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# Effects of Intravitreal Injection Bevacizumab in Posterior Segment Vasculopathies - A Clinical Study

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**Abstract:** ***Aim: The aimwas to study effects of intravitreal anti - vascular endothelial growth factor injection Avastin in posterior segment vasculopathies. Methods: In this prospective, single centre study, 79 eyes, including bilateral cases in age group 61 - 70 years of different posterior segment vasculopathies were given bevacizumab with dose of 1.25mg/0.05ml. post - operative vision was assessed, and OCT was done immediately and on follow up after 1 week, 4weeks. Results: Out of 79 eyes with age group 61 - 70 years, 58.67% of subjects were male and 34.67% of them were females respectively, majority were with PDR (28%) followed by BRVO (26%), CNVM (24%), CRVO (12%), ROP (6.67%), NG (1.33%) and wetARMD (1.33%) out of which there were 9 bilateral cases, 5 cases belong to PDR and intravitreal injection bilaterally was required while there were 4 bilateral active CNVM cases. majority of subjects had hypertension (41.42%) and diabetes mellitus (41.42%). Out of 5 babies 1 baby had respiratory distress. Majority of subjects had IOP 10 - 21 mm of Hg in right eye (97.14%) and left eye (92.86%) and majority of subjects had visual acuity <6/60 in right eye (58.57%) and left eye (51.43%). pre - injection. Pre - op mean OCT among subjects was 419.61. Post injection, 6/6 vision was achieved by 15 (18.99%) subjects 4 weeks later after injection AVASTIN, 19 Eyes required 2 doses of injection in CNVM (6.32%), followed by BRVO (5.06%), CRVO (2.53%), STBRVO (2.53%), ITBRVO (1.26%). Mean central macular thickness on OCT was 418.58, 333.21 and 304.32 at immediate, 1 week later and 4 week later after injection AVASTIN respectively. Conclusions: The present clinical prospective study undertaken to study effects of intravitreal anti VEGF injection Avastin in posterior segment vasculopathies concludes that Intravitreal bevacizumab application provides significant improvement in visual acuity of various posterior segment vasculopathies and may therefore be a promising approach in the primary treatment of posterior segment vasculopathies.***

**Keywords:** Retinopathy, vasculopathy, bevacizumab, vascular endothelial growth factor

## 1. Introduction

Posterior segment eye disease forms an important cause of preventable blindness. [1] Screening for cataract alone in the population, which is vulnerable to diseases affecting the retina and optic nerve might not be sufficient in the community. Information on the epidemiological data is important to understand the magnitude of the problem and is a pre – requisite target of reducing the prevalence of blindness to <0.3%, as per the Vision 2020, National Program for Control of Blindness. [2] Increased life expectancy, lifestyle changes are leading to a rise in the prevalence of DM and its complications like diabetic retinopathy. Increased prevalence of glaucoma is also noted in subjects with DM. [3]

Intravitreal injections have caused huge revolution in the treatment of variety of diseases such as Age - related macular degeneration, diabetic macular oedema, proliferative diabetic retinopathy, retinal vein occlusions, and many more. Intravitreal injections are used to administer medications to treat a variety of retinal conditions such as Age - related macular degeneration, retinal vein occlusion, diabetic retinopathy. The anti VEGF Drugs help to reduce fluid leakage associated with these disorders. [4]

It has been well established that vascular endothelial growth factor (VEGF) plays a vital role in promoting neovascularization and increased vascular permeability in diabetic eyes. Levels of ocular VEGF are correlated with both the growth and permeability of new vessels. [5] Furthermore, introduction of VEGF into normal primate eyes induces the same pathological processes as seen in diabetic retinopathy, namely micro aneurysm formation and increased vascular permeability. Also, studies have shown vitreous samples from patients with DME contain elevated VEGF levels. [6]

Avastin is the brand name for the drug, which is called bevacizumab. It blocks the growth and leaking of fluid from abnormal blood vessels in the back of the eye. Those blood vessels can leak and affect vision, causing vision loss from wet AMD and diabetic eye disease. [7]

Avastin was first approved by the Food and Drug Administration (FDA) to treat different types of cancer. Its use to treat eye disease is considered an “off - label” use. The FDA allows “off label” drug use if doctors are well

informed about the product and studies prove the drug is helpful. Many studies have shown Avastin as safe and effective for eye disease since it was first used in 2005. Avastin blocks VEGF, slowing the growth of blood vessels in the eye. [7]

In this research, the study was conducted on immediate and long - term visual outcome post intravitreal injection with Avastin and study posterior segment vasculopathies, with an aim to study effects of intravitreal anti - VEGF injection Avastin in posterior segment vasculopathies. Our objectives were tostudy different posterior segment vasculopathies, to study immediate visual outcome after intravitreal injections, to study long term visual outcome after intravitreal injections, to study macular thickness on OCT.

