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COMPARISON OF EFFICACY AND RECURRENCE RATES OF RANIBIZUMAB AND RANIBIZUMAB BIOSIMILAR IN RETINOPATHY OF PREMATURITY

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Intravitreal Anti-vascular endothelial growth factor (AntiVEGF) therapy has revolutionized the treatment of Retinopathy of Prematurity (ROP). While Aflibercept is the only U.S. Food and Drug Administration (FDA) approved AntiVEGF for treatment of ROP, Ranibizumab and its biosimilars have offered an affordable option for such patients but there is no data comparing their effectiveness. So in this study we aim to compare the recurrence rate and outcomes of Ranibizumab biosimilars as compared to Ranibizumab Intravitreal AntiVEGFs.

We retrospectively analyzed the data of babies undergoing intravitreal AntiVEGF injections for treatment of ROP From december 2022 to december 2025. Babies treated with intravitreal injections of Ranibizumab and Ranibizumab biosimilar who were not lost to followup were included in the study and divided into Two Groups Group A and Group B. Group A received Intravitreal injections of Ranibizumab and Group B were treated with injections of Ranibizumab biosimilar. We studied and compared the demographic characteristics, morphological details of ROP, response to treatment, incidence of recurrence, Interval of recurrence from the time of injection, need for repeat treatments and anatomical outcomes.

We had 52 eyes in Group A and 46 eyes in Group B who underwent respective injections for ROP. Both groups were comparable with respect to baseline demographic characteristics. In either of the groups the most common indication was Aggressive ROP (AROP) ($p=0.0747$). All eyes responded to the initial antiVEGF injections given in both groups. 53.85% eyes in Group A and 65.22% eyes in Group B had recurrence ($p=0.25$). PMA of recurrence was significantly lower in Group B (38.73 ± 4.57 weeks) as compared to Group A (43.14 ± 1.76 weeks); $P<0.0001$. Group B also had a significantly earlier recurrence at 6.13 ± 2.13 weeks as compared to Group A (8.36 ± 1.25 weeks); $P<0.0001$. Recurrences in both the groups were majorly staged ROP. Out of the eyes undergoing reintervention 52% in Group A and 71.79% in group B had recurrence ($p=0.0385$). Majority of the eyes in either group were treated with laser upon reintervention (0.1279). 92% eyes in group A and 84.09% in Group B had good anatomical outcomes.

In Our study both the ranibizumab and the biosimilar groups had comparable recurrences. However, the recurrence was earlier and at a lower PMA in case of biosimilars. Most recurrences were managed by laser in either of the two groups. This is a very small sample size and detailed studies need to be done, but for now biosimilars are slowly becoming crowd-favorite in middle income countries like India due to better affordability.

Prajapati V, Choudhary T, Chauhan W, Shah S, Handa R, Jahan B, Malviya S, Sengupta S. Efficacy of a biosimilar ranibizumab monotherapy for the treatment of retinopathy of prematurity. Indian J Ophthalmol. 2023 Feb;71(2):411-415. doi: 10.4103/ijo.IJO_973_22. PMID: 36727329; PMCID: PMC10228963.