures:

Primary Outcome: BCVA measured using the Snellen chart and CMT assessed by optical coherence tomography (OCT Topcon 3D Maestro Version 8.1X. 39040 MANEX811) at baseline and at every 1-month follow-up.

Safety Measures: Adverse events were monitored throughout the study period.

Statistical Analysis: Statistical analysis was performed using R version 4.4.2. Charts were drawn using Microsoft Office-Excel 365. Data was analyzed using an independent-t test, Wilcoxon W test and Mann-Whitney U test. Statistical significance was set at $p < 0.05$.

3. OBSERVATION & RESULTS

A total of 38 eyes were included in the study, with 13 eyes receiving intravitreal injections of Razumab (R) and 25 eyes treated with Accentrix (A). To evaluate treatment efficacy, Wilcoxon signed-rank tests were conducted to assess changes in VA and CMT before and after treatment in the overall cohort.

The descriptive statistics and normality assessments for age, VA, and CMT in the total cohort of 38 eyes in which the median age of participants was 66.5 years (IQR = 13.5), with a range from 45 to 86 years. Median pre-treatment VA was 0.3 LogMAR (IQR = 0.4), which improved to a median of 0.2 LogMAR (IQR = 0.3) post-treatment. Median CMT decreased from 298 µm (IQR = 63.1) to 276 µm (IQR = 42.9) following treatment. Normality of the data was assessed using the Shapiro-Wilk test. Pre- and post-treatment VA, as well as post-treatment CMT, showed statistically significant deviation from normality ($p < 0.001$), whereas age ($p = 0.063$) and pre-treatment CMT ($p = 0.365$) did not. Variables with non-normal distributions were flagged for the use of non-parametric statistical methods in subsequent analyses (as shown in Table 1). To compare outcomes between the treatment groups, Mann-Whitney U tests were performed. No statistically significant differences were found in either pre- and post-treatment VA ($p > 0.6$) or CMT ($p > 0.08$) between the Razumab and Accentrix groups (as shown in Table 2). A statistically significant improvement in VA was observed post-treatment ($W = 185$, $p = 0.001$), with 18 tied pairs. Similarly, a significant reduction in CMT was noted following treatment ($W = 553$, $p = 0.001$), with 1 tied pair. The alternative hypothesis tested was that the median difference (pre-treatment minus post-treatment) was greater than zero, indicating clinical improvement (as shown in Table 3). Subgroup analyses revealed that both the Accentrix and Razumab groups experienced statistically significant improvement in VA. The Accentrix group showed improvement ($W = 56$, $p = 0.04$), as did the Razumab group ($W = 41$, $p = 0.02$). In terms of anatomical outcome, the Accentrix group demonstrated a significant reduction in CMT ($W = 239$, $p = 0.01$), whereas the Razumab group showed a non-significant trend toward reduction ($W = 70$, $p = 0.09$) (as shown in Table 4). The within-group comparisons of VA and CMT for the Accentrix and Razumab treatment groups using the Wilcoxon signed-rank test shows, in the Accentrix group, a statistically significant improvement in VA was observed following treatment ($W = 56$, $p = 0.04$), along with a significant reduction in CMT ($W = 239$, $p = 0.01$). Similarly, the Razumab group demonstrated a significant improvement in VA ($W = 41$, $p = 0.02$). However, the reduction in CMT for the Razumab group did not reach statistical significance ($W = 70$, $p = 0.09$). These results supported a significant functional improvement in both treatment groups, while anatomical improvement was more

pronounced in the Accentrix group (as shown in Table 5).

The changes in CMT before and after treatment with both Razumab and Accentrix resulted in notable reductions in CMT, indicative of resolution of macular edema. However, Accentrix showed a slightly more consistent and pronounced reduction, suggesting a marginally superior anatomical response (as shown in Figure 1). The changes in VA measured in LogMAR units in which both agents led to functional visual improvement in patients with DME. While Accentrix demonstrated more substantial improvement in select cases, Razumab achieved comparable gains in most patients. These findings highlighted the clinical efficacy of both drugs, with Razumab serving as a cost-effective biosimilar alternative to Accentrix (as shown in Figure 2).

Table 1. Correlation between Age and Efficacy of treatment in the total cohort

Descriptives					
	Age	**Pre VA**	**Pre CMT**	**Post VA**	**Post CMT**
N	38	38	38	38	38
Median	66.5	0.3	298	0.2	276
IQR	13.5	0.4	63.1	0.3	42.9
Minimum	45	-1.9	217	-1.9	219
Maximum	86	1	418	1	447
Shapiro-Wilk p	0.063	< .001	0.365	< .001	< .001
Non-normal distributions (Shapiro-Wilk *p* < 0.05) are flagged for consideration in statistical tests.					