## 2. Materials and Methods

This was a prospective, single centre study conducted at department of ophthalmology of tertiary care hospital in India from November 2020 to May 2022. Total 75 patients with posterior segment vasculopathies who were satisfying inclusion criteria were enrolled in the study. Inclusion criteria were: All patients with retinal vasculopathies, patients of choroidal vasculopathies, and patients of neovascular glaucoma. Exclusion criteria were patients who have already had intravitreal and retinal interventions medically or surgically, patients with central corneal opacities, unconscious or comatose patients, and patients not willing to participate. All the subjects included in the study volunteered after proper consent and reported for follow up at right time. The study was conducted after obtaining clearance from the ethical committee of the institute.

In 79 eyes including bilateral cases, dose of 1.25mg in 0.05 ml solution of bevacizumab was given in adult patients 1 month apart. Post operative vision was assessed and optical coherence tomography (OCT) was done immediately and on follow up after 1 week and after 4 weeks. In 5 babies, intravitreal injection AVASTIN was given bilaterally in 10 eyes with dose of 0.625mg/0.025 ml of solution and followed up for 1st week, 2nd week and 3rd week for fundus examination using indirect ophthalmoscopy.

***Data collection***

Data was collected through history and general examination, past history, ocular examination, intra - ocular pressure (non - contact tonometer), fundoscopy (direct and indirect).

Fundus Photography: Fundus camera is a specialized low power microscope with an attached camera used to take magnified photographs of the optic disc and macula and help to document abnormalities of the fundus.

Optical Coherence Tomography (OCT): Non - invasive on contact diagnostic method that uses infrared light to analyse the retina. Macular oedema in DMO seen as hypo reflective spaces within the retina, macular thickening and loss of foveal depression.

Fundus fluorescein angiography: Fluorescein angiography is the technique of injecting a yellowish dye into a patient's antecubital vein, then photographically stimulating this dye with a blue green light at certain wavelengths to induce fluorescence, in the retinal vascular system of the human eye, and recording this fluorescence on photographic film using a fundus camera.

***Statistical analysis***

The Quantitative data was expressed as mean and standard deviation. Qualitative data was expressed as number and percentage. All analyses were performed using IBM SPSS statistics, version 20, for Windows.

## 3. Results

The above table shows the age distribution of the study subjects. Out of 75 patients, majority were in age group 61 - 70 years (42.67%) followed by 51 - 60 years (25.33%). There were 5 (6.67%) ROP babies. The above table shows the gender distribution of all the study subjects. In this study adults had 58.67% of subjects were male and 34.67% of them were females respectively. The **Figure 1** shows posterior segment vasculopathy distribution of the study subjects. Out of 75 patients, majority were with PDR (28%) followed by BRVO (26%), CNVM (24%), CRVO (12%), ROP (6.67%), NG (1.33%) and wet ARMD (1.33%). The above table shows affected eye in adults with posterior segment vasculopathy among subjects. Out of 70 adult patients, majority of affected eye was right side (41.14%) followed by left eye (40%) and bilateral (12.86%).

Among 9 bilateral cases of 5 cases belong to PDR and intravitreal injection bilaterally was required while there were 4 bilateral active CNVM cases. The above table shows affected eye with posterior segment vasculopathy among subjects. Out of 5 babies, both eyes were equally affected.

The **Table 1** shows co - morbidities with posterior segment vasculopathy among subjects. Out of 70 patients, majority of subjects had hypertension (41.42%) and diabetes mellitus (41.42%). Out of 5 babies 1 baby had respiratory distress.

**Table2** shows comparison of Vision (D) before and after injection AVASTIN among study subjects. It was observed that, 6/6 vision was achieved by 15 (18.99%) subjects 4 weeks later after injection AVASTIN. This shows there was gradual improvement in distant vision after injection AVASTIN with statistical significance. The above table shows comparison of OCT after injection AVASTIN among study eyes. It was observed that, pre - injection mean OCT among subjects was 419.61 followed by 418.58, 333.21 and 304.32 at immediate, 1 week later and 4 week later after injection AVASTIN respectively. This shows there was gradual decrease in OCT after injection AVASTIN with statistical significance ($P<0.001$).

