Section: Ophthalmology

Original Research Article

# ASSESSMENT OF VISUAL ACUITY IMPROVEMENT AND CENTRAL MACULAR THICKNESS REDUCTION AFTER RANIBIZUMAB THERAPY IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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## ABSTRACT

**Background:** Neovascular age-related macular degeneration (nAMD) is a leading cause of irreversible visual impairment among the elderly. Vascular endothelial growth factor (VEGF) plays a key role in choroidal neovascularization. Intravitreal anti-VEGF agents such as Ranibizumab have become first-line therapy. Optical coherence tomography (OCT) enables objective monitoring of macular morphology and treatment response. The objective is to evaluate the efficacy of intravitreal ranibizumab in patients with neovascular AMD by assessing changes in best corrected visual acuity (BCVA) and central macular thickness (CMT) using OCT following three consecutive monthly injections. **Materials and Methods:** This hospital-based observational cross-sectional study was conducted in the Department of Ophthalmology at Santhiram Medical College and General Hospital from April 2023 to March 2025. Fifty patients (50 eyes) with OCT-confirmed subfoveal neovascular AMD received three monthly intravitreal injections of ranibizumab (0.5 mg/0.05 ml). Comprehensive ocular examination and OCT imaging were performed at baseline and follow-up visits. BCVA (Snellen, converted to logMAR) and CMT were analyzed using paired t-tests and repeated measures ANOVA. A p-value <0.05 was considered statistically significant. **Result:** The mean age of participants was 67 years; 56% were male. Mean BCVA improved significantly from 1.40 logMAR at baseline to 0.95 logMAR at 6 weeks after the third injection ($p<0.00001$). A slight decline (0.98 logMAR) was noted at 12 weeks post-third injection but remained significantly better than baseline. Mean CMT decreased from 349.7 µm at baseline to 220.3 µm at 6 weeks after the third injection ($p<0.01$), with a mild increase at 12 weeks (235.7 µm). Pigment epithelial detachment (PED) showed reduction or resolution in most cases after treatment. No serious ocular or systemic adverse events were reported. **Conclusion:** Three consecutive monthly intravitreal ranibizumab injections resulted in significant functional and anatomical improvement in patients with neovascular AMD. OCT proved to be an essential tool for monitoring treatment response. Ranibizumab is effective and safe for short-term management of neovascular AMD.

## INTRODUCTION

Age – related macular degeneration is a degenerative disorder affecting the macula, it is a leading cause of irreversible visual impairment among elderly, affecting a total of 50-60 million world-wide.[1] ARMD increases in prevalence with age although an estimated 80% of patients with ARMD have dry non -neovascular form, the wet or neovascular form is responsible for almost 90% severe visual loss from AMD.[2,3]

AMRD proves to be a major public health concern, not only because of its current and predicted increased prevalence, but also because of the disabling impact it has on those suffering vision loss as a result of advanced AMRD.


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Antioxidant vitamin and mineral supplements, photodynamic therapy (PDT), laser photocoagulation and surgery were the main modalities used in the treatment of AMD. Of therapeutical interest recently as first line of management are the anti-VEGF agents, Pegaptanib, Ranibizumab, Bevacizumab and Aflibercept.[4]

Ranibizumab is a recombinant humanized IgG1 monoclonal antibody fragment that binds and inhibits vascular endothelial growth factor A (VEGF-A)thus prevents choroidal neovascularization. VEGF is a biochemical signal protein that promotes angiogenesis throughout the body and in the eye. Through binding to VEGF-A, ranibizumab interrupts the interaction of VEGF with its receptors, and thus prevents the subsequent growth of new blood vessels.[5]

Optical coherence tomography (OCT) is an imaging modality that offers a unique ability to define cross sectional architecture of the retina and may assist in evaluating the response of the retina and RPE to therapy by allowing structural changes to be monitored accurately. It has emerged as an essential adjunct for the diagnosis and monitoring of patients with AMD.[6,7]

Hence this study was carried out to analyze the efficacy of intravitreal Ranibizumab in Neovascular age related macular degeneration by assessing the visual outcome and morphological changes in the macula using OCT by administering three consecutive monthly injections.