Table 2. Difference in pre- and post-VA and CMT (2 variables within)

Mann-Whitney U		
	Statistic	**p**
Pre VA	145	0.583
Post VA	148	0.644
Pre CMT	137	0.433
Post CMT	106	0.082
Note. $H_a\ \mu_A \neq \mu_R$		

Table 3. Pre and post-changes between groups A and R

Wilcoxon W			
		Statistic	**p**
Pre VA	Post VA	185	0.001
Pre CMT	Post CMT	553	0.001
Note. $H_a\ \mu_{\text{Measure 1 - Measure 2}} > 0$			
[a] 18 pair(s) of values were tied			
[b] 1 pair(s) of values were tied			

Table 4: Pre and Post-Changes in Group A and R

Descriptives	
	Median (IQR)
Pre VA (Accentrix)	0.3 (0.3)
Pre VA (Razumab)	0.3 (0.4)
Pre CMT (Accentrix)	281(64)
Pre CMT (Razumab)	310 (42)
Post VA (Accentrix)	0.2 (0.3)
Post VA (Razumab)	0.2 (0.3)
Post CMT (Accentrix)	272 (21)
Post CMT (Razumab)	300 (37)

Table 5. Comparison of VA and CMT within Group A and R

Wilcoxon W			
		Statistic	**p**
Pre VA (Accentrix)	Post VA (Accentrix)	56	0.04
Pre VA (Razumab)	Post VA (Razumab)	41	0.02
Pre CMT (Accentrix)	Post CMT (Accentrix)	239	0.01
Pre CMT (Razumab)	Post CMT (Razumab)	70	0.09
Note. H_a μ Pre ≠ μ Post			

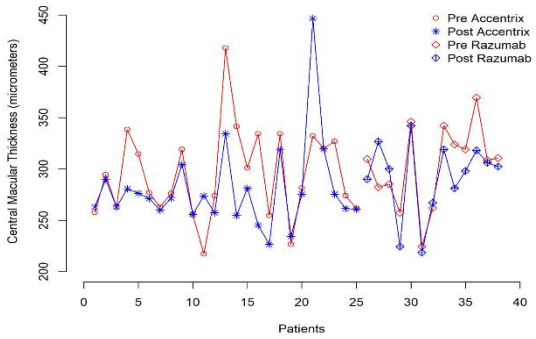

Fig 1 Pre and Post CMT changes after Accentrix or Razumab[1]

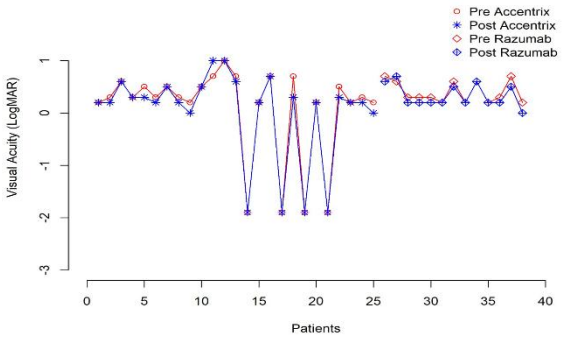

Fig 2 Pre and Post VA changes after Accentrix or Razumab[2]

4. DISCUSSION

In this study, it has evaluated the efficacy of intravitreal Accentrix and Razumab in patients with DME has been evaluated. Both agents led to statistically significant improvements in VA; however, only Accentrix resulted in a statistically significant reduction in CMT. The observed improvement in VA with both treatments aligns with previous studies that support the use of anti-VEGF agents in managing DME. The findings further suggest that while Razumab is good in enhancing functional

[1] The X-axis shows individual patients, while the Y-axis shows CMT values in μm. Red circles and triangles indicate pre-treatment CMT for A and R, respectively, blue stars and diamonds shows post-treatment values.
[2] The X-axis denotes individual patients, and the Y-axis shows visual acuity, with lower LogMAR values indicating better vision. Red markers denote pre-treatment values, and blue markers denote post-treatment values for each drug.

outcomes, its anatomical effect on CMT may be less than compared of Accentrix. This discrepancy may be attributed to pharmacokinetic or molecular differences between the agents, including potential variation in binding affinity or intravitreal stability. In a previous study by Chakraborty et al. [8], they concluded that biosimilar RBZ is similar to innovator RBZ in improving vision and reducing CMT in eyes with DME in the short term. A reassessment of the previously defined results shows that Accentrix performs better than Razumab in terms of anatomical benefits. The significant reduction in CMT observed after Accentrix administration aligns with its better efficacy in reducing retinal edema through VEGF inhibition [8]. In contrast, the absence of a significant CMT reduction in the Razumab group—otherwise there is an improvement in VA—may indicate a dissociation between anatomical and functional outcomes in certain patients. Such findings define the need for individualised treatment strategies and suggest a potential role for multimodal therapy in managing complex or suboptimal responders. Although the findings appear favorable, they require interpretation in the context of certain limitations. The relatively small sample size may constrain the generalizability of the results. Furthermore, the short follow-up duration limits the ability to assess long-term outcomes, including the sustainability of treatment effects and recurrence rates. To enhance the reliability and applicability of these observations, larger, randomised controlled trials with extended follow-up are warranted to better establish the comparative effectiveness and durability of response [10] between Razumab and Accentrix.

5. CONCLUSION

This study demonstrates that intravitreal injections of both Accentrix and Razumab lead to significant improvements in VA in patients with DME [12][14]. CMT significantly decreased following Accentrix treatment, whereas the reduction observed with Razumab was not statistically significant. These findings suggest that while both agents are effective in improving visual outcomes, Accentrix may offer superior anatomical benefits. Further studies with larger sample sizes and longer follow-up are warranted to confirm these results and guide clinical decision-making.

In conclusion, both Accentrix and Razumab improve visual acuity in DME patients, with Accentrix demonstrating superior anatomical efficacy. These findings may aid clinicians in selecting appropriate therapy based on individual patient needs and response patterns.

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