Original article

Effectiveness of Intravitreal Bevacizumab Monotherapy in the Treatment of Retinopathy of Prematurity: An Experience of a Tertiary Care Hospital in Central Punjab

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ABSTRACT

Background: Retinopathy of prematurity (ROP) is a leading cause of preventable childhood blindness especially in low- and middle-income countries where neonatal survival has improved but screening remains limited. Intravitreal anti VEGF agents offer a promising alternative to laser photocoagulation. The objective of this study was to determine the frequency of ROP in preterm neonates and assess the effectiveness of intravitreal bevacizumab IVB monotherapy for Stage 3 ROP.

Methods: This prospective interventional study was conducted at Sir Ganga ram hospital Lahore from September 2021 to March 2023. A non-probability consecutive sampling was used to recruit eligible preterm neonates (<35 weeks gestation; 1000 to 2200 grams birth weight) referred from the neonatal unit. Data was collected through structured clinical assessments and standardized retinal examinations using indirect ophthalmoscopy using structured questionnaires. Neonates with Stage 3 ROP and Zones three were treated with 0.625 milligram IVB under topical anesthesia and followed weekly for regression descriptive analysis was performed.

Results: Among 463 neonates screened, 115 (24.8%) had ROP. of these 31 (26.9%) met treatment criteria. IVB alone led to complete regression in 23 (74.2%) within 8 to 12 weeks. Eight (25.8%) required adjunct laser therapy, achieving 100% resolution. No adverse ocular or systemic outcomes or recurrences were reported at one year follow-up.

Conclusion: IVB monotherapy was safe and effective for Stage 3 ROP in this low resource setting. These findings supported teams where laser treatment access is limited.

Keywords:

Retinopathy of Prematurity, Bevacizumab, Infant, Premature

INTRODUCTION

Retinopathy of prematurity (ROP) is a visual proliferative retinal disorder and the leading cause of childhood blindness worldwide. While ROP incidence in high income countries is around 5 to 8% but it climbs to 25 to 30% in middle income nations.[1] In Pakistan, tertiary centers documented prevalence of 8%, highlighting rising incidence with improving neonatal survival and limited screening coverage.[2] ROP most commonly affects infants born at ≤32 weeks gestation or ≤1500 g birth weight. Additional risk factors include oxygen supplements, anemia, intra ventricular hemorrhage, and poor post-natal weight gain.[3] Mild ROP often regresses spontaneously but aggressive form like Stage 3 or aggressive posterior ROP (APROP) threaten retinal detachment and blindness without timely intervention.[4] Laser photocoagulation has long been the standard treatment. However, it requires general anesthesia and is associated with high post treatment myopia.[5] Over the past decade, intravitreal anti-VEGF injections such as bevacizumab (IVB) and ranibizumab (IVR) have emerged as a viable alternative. The BEAT-ROP trial and subsequent follow up confirmed less efficacy in Zone 1 and posterior Zone 2, Stage 3 + ROP, with significantly fewer recurrence 4% versus 22% and less myopic shift at two years.[6] The CARE-ROP and network meta-analysis 2024 further validated low dose IV and IVR as non-inferior to laser in anatomical outcomes while being associated with better refractive profile.[7] However, concerns remain about systemic safety and long term neurodevelopmental impact. Despite robust international data, there is limited prospective on monotherapy focused evidence from low resource setting like Pakistan particularly regarding regression rates, recurrence and

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neurodevelopmental safety following IVB injection. The objective of this study was to determine the frequency of ROP in preterm infants and evaluate the effectiveness of IVF monotherapy in in inducing ROP regression.

SUBJECTS AND METHODS

This prospective study interventional was carried out in the Department of Ophthalmology at Sir Ganga Ram Hospital Lahore, Pakistan in collaboration with Department of Pediatrics. Preterm neonates referred from the neonatal unit were screened and managed for retinopathy of prematurity (ROP). The study was conducted between September 2021 and March 2023 after approval from Institutional Ethical Review Board.