## MATERIALS AND METHODS

It was a Hospital based observational cross sectional study conducted in Patients attending the Department of Ophthalmology, Santhiram medical college and General Hospital, Nandyal between April –2023-March -2025. 50 patients (50 eyes) with neovascular age-related macular degeneration.

**Inclusion Criteria**

- Patients willing to participate in the study
- Clinical diagnosis of neovascular ARMD well defined with sub foveal involvement confirmed by Optical coherence Tomography
- Patients who has given written and informed consent for the Injection.

**Exclusion Criteria:**

- Patients who are not willing to participate
- H/O Ophthalmological diseases other than ARMD that might compromise it's visual acuity or peripheral vision during the study (amblyopia, uveitis, uncontrolled glaucoma, optic neuropathy)
- H/O Any neurological or psychiatric diseases
- Unable to communicate
- Subjects with active intra ocular inflammation
- Subjects with uncontrolled hypertension or recent history of thromboembolic episodes

**Methodology:** Written informed consent was taken for all recruited patients explaining to them about the drug Ranibizumab and the possible adverse effects associated with it. Detailed history and examination viz. visual acuity by Snellen's chart, refraction, best corrected visual acuity (BCVA), anterior segment examination by slit lamp, intra ocular pressure measurement by Goldmann's applanation tonometry, fundus examination with indirect ophthalmoscope and slit lamp biomicroscopy using +78D and +90D were done. Optical Coherence Tomography (OCT) was done at the initial visit to confirm the presence of choroidal neovascular membrane (CNVM), and at every visit to know the progression of the disease. All patients had blood pressure measurements and were also monitored for symptoms of possible thromboembolic events.

**Statistical analysis:** The data were then analyzed using SPSS (version 16.0; SPSS Inc., Chicago, IL). Descriptive statistics such as proportions, measures of central tendency and measures of dispersion were used to describe the data initially. Snellen's acuities were converted to logarithm of the minimum angle of resolution (log MAR) to facilitate statistical analysis, subsequently, paired-t test and repeated measures analysis of variance (RMANOVA) were used to compare the changes in the mean BCVA and mean CMT. Pearson's Correlation Coefficient was used to depict the relationship between BCVA and CMT. P value $< 0.05$ was considered to be statistically significant.

## RESULTS

**Table 1: distribution of study population by age and gender**

| Age Group [Years] | Sex | | Total |
|---|---|---|---|
| | Male | Female | |
| 60-69 | 15 (30%) | 13(26%) | 28 (56%) |
| 70-79 | 13 (26%) | 9(18%) | 22 (44%) |
| Total | 28 (56%) | 22(44%) | 50 (100%) |

This table depict the distribution of the study population by age and gender. Most of our study subjects (56%) belonged to the age group between 60 and 69 years with mean age being 67yrs. Males constituted 56% of our study subjects.


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**Table 2: Anterior segment of the affected eye**

| Age | Cataract (SIMC) | Pseudophakia | Total |
|---|---|---|---|
| 60-69yrs | 25(50%) | 3 (6%) | 28 (56%) |
| 70-79yrs | 16(32%) | 6 (12%) | 22 (44%) |
| Total | 41(82%) | 9 (18%) | 50 (100%) |

The above table depicts the anterior segment finding of the affected eye. In age group of 60-69 years, 50% had senile immature cataract and 6% were pseudophakic. In the age group of 70-79 years, 32% patients had senile immature cataract and 12% were pseudophakic.

