

# Efficacy And Safety of Intravitreal Ranibizumab in Macular Edema Patients

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**Abstract- Aim:** To evaluate the efficacy and safety of intravitreal ranibizumab in macular edema patients.

**Setting:** Manjunatha eye hospital, Kundapura, Udupi. Design: Clinical prospective study

**Materials and methods:** A prospective observational study was conducted in 12 eyes of 9 patients between 01/05/2022 to 30/04/2023. All patients belonging to either sex irrespective of age who had macular edema due to various retinal disorders like PDR, CNVM were all included in the study. Patients with tractional retinal detachment, known cases of glaucoma, patients who had thromboembolic episodes like myocardial infarction, stroke in the last 6months were excluded from the study. All the patients underwent initial ophthalmological examination with visual acuity, refraction, anterior segment examination, intraocular pressure, dilated fundoscopy with Indirect ophthalmoscope with 20D lens and slit lam with 78Dlens and OCT scan. All the patients were given intravitreal injection ranibizumab 0.5mg/0.05ml on monthly basis. Patients were followed up 1week and visual acuity, anterior segment evaluation, IOP, posterior segment examination and OCT were done.

**Statistical analysis:** Data was analyzed using descriptive statistics.

**Results:** A total of 12eyes of 9patients were recruited in the study. Out of 09 patients, 06 were males and 03were females. The age of the patients included in the study ranges from 56 to 78 years. Intravitreal injection was administered 07 in right eyes and 05 left eyes. Macular edema was due to PDR with CSME in 03 eyes and CNVM in 09eyes. Mean BCVA in PDR eyes was 4/60, in CNVM eyes was 3/60. After intravitreal injection of ranibizumab, BCVA improved to 6/60-6/24 in 10eyes, 6/24-6/12 in 02eyes after 1week. At the end of 6months, BCVA was 6/24-6/12 in 11eyes and 01eyes. CMT was >45mm in 09 eyes and 300-450mm in 03eyes at the end of 1week post injection. At the end of 6months, CMT was reduced to 300- 450mm in 11eyes and <300mm in 01eyes.

**Conclusion:** Intravitreal ranibizumab monthly injections are safer and effective in improving visual acuity and macular thickness in patients with macular edema due to various retinal diseases.

**Index Terms-** intravitreal injection, Ranibizumab, macular edema, retinal disorders.

## I. INTRODUCTION

Ranibizumab is an antigen-binding (Fab) fragment of a humanized monoclonal antibody with a molecular weight of 48 kDa that also binds all the isoforms of VEGF-A.<sup>[1,2]</sup> The differences in the molecular weight and structure of bevacizumab and ranibizumab influence their penetration, half-lives, and efficacy. The efficacy of ranibizumab in the management of CNVM secondary to age-related macular degeneration (ARMD) has been well documented.<sup>[3]</sup>

Ranibizumab acts as an anti-VEGF agent and reduces the macular thickness. Most of the causes for macular edema occurs due to neovascularization like proliferative diabetic retinopathy, choroidal neovascular membrane, retinal vein occlusions etc. Hence we aimed to study the efficacy of intravitreal ranibizumab in improving visual acuity and reducing the macular edema.

### Objectives of the study:

1. To evaluate the efficacy of intravitreal ranibizumab in patients with macular edema due to various retinal disorders.
2. To evaluate the safety of intravitreal ranibizumab in patients with macular edema due to various retinal disorders.

### Materials and Methods:

A prospective observational study was conducted in 12 eyes of 10 patients attending the outpatient department of Manjunatha Eye hospital, Kundapura, Udupi. The study period was between 01/05/2022 to 30/04/2023. The patients were included in the study by applying the following Inclusion and Exclusion criteria.

Inclusion criteria: Patients belonging to either sex irrespective of age who had macular edema due to various retinal disorders like Proliferative Diabetic Retinopathy, clinically significant macular edema, retinal vein occlusions, CMEs, choroidal neovascular membrane who were attending outpatient department of Manjunatha eye hospital were all included in the study.

**Exclusion criteria:**

1. Patients with tractional retinal detachment
2. Patients who are known cases of glaucoma
3. Patients who had thromboembolic episodes like myocardial infarction, stroke in the last 6months.

**Methodology:**

Patients fulfilling inclusion criteria were recruited into this study.

The aims and objectives of the intended study was properly explained to the subjects and informed consent was taken. Data was collected as per the proforma sheet.

All the patients underwent initial ophthalmological examination with visual acuity, refraction, anterior segment examination, intraocular pressure and dilated funduscopy with Indirect ophthalmoscope with 20D lens and slit lam with 78Dlens.

Optical coherence topography was done to all eyes to measure the central macular thickness and correlate post injection.