ROP screening followed the international classification of retinopathy of prematurity.[8] The first retinal examination was performed at four weeks after birth, based on American Academy of Pediatrics guidelines which recommend initial screening between 4 to 6 weeks.[9] Infants included in the study were born before 35 weeks of gestation and had a birth weight between 1000 and 2200 grams. Any baby presenting with Stage 4 or 5 ROP, requiring surgical intervention, unfit for intravitreal injections, or needing repeat anti-VEGF injections was excluded.

All retinal examinations were performed by a consistent ophthalmology team using indirect ophthalmoscopy with scleral indentation and 28 D lens under pharmacology mydriasis and topical anesthesia. Infants without signs of ROP at initial screening were reevaluated every two weeks until 40 weeks gestational age. Those with Zone 3, Stage 1 or 2 disease without pre-plus or plus disease were monitored at one to two weeks intervals depending on vascular activity and Zone involvement in accordance with American Academy of Pediatrics screening intervals[9], to monitor for spontaneous regression and ensure timely detection of progression.

Those preterm babies identified with clinical features of ROP were assessed and documented according to the international classification of ROP including Zone 1-3, Stage 1-5. Presence or absence of pre-plus or plus disease and laterality unilateral or bilateral involvement.[8] Neonates diagnosed with Stage 3 ROP in Zone 1-2 or three with or without pre-plus or plus disease, either at first presentation or during follow up were considered for treatment with intravitreal bevacizumab (IVB) monotherapy. Prior to treatment the parents or guardians were counseled regarding the disease severity potential complications including blindness and retinal detachment and the risk and benefits of IVB injections, informed consent was obtained. Bevacizumab 0.625 mg/0.025 mL was ordered from licensed compounding pharmacy in prefilled 31-gauge insulin syringes. All injections were performed in the operating theatre under aseptic conditions. After installing topical proparacaine and applying a sterile speculum, the ocular surface was cleaned with 5% povidone iodine. The injection was delivered via the pars plana in the suprotemporal quadrant, 2M from the limbus using a 31-gauge needle. In bilateral cases, the same procedure was repeated for the fellow eye in the same sitting.

Vital signs were monitored throughout the procedure by a pediatric anesthetist. Post injection, moxifloxacin eye drops were prescribed four times daily for one week. Infants were admitted to the pediatric unit for monitoring for potential systemic complications, including intermittent hypoxia. Once stable, they were discharged for outpatient follow up.

One week after injection, pupils were dilated using combination of cyclopentolate, tropicamide, and phenylephrine and the retina was examined with the 28 D lens. Follow up evaluations were continued weekly after one month and then every two weeks until regression was confirmed.

If regression was inadequate or if there was evidence of progression or recurrence, diode laser photocoagulation was performed under general anesthesia. Laser spots were applied in all quadrants of the avascular retina using an 810-nanometer diode laser, from the vascularized retina to the Ora serrata. Post laser care included antibiotics and steroid drop for one week. Follow up were scheduled weekly for the first month and then monthly until the disease resolved.

Data were analyzed descriptive statistics included frequencies and percentages for categorical variables (gender, ROP Stages, treatment outcomes) and means with standard deviations for continuous variables (gestational age, birthweight). Neonates were grouped by ROP status (no ROP, ROP not requiring treatment, ROP requiring treatment) and subgroup comparisons were made descriptively. Weekly follow up trends and treatment outcomes were analyzed. No inferential statistics were applied as the study aimed to describe clinical patterns and treatment responses.