**Table 3: Mean BCVA (LOGMAR) at every visit**

| | Mean log MAR Values | Mean Snellen's Visual Acuity | P value |
|---|---|---|---|
| BCVA at baseline | 1.40828 | 2/60 – 3/60 | -- |
| BCVA 4weeks after 1st Inj. | 1.21254 | 3/60 – 4/60 | <0.00001 |
| BCVA 4weeks after 2nd Inj. | 1.1024 | 4/60 – 5/60 | <0.00001 |
| BCVA 6 weeks after 3rdInj. | .95414 | 5/60-6/60 | <0.00001 |
| BCVA 12 weeks after 4th Inj. | 0.98384 | 6/60-6/36 | <0.00044 |

*'p' value of <0.05 indicates statistical significance.

The above table depict the change in best corrected visual acuity over the period of 5 months from the time of the first injection upto 12 weeks after 3rd injection. For the purpose of analysis Snellen's visual acuity was converted to logMAR values.

Mean visual acuity (logMAR) at baseline was 1.40, at 4 weeks after 1st injection the mean was 1.21, at 4 weeks after 2nd injection the mean was 1.10, at 6 weeks after 3rd injection the mean was 0.95 and at 12 weeks after 3rdinjection the mean was 0.98. There was a gradual improvement in mean visual acuity at every visit except at 12 weeks after 3rd injection when there was a slight drop in comparison to the previous visit. The student's _t' test was used to compare the mean visual acuity at baseline (presentation) and the mean visual acuity at every subsequent visit and the difference at every visit was found to be statistically significant ($p<0.05$). The maximum improvement in vision was after the first injection.

**Table 4: mean central macular thickness at every visit**

| | Mean CMT µm | P value |
|---|---|---|
| CMT at Baseline | 349.72 | -- |
| CMT 4 weeks after 1st Inj. | 328.54 | 0.3248 |
| CMT 4 weeks after 2nd Inj. | 261.96 | 0.00000386 |
| CMT 6 weeks after 3rd Inj. | 220.28 | 0.0043 |
| CMT 12 weeks after 3rd Inj. | 235.70 | 0.1769 |

*'p value of <0.05 indicates statistical significance

Mean CMT at baseline prior to intervention was found to be 349.72 µm at 4 weeks after 1st injection the mean was 328.54 µm at 4 weeks after 2nd injection it was 261.9 µm 6, at 6 weeks after 3rd injection it was 220.28µm and at 12 weeks after 3rd injection it was 235.70 µm. There was a gradual improvement, which is reduction in mean CMT at every visit except at 12 weeks after 3rd injection when there was a slight increase in mean CMT compared to previous visit. The student's _t' test was used to compare the baseline mean CMT and the mean CMT at every subsequent visit and the difference at every visit was found to be statistically significant ($p<0.05$). It was also found that the maximum reduction in mean CMT was after the first injection itself.

**Table 5: changes in pigment epithelial detachment over time**

| | PED at Presentation | PED at 4 wks after 1st Inj. | PED at 4 wks after 2nd Inj. | PED at 6 wks after 3rd Inj. | Ped at 12 wks after 3rd Inj. |
|---|---|---|---|---|---|
| Present | 12 | 8 | 0 | 4 | 4 |
| Increased | 0 | 0 | 0 | 0 | 5 |
| Reduced | 0 | 4 | 12 | 6 | 1 |
| Absent | 38 | 38 | 38 | 40 | 40 |

The above graph depicts the change in pigment epithelial detachment (PED) over 5 months from the time of 1st injection to 12 weeks after the 3rd injection. Since quantitative assessment was not possible, this is only a graphical representation of the change. At the initial visit, 23.33% of all the patients showed the presence of PED. At 4 weeks after 2nd injection all of them showed a reduction in the size of PED. At 6 weeks after 3rd injection, 40 patients showed a complete absence of PED with 6 of the other patients showing a further decrease in the size of PED but 4 new patients showed a presence of PED for the first time. At 12 weeks after 3rd injection, 4 patients continued to show the same size of PED, 5 of the 6 patients showed an increase in size with one showing a decrease in size.