It was observed that, pre - op mean OCT among subjects in different etiology shows gradual decrease in OCT after injection AVASTIN immediate, 1 week later and 4 weeks later respectively with statistical significance. ($P<0.05$).19 Eyes required 2 doses of injection in CNVM (6.32%), followed by BRVO (5.06%), CRVO (2.53%), STBRVO (2.53%), ITBRVO (1.26%).

***Visual acuity***

Among PDR, it was observed that, visual acuity 6/12 was achieved by 4 eyes (15.38%) 4 weeks later. Among CNVM, it was observed that, visual acuity 6/6 was achieved by 5 eyes (22.72%) 4 weeks later. Among CRVO, it was observed that, visual acuity 6/6 was achieved by 3 subjects (33.33%) 4 weeks later. Among BRVO, it was observed that, visual acuity 6/6 was gained by 3 subjects (42.85%) 4 weeks later. Among STBRVO, it was observed that, visual acuity 6/6 was gained by 3 subjects (42.85%) 4 weeks later. Among ITBRVO, it was observed that, visual acuity 6/6 was achieved by 1 subject (25%) 4 weeks later. Among NG, it was observed that, patients vision remained 6/36 post - injection after 4 weeks and there was regression of Neovascularisation of IRIS. Among wet ARMD, it was observed that, visual acuity 6/9 was achieved after 4 weeks.

***Macular thickness vs. vision post - injection***

Among PDR, it was observed that, 4 eyes (33.33%) achieved 6/6 vision after 4 weeks with macular thickness <300microns after 2nd dose of injection and 1 subject after 1st dose itself at macular thickness, <300microns. Among CNVM, it was observed that, 3 subjects (50%) achieved 6/6 vision at 4 weeks. Out of 3 subjects, 2 (33.33%) subjects achieved 6/6 vision after 2nd dose of injection at 4weeks at macular thickness <300 microns. Among CVRO, it was observed that, 3 subjects (50%) achieved 6/6 vision at 4 weeks. Out of 3 subjects, 2 (33.33%) subjects achieved 6/6 vision after 2nd dose of injection at 4weeks at macular thickness <300 microns. Among BRVO, it was observed that, 3 (60%) subjects gained 6/6 vision at 4 weeks, out of which 2 (20%) subjects achieved at 1st dose itself and 1 (40%) subject after 2nd dose of injection after 4 weeks at macular thickness <300microns. Among STBRVO, it was observed that, 3 subjects (50%) gained 6/6 vision after 4weeks at macular thickness <300microns. Among ITBRVO, it was observed that, 1 (33.33%) subject gained 6/6 vision after 4 weeks at macular thickness <300microns. Among NG, It was observed that Pre - injection vision was 6/60 that imroved to 6/36 after 4 weeks at macular thickness 301 – 400 microns. Among wetAMRD, It was observed that, that Pre - injection vision was 6/60 that improved to 6/9 after 4 weeks at macular thickness 301 – 400 microns.

## 4. Discussion

The present study was clinical prospective study undertaken to study effects of intravitreal anti VEGF injection Avastin in posterior segment vasculopathies. In the present study, out of 75 patients, majority were in age group 61 - 70 years (42.67%) followed by 51 - 60 years (25.33%). There were 5 (6.67%) ROP babies. The mean age of patients was 58.13 years. Gulsah Gumus et al, [8] investigated the early effects of intravitreal bevacizumab (IVB) injection observed the mean age of patients was 60.1±7.4 years. This finding was in accordance to present study. N. N. Kabedi et al, [9] in a study on choroidal vasculopathy (PCV) in eyes treated with intravitreal bevacizumab (BVZ) observed mean age of patients was 66.3 ± 5.6 years.

In this study adults had 58.67% of subjects were male and 34.67% of them were females respectively. Gulsah Gumus et al, [8] investigated the early effects of intravitreal bevacizumab observed among 42 patients, 22 were women (52.4%); 20 were men (47.6%). This was in contrast to present study. N. N. Kabedi et al, [9] in a study on choroidal vasculopathy (PCV) in eyes treated with intravitreal bevacizumab (BVZ) observed study involved 22 eyes of 12 patients (7 men and 5 women). This was similar to present study.