RESULTS

A total of 463 preterm neonates referred by the Pediatric Department of Sir Ganga Ram Hospital Lahore to the Eye Department of same hospital were screened. Among them, 223 (48.2%) were male and 240 (51.8%) were female. Based on gestational age, 196 (42.3%) neonates were born between 32–35 weeks, 219 (47.3%) between 30–32 weeks, and 48 (10.4%) were born before 30 weeks. The mean gestational age was 31.4 ± 1.5 weeks. Regarding birth weight, 256 (55.3%) neonates weighed between

Table 1: Clinical and demographic characteristics of screened preterm neonates (n = 463)

Variables	Total preterm neonates screened n= 463	Retinopathy of prematurity not requiring treatment n= 84	Retinopathy of prematurity requiring treatment n = 31
Mean gestational age (weeks)	31.4 ± 1.5	30.6 ± 1.4	30.1 ± 1.2
Mean birth weight (grams)	1296 ± 265	1221 ± 228	1182 ± 215

Table 2: Frequency of retinopathy of prematurity and distribution of ROP Stage and Zone among neonates treated with intravitreal bevacizumab (n=31)

Variable	Frequency	Percentage
Retinopathy of prematurity (n=463)		
Yes	115	24.8%
No	348	75.2%
Regression in ROP (n=84)		
After 3rd week	27	32.1%
After 4th week	26	31.0%
After 5th week	4	4.8%
After 6th week	17	20.2%
After 7th week	10	11.9%
ROP Stage and Zone among neonates (n=31)		
Stage 3, Zone 3 with pre-plus disease	5	16.1%
Stage 3, Zone 2 without pre-plus or plus disease	7	22.6%
Stage 3, Zone 2 with plus disease	5	16.1%
Stage 3, Zone 2 with pre-plus disease	8	25.8%
Stage 3, Zone 1–2 with plus disease	4	12.9%
Stage 3, Zone 1 with pre-plus disease	2	6.5%

Table 3: Treatment outcomes of neonates with Stage 3 ROP treated with intravitreal bevacizumab

Treatment outcome	Frequency	Percentage
Treated with IVB monotherapy only (n = 31)		
Achieved complete regression within 8–12 weeks	23	74.2%
Not achieved complete regression within 8–12 weeks	8	25.8%
Additional laser photocoagulation after IVB (n = 8)		
Achieved complete regression after IVB + laser within 2–3 months	8	100.0%
Not achieved complete regression after IVB + laser within 2–3 months	0	0.0%
Adverse events (n = 31)		
Recurrence of ROP at 1-year follow-up	0	0.0%
Ocular or systemic complications post-IVB	0	0.0%
Required extended NICU stay post-IVB	0	0.0%

1000–1500 g, 172 (37.1%) between 1501–2000 g, and 35 (7.6%) weighed more than 2000 g, with a mean birth weight of 1296 ± 265 g.

Out of the 463 neonates, 348 (75.2%) had no evidence of ROP on first screening. These patients continued biweekly or triweekly screening until reaching 40 weeks of gestation. ROP was detected in 115 (24.8%) neonates. Among them, 84 (73%) presented with Stage 1 or 2 ROP in Zone 3 and did not require any intervention. The mean gestational age and birth weight in this group were 30.6 ± 1.4 weeks and 1221 ± 228 g, respectively (Table 1).

These neonates were monitored weekly to assess progression, or regression in ROP severity with no intervention. Of these 84 neonates, 27 recovered after the 3rd weekly follow up, 26 recovered after 4th weekly follow up, 4 neonates recovered after 5th weekly follow up, 17 recovered after 6th weekly follow up and 10 recovered after 7th weekly follow up. The remaining 31 (26.9%) neonates had Stage 3 ROP in Zones 1–3 with or without plus disease and were treated with intravitreal Bevacizumab (IVB) monotherapy. No procedural complications, such as vitreous hemorrhage, or endophthalmitis, were noted. All patients were discharged within 12 hours of the procedure, and no one required prolonged NICU admission (Table 2).

At the first follow-up (1 week post-injection), regression of plus disease and vessel tortuosity was noted in all treated cases. Progressive improvement in disease Stage continued through weekly follow-ups. Complete ROP regression was achieved in 23 (74.2%) neonates within 8–12 weeks post-injection. No recurrence was observed during 1-year follow-up. The remaining 8 (25.8%) neonates showed partial regression post-IVB, with persistent Stage 3 disease in Zones 1–2. These patients underwent additional laser photocoagulation 2–3 weeks

after IVB. All cases showed full regression within 2–3 months post-laser without reactivation at 1-year follow-up (Table 3).