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## DISCUSSION

Out of 50 patients that we enrolled, 56% of them belonged to the age group of 60-69 years with the mean age being 67 years. This is consistent with findings of Bashshur et al where the average age was 68.3 years. Males constituted 63.33% of our study subjects.[8]

In the 50 study subjects, the anterior segment in the eye with neovascular AMD showed cataract in 82% of the patients and 18% of them were pseudophakia Similar report has been made by Arias et al,[9] where in 72% of the patients were phakic (loading dose group) however studies have shown that data regarding the relationship between cataract and AMD is still inconsistent.

Most of our patients had poor visual acuity at presentation with 25(50%) of them having a snellen's visual acuity of <2/60 prior to intervention. This may be due to the fact that patients did not present to us until they found a significant drop in vision owing to economic constraints. At 6 weeks after 3rd injection, 49 (96.67%) of them improved and had a visual acuity of >3/60. However, there was one patient who presented with vision of counting fingers close to face and did not show any further improvements due to development of an early scar. respectively which is correlation with the studies done by Rosen feld et al (2011), Bashshur et al.[8,10]

We made a comparison between the change in vision at 12 weeks after 3rd injection with vision 6 weeks after 3rd injection. We found that 76.67% of the patients showed no change in vision in the last visit and 23.33% of them actually showed a drop in vision compared to the previous visit.

At the first visit, prior to intervention 30 (60%) patients had a CMT of >350 µm. The maximum CMT that was noted was 690µm. 4 weeks after the first injection itself 30 (60%) patients had a CMT<350 µm. 4 weeks after 2nd injection 48 (96.67%) had a CMT <350 µm, 6 weeks after 3rd injection 40 (80%) had a CMT <250µm, 12 weeks after 3rd injection 35 (70%) had a CMT<250µm, respectively which is correlation with the studies done by Rosen feld et al (2011),[10] Frank G.Holz (2011),[11] CMT (101□m), Bashshur et al,[8] (358 □m).

When we looked at CME and SRF, 30 patients (60%) showed the presence of CME and 37 patients (73.33%) showed the presence of SRF at the initial visit. Interestingly, a majority of the patients showed a reduction in CME and SRF at 4 weeks after the first injection itself. However, a majority of them showed an absence of CME and SRF at 12 weeks (i.e 6 weeks after 3rd injection). Bashshur et al,[8] also found that a majority (76%) of the patients had a resolution of SRF on OCT at 12 weeks.

The adverse effects noted by Rosenfeld et al10 during a short term follow up were endophthalmitis, conjunctival hemorrhage, vitreous floaters, Cataract, Vitreous detachment, increased intra ocular pressure, eye pain, acute blood pressure rise, stroke, myocardial infarction, and death. However, none of these adverse effects were encountered during our study period as a result of the intervention. None of these adverse effects have been noted in other short term studies done by Rich et al,[12] Bashshur et al,[8] Chen et al as well.[13]

**Limitations:** We recognize that the small sample size, non-ETDRS vision measurements and short follow-up are limitations of this study. We were also not able to provide quantitative information regarding CMT, SRF and PED.

## CONCLUSION

This was a hospital based cross-sectional study. We recruited 50 patients (50 eyes) with neovascular age-related macular degeneration which satisfied our inclusion criteria. There were 28 males and 22 females. A majority of our study subjects belonged to the age group between 60-69 years with mean age being 67 years. After a complete evaluation, three consecutive monthly injections of intravitreal Ranibizumab (0.5mg, 0.05ml) were administered. Patients were followed up for a period of three months after third injection. None of the patients had any serious adverse effects due to intervention. At every visit, the response to treatment was monitored functionally by best corrected visual acuity and morphologically by OCT using central macular thickness measurements.

Based on the findings of this study, it can be concluded that three consecutive monthly injections of Ranibizumab produced significant improvement in visual acuity and central macular thickness, thus proving efficacious in the treatment of neovascular age- related macular degeneration.

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