The posterior segment vasculopathy distribution of the study subjects showed out of 75 patients, majority were with PDR (28%) followed by BRVO (26%), CNVM (24%) CRVO (12%), ROP (6, 67%), NG (1.33%) and wet ARMD (1.33%). Gulsah Gumus et al, [8] investigated the early effects of intravitreal bevacizumab (IVB) injection observed among 42 patient's majority of patients had etiology of Diabetic macular edema (64.28%) followed by Age - related macular degeneration (19.1%), Retinal vein branch occlusion (7.14%) and Central retinal vein occlusion (7.14%). Danny S Ng et al, [10] studied safety profile of multiple doses of bevacizumab observed majority of indication for it was ARMD (27.21%) followed by CNV (24.46%).

It was observed that, visual acuity as per different etiologies showed that vision <6/60 improved to 6/6 gradually 4 weeks later after injection AVASTIN with statistical significance. Similarlyvisual acuity 6/6 was achieved in CNVM (22.72%), CRVO (33.33%), BRVO (42.85%), STBRVO (33.33%), ITBRVO (25%) at 4 weeks with statistical significance. MB Parodi et al, [11] in a study to compare the effects on visual acuity of laser treatment (LT), photodynamic therapy (PDT) with verteporfin, and intravitreal bevacizumab treatment in patients with juxtafoveal choroidal neovascularization secondary to pathologic myopia observed mean best - corrected visual acuity in the anti - vascular endothelial growth factor group increased from 0.6 logMAR (SD, 0.3 logMAR) at baseline to 0.42 logMAR (SD, 0.35 logMAR) at the end of the study (P = 0.006). This finding was similar to present study.

Tufail A et al, [12] evaluated the efficacy and safety of intravitreous bevacizumab injections for the treatment of neovascular age related macular degeneration observed the bevacizumab group, 21 (32%) patients gained 15 or more letters from baseline visual acuity compared with two (3%) in the standard care group (P<0.001). Ozkiris A et al, [13] evaluated the effectiveness of intravitreal bevacizumab injection as primary treatment of diabetic macular oedema observed mean baseline best - corrected LogMAR value for visual acuities of the patients before intravitreal bevacizumab injection was 1.09+/ - 0.23. After treatment, it was 0.90+/ - 0.17 at the 1 - month and the differences were significant when compared with baseline value (P<0.001). Atul Kumar et al, [14] studied visual acuity response after intravitreal bevacizumab (Avastin) in patients with diffuse diabetic macular edema observed mean baseline acuity was 20/494 (log Mar=1.338±0.455) and the mean acuity at three months following the second intravitreal injection was 20/295 (log Mar=1.094±0.254), a difference that was highly significant (P =0.008). The mean central macular thickness at baseline was 492 µm which decreased to 369 µm (P =0.001) at the end of six months.

The comparison of OCT after injection AVASTIN among study subjects showed that, pre - op mean OCT among subjects was419.61 followed by 418.58, 333.21 and 304.32 at immediate, 1 week later and 4 week later after injection AVASTIN respectively. This shows there was gradual decrease in OCT after injection AVASTIN with statistical significance. (P<0.05) It was observed that, pre - op mean OCT among subjects in different etiology shows gradual decrease in OCT after injection AVASTIN 1 week later and 4 weeks later respectively with statistical significance. (P<0.05). Atul Kumar et al, [14] studied visual acuity response after intravitreal bevacizumab (Avastin) in patients with diffuse diabetic macular edema observed mean central macular thickness at baseline was 492 µm which decreased to 369 µm (P =0.001) at the end of six months. Intravitreal bevacizumab resulted in a significant decrease in macular thickness. This finding was in accordance to present study. Bevacizumab has already been used for DME. The capillary permeability seen in DME is secondary to release of VEGF, primarily VEGF - A whose release is inhibited by the pan anti - VEGF monoclonal antibody, Avastin. [15]

Similar to the study published by Haritoglou et al. [16] the present study also demonstrated significant improvement in decrease of central macular thickness after two intravitreal bevacizumab injections. Additionally, the study also shows the beneficial effect of intravitreal bevacizumab in patients with DME associated with active PDR. In other study by Arevalo JF et al. [17] published review of the clinical records of 88 consecutive patients (110 eyes) with DMEwhich shows Mean central macular thickness at baseline by OCT was 387.0+/ - 182.8 mum and decreased to a mean of 275.7+/ - 108.3 at end of follow - up. No ocular or systemic adverse events were observed.