DISCUSSION

In developed as well as developing nations, incidence of retinopathy of prematurity (ROP) is on a rise due to the improved survival rate of pre-term infants with low birth weight. The variable use of oxygen in NICU for preterm babies' survival increases the chance of ROP formation. In addition, lack of ROP awareness and screening services in resource-limited regions of the world is a factor for its progression resulting in blindness.[1]

ROP treatment has been evolved over past years with current options like screening, cryotherapy, laser photocoagulation and more recently anti VEGF.[10] Laser or cryotherapy for ROP typically requires general anesthesia posing related risks. Though effective, laser may cause adverse effects such as peripheral field loss, cataract, hemorrhage, synechiae, strabismus high myopia and scarring.[11]

This study was conducted by ROP specialists at a single tertiary public hospital utilized intravitreal bevacizumab and off label cost effective anti-VEGF agent. Bevacizumab is a humanized monoclonal antibody that blocks all the VEGF isoforms and has a systemic half-life of approximately 20 days.[12] Patients received a single dose of IVB bevacizumab (0.625 mg/0.025 mL) the most recommended dose for ROP, achieving complete resolution in 23 (74.2%) cases.[13] In the BEAT-ROP study group, the lower limit of bevacizumab 0.031 mg was used, which was only 0.6% of the dose, and found to be equally effective to other recommended doses for ROP treatment.[14] Administration of this low dose demonstrated better structural outcomes and reduced risk of neurodevelopmental or other organs disabilities.[15] Lately, multicenter, dose de-escalation phase-1 study, conducted by the Pediatric Eye Disease Investigator Group (PEDIG) reported that 0.004 mg of bevacizumab could be the lowest effective dose minimizing systemic adverse effects and promoting normal retinal vascu-larization.[16]

All neonates in this study received intravitreal injections under topical anesthesia in the eye theater without any anesthesia related complications. Unlike, a previous study that used sedation for older or fragile infants no sedation was needed.[17] In this study, IVB was injected in the superotemporal quadrant 2mm from the limbus. No ocular complications e.g. hemorrhage, cataract, detachment, endophthalmitis or need for extended NICU stay were observed. All patients were discharged within 12 hours. Similarly reported no immediate or delayed adverse effects requiring prolonged hospitalization.[18] SAFER-ROP study suggested that site of injection 0.75 mm to 1.0 mm from the limbus is a safe Zone to reduce intravitreal anti-VEGF related complications in ROP.[19] Another study documented effects like intraocular inflammation, corneal opacification, endophthalmitis, cataract formation, ocular hemorrhage, and retinal detachment.[20] In this study, most patients had bilateral ROP requiring IVB injection in one sitting in both eyes. Similarly, one study demonstrated bilateral injection of anti-VEGF (on same day) in 67.8% of the neonates.[21] Although bilateral injecting anti-VEGF on same day in bilateral ROP babies is logistically more convenient, this same day procedure practice is not recommended for bevacizumab in VRSI and AIOS guidelines.[21] However, the researcher assumed delay in treatment to the second affected eye can affect functional and anatomical success.

Of all neonates, 48.2% were males and 51.8% females. In another study group, male sex distribution was reported to be higher 50.4% than their female 49.6% ROP neonates.[22] In this study, initial ROP screening was performed at 4 weeks post-delivery. Of 463 neonates, the mean gestational age was 31.4 weeks, 196 were born at 32 to 35 weeks, 219 at 30-32 weeks and 48, before 30 weeks. Mean birth weight was 1296 ± 265 g, with 256 infants weighing 1000 to 1500 g. 172 between 1501 to 2000 g and 35 over 2000 g. A recent local study similarly reported a mean gestational age of 30 ± 1.4 weeks and birth weight of 1275 ± 155 g in infants with type 1 ROP.[23]