All the patients underwent following systemic examination and blood investigations prior to the procedure- Blood pressure test and physician evaluation Random blood sugars

Glycated Hemoglobin(HbA1C) HIV  
HBsAg

All the patients were given intravitreal injection ranibizumab 0.5mg/0.05ml on monthly basis.

Procedure:

Under aseptic precautions, Intravitreal ranibizumab 0.5mg/0.05ml injected using a sharp tipped 30-gauge needle after measuring parsplana(4mm from limbus in phakic / 3.5mm in pseudophakic eyes) in inferotemporal quadrant of the eye under topical anesthesia. Following injection, topical antibiotic was instilled and eye was patched for 2 hours. Oral acetazolamide 250mg tablet was given to all the patients after the injection. Patients were given topical Gatifloxacin 0.5% with prednisolone acetate combination eye drops 1drop 2hourly and then tapered weekly, timolol 0.5% once at night.

All the patients were given 3 injections on monthly basis.

Patients were then followed up at 1 week after every monthly injections, then at 3months and 6months. Every follow up, patients underwent following tests- best corrected visual acuity, anterior segment, intraocular pressure measurement and dilated funduscopy. OCT was repeated at 1month and 3months follow up.

Data was analyzed using descriptive statistics.

Results:

A total of 12eyes of 9patients were recruited in the study. Out of 09 patients, 06 were males and 03were females. The age of the patients included in the study ranges from 56 to 78 years. Intravitreal injection was administered 07 in right eyes and 05 left eyes.

Macular edema due to various disorders were distributed as in table no.1

Causes	No of eyes
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Diabetic macular edema	03
Choroidal neovascular membrane	09
Total	12

Table no.1

Pre-intravitreal bevacizumab, BCVA and central macular thickness is distributed as in table no.2 , (fig1)

Causes	Mean BCVA (Snellen's)	Mean CMT(mm) [Range]
Diabetic macular edema	4/60	634mm [416mm- 776mm]
Choroidal neovascular membrane	3/60	512mm [451mm- 732mm]

Table no.2

Post injection at 1 week, BCVA is tabulated in table no.3

BCVA Causes	6/60- 6/24	6/24-6/12
Diabetic macular edema	03	00
Choroidal neovascular membrane	07	02
Total	10 (83.3%)	02 (16.67%)

Table no.3

Post injection at 6months , BCVA as follows (table no.4)

BCVA Causes	6/24-6/12	6/12-6/6
Diabetic macular edema	02	01
Choroidal neovascular membrane	09	00

Total	11 (91.67%)	01 (8.33%)
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Table no.4

Central macular thickness at 1 week post injection as in table no.5.

CMT Causes	>450mm	301mm-450mm
Diabetic macular edema	02	01
Choroidal neovascular membrane	07	02
Total	09 (75%)	03 (25%)

Table no.5

Central macular thickness at 6 months as in table no.6 (fig2)

CMT Causes	301mm-450mm	<300mm
Diabetic macular edema	02	01
Choroidal neovascular membrane	09	00
Total	11 (91.67%)	01 (8.33%)

Table no.6

Discussion: VEGF plays a key role in the pathogenesis of DME.<sup>[4,5,6]</sup> Several reviews have been conducted on the efficacy of the two anti-VEGFs, bevacizumab and ranibizumab, in the treatment of DME.<sup>[4,7,8,9]</sup> Ranibizumab, a recombinant humanized monoclonal IgG1 antibody, is approved for choroidal neovascularization in the context of ARMD and DME. Despite their widespread clinical applications, the pharmacokinetics of intravitreal bevacizumab and ranibizumab concerning untreated eyes has not been extensively studied.<sup>[10]</sup>

We found an improvement in visual acuity by 83% who had improved to better than 6/60 at the end of 1 week post injection. At the end of 6 months, 92% had BCVA better than 6/24. 1 patient with diabetic macular edema had recurrence and aggravation of macular edema following cataract extraction. A repeat intravitreal ranibizumab injection was given at 4 weeks post phacoemulsification. Patient had 6/9p vision at then of 2 weeks post injection. None of the patients had any IOP surge or any other serious adverse effects like vitreous hemorrhage, retinal detachment, endophthalmitis etc.

**Conclusion:** Intravitreal ranibizumab injections are safer, easily accessible, and effective in improving visual acuity and macular thickness in patients with macular edema due to various retinal diseases.

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Fig1.

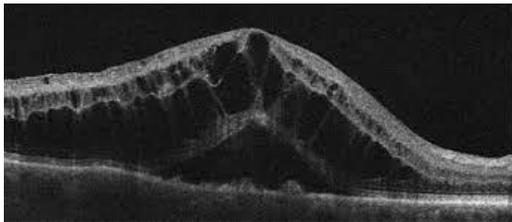


Fig 2.