In the present study, out of 70 patients 5 were babies with ROP, that included 3 males and 2 females. The mean gestational age of the babies were 25 ± 2.44 weeks. The mean birth weight among babies was 1231± 236.9 grams. All babies affected in both eyes. Out of 5 babies, 4 had zone 1 ROP and one baby had zone 2 ROP. Injection AVASTIN was given all study subjects in both eyes with dose of 0.625 mg. All babies showed that there was significant regression of NVE and there was vascularization of avascular area in all eyes of babies. HA Mintz - Hittner et al, [18] in a study observed Intravitreal injection of bevacizumab was safe and effective in treating stage 3 ROP in zone I and posterior zone II in small series of patients of ROP with 42% regression at end of treatment. This finding was in accordance with present study. Yingying Chen et al [19] in a study observed treatment with 0.3 mg ranibizumab can reduce the recurrence rate of ROP by 40% without prolonging retinal vascularization or causing serious systemic complications.

## 5. Conclusion

The present clinical prospective study undertaken to study effects of intravitreal anti VEGF injection Avastin in posterior segment vasculopathies concludes that Intravitreal bevacizumab application provides significant improvement in visual acuity of various posterior segment vasculopathies and may therefore be a promising approach in the primary treatment of posterior segment vasculopathies.

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**Tables**

**Table 1:** Baseline demographics of patients

| Variables | No of Patients (N = 70) |
|---|---|
| Age group, n (%) | |
| Adults (years) | |
| ≤40 | 03 (4%) |
| 41 - 50 | 05 (6.67%) |
| 51 - 60 | 19 (25.33%) |
| 61 - 70 | 32 (42.67%) |
| >70 | 11 (11.67%) |
| Babies (<32weeks) | 05 (6.67%) |
| Gender, n (%) | |
| Male | 44 (58.67%) |
| Female | 26 (34.67%) |
| Boy | 03 (4.00%) |
| Girl | 02 (2.66%) |
| Comorbidities, n (%) | |
| Hypertension | 29 (41.42%) |
| Diabetes mellitus | 29 (41.42%) |

**Table 2:** Comparison of vision and macular thickness (by OCT) after injection Avastin among patients' eyes (n=79)

| Vision | Pre - op | After injection Avastin | | | P value |
|---|---|---|---|---|---|
| | | Immediate | 1 week later | 4 week later | |
| 6/6 | 00 | 00 | 02 | 15 | 0.0132 |
| 6/9 | 00 | 00 | 04 | 13 | |
| 6/12 | 00 | 02 | 11 | 7 | |
| 6/18 | 05 | 07 | 14 | 7 | |
| 6/24 | 04 | 11 | 10 | 9 | |
| 6/36 | 11 | 10 | 8 | 6 | |
| 6/60 | 12 | 13 | 8 | 7 | |
| <6/60 | 49 | 36 | 22 | 15 | |
| Mean macular thickness (n=79) | 419.61 ± 137.3 | 418.58 ± 138.1 | 333.21 ± 102.6 | 304.32 ±96.7 | <0.001 |
| PDR (n=26) | 500.5±151.3 | 500.5± 151.3 | 390.6±119.2 | 365.6±124.3 | <0.001 |
| CNVM (n=22) | 345.7±100.4 | 342.1±101.2 | 293.4±78.4 | 271.5±64.8 | <0.001 |
| CRVO (n=9) | 461.5±180.6 | 461.5±180.6 | 328±137.1 | 298.3±138.7 | <0.001 |
| BRVO (n=7) | 439.2±88.4 | 439.2±88.4 | 296.2±89.4 | 292.8±90.9 | <0.001 |
| STBRVO (n=9) | 405.8±109.2 | 405.8±109.2 | 337.8±114.2 | 284.7±79.1 | <0.001 |
| ITBRVO (n=4) | 461±175.8 | 461±175.8 | 365.5±85.8 | 310.5±70.1 | <0.001 |
| NG (n=1) | 578 | 578 | 468 | 432 | <0.001 |
| Wet ARMD (n=1) | 322 | 322 | 289 | 269 | <0.001 |

**Figures**

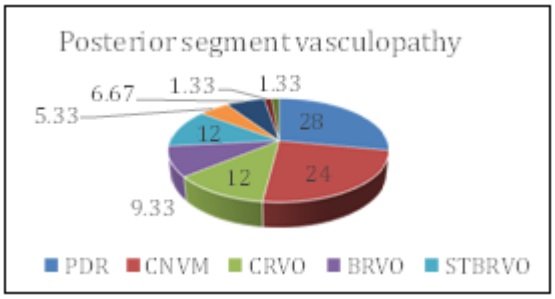


**Figure 1:** Distribution according to posterior segment vasculopathy