Most patients in present study treated with IVB monotherapy had ROP in Zone 2 with pre-plus/plus disease. Regression and peripheral retinal vascularization occurred in these neonates within 2-3 months post injection. Out of 31 ROP injected with IVB, 8 (25.8%) neonates required additional laser application as ROP findings in Zone 1-2 showed initial regression and some peripheral vascularization but then remained static. Aggressive posterior ROP in Zone 1 has been reported in many studies and identified as a risk factor for ROP recurrence following IVB.[24-26] In a previously published study, among 202 infants that developed ROP, 66 progressed to ROP requiring treatment. In these, 57 (12.6%) neonates underwent ROP treatment (14 intravitreal anti-VEGF, 33 laser photocoagulation therapy and 10 needed both treatments) and the remaining 9 patients had spontaneous improvement of ROP requiring no treatment.[22] In another study, a total of 67 (38%) of 178 infants screened for ROP developed any grade of ROP and of these, 11 (16%) patients received intravitreal anti-VEGF. [24] No Stage 4 or 5 was seen in this study. A reason for this could be single tertiary center study, early screening with strict regular follow up and early interventions and as and when required. Thus, timely screening, identification of staging, Zone or ROP and early IVB intervention resulted in prevention to progression of ROP to Stage 4 and

beyond. Retinal examinations with long-term follow-ups are required as ROP can recur as late as 69 weeks post injection of anti-VEGF drugs.[27] In this study, all ROP IVB monotherapy and combined laser treated patients had fundus examination at 24 weeks and then 48 weeks post injection, to rule out any ROP reactivation. Our last follow-up had no ocular reactivation. In comparison, Ling & co researchers documented an overall recurrence rate of 12.9% (44 of 340 eyes) after treatment with IVB, IVR (ranibizumab) and laser. Compared with the laser group, the IVB and IVR groups exhibited recurrence at later ages (43.4 ± 3.5 weeks for the IVB group, 42.3 ± 2.0 weeks for the IVR group, and 39.5 ± 2.8 weeks for the laser group; p-value = 0.0058.[28] A recent study by Feng-Yue Wu and colleagues reported 36.4% (12 of 33 eyes) recurrences 45.3 (5.1, 50.9) months after initial IVR treatments. They used IVR in comparison to IVB in our case series.[27] Similar findings were reported by Verma and coresearchers with reactivation identified in 8 (33.3%) eyes with a mean follow-up time of 50.2 ± 1.4 weeks after IVB.[18] Thus, longer follow up with anti VEGF is needed to rule out recurrence. In addition to ocular evaluation to rule out ROP recurrence, our case study (IVB monotherapy and laser) had pediatric evaluation on last 48 week follow up and no developmental delays were seen. Studies on systemic safety have reported lower motor skills and more possibilities of developing neurodevelopmental disability in patients receiving bevacizumab compared with laser therapy.[29] As VEGF has an important role in development of retina, lungs, and brain, a long-term follow-up is needed to assess any developmental issues in organ systems.

This study has a limited sample size with the last follow up at 48 weeks. Longer follow up for ROP reactivation and pediatric evaluation are required since the recurrence of ROP and neurodevelopmental delays can occur up to 69 weeks post treatment using anti VEGF.

CONCLUSION

Intravitreal anti-VEFG bevacizumab therapy is effective in ROP regression. Effective screening and timely management are essential to identify high-risk infants and avoid visual morbidity. Additionally, this treatment is suitable for babies who do not qualify for laser therapy due to poorly dilating pupils and vitreous haze.

Author Contributions

Huma Kayani Saigol: Conception and design, analysis and interpretation of data, drafting the article, critical revision for important intellectual content, final approval.
Khurram Chuhan: Collection data, theatre assistance and follow up.
Abdul Rauf: Collection data, theatre assistance and follow up.
Seemab Akbar: Collection data and follow up.
Maham Javed: Collection and statistical analysis.
Madeeha Naeem: Collection of data and theatre injection assistance.
Muhammad Salman: Patients collection data management and parental guidance for follow up.

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