



INTRAVITREAL BEVACIZUMAB VS RANIBIZUMAB ON DIABETIC MACULAR EDEMA.

Ophthalmology

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ABSTRACT

The macular edema is the result of collection of fluid in the macula which leads to swelling, thickening and distortion of the vision. Anti-vascular endothelial growth factor (antiVEGF) agents are the new gold standard treatment for diabetic macular edema. The Ranibizumab and Intravitreal Bevacizumab are the commonest antiVEGF used for the treatment. The aim of the present study was to determine the use of Intravitreal Bevacizumab vs Ranibizumab in management of diabetic macular edema. The study was conducted in ASCOMS and Hospital over the period of 3 months after obtaining ethical permission from ethical committee in ASCOMS and Hospital. A total of 50 patients were randomly categorized into two groups, group-A; consist of 25 eyes who received 1.25 mg Intravitreal Bevacizumab and group-B; consist of 25 eyes who received 0.5mg Intravitreal Ranibizumab. A detailed history was taken and ocular examination was performed. All the patients (eyes) were followed up for best corrected visual acuity and macular thickness before injection and after 3 months of intervention. The mean age of the study patients was 45.7 ± 9.2 years in group -A and 45.4 ± 6.14 years in group-B. The majority of the patients were females with the female male ratio 1.28:1. The mean HbA1c score in group -A was 7.89 ± 1.02 and in group-B the HbA1c score was 7.72 ± 1.19 . it was concluded that the use of intravitreal ranibizumab was more effective than Intravitreal Bevacizumab in the treatment of diabetic macular edema.

KEYWORDS

Diabetes, Macular edema, Ranibizumab, Intravitreal Bevacizumab, Visual acuity and CCT.

Introduction

The macular edema is the result of collection of fluid in the macula results from abnormal leakage and accumulation of fluid in the macula from damaged blood vessels and leads to swelling, thickening and distortion of the vision.¹

The diabetic macular edema is characterized by thickness of retina due to accumulation of intraretinal fluid, primarily in the inner and outer plexiform layers. It can be the result of hyperpermeability of the retinal vasculature.²

About 6.8% diabetic patients suffers from diabetic macular edema.³ The treatment pattern of diabetic macular edema includes anti-inflammatory, vascular endothelial growth factor inhibitors (anti-VEGFs) or combination of the treatment. The management of diabetic macular edema stabilizes the vision and also improves the patients' quality of life.⁴

Anti-vascular endothelial growth factor (antiVEGF) agents are the new gold standard treatment for diabetic macular edema.⁵ The Ranibizumab and Intravitreal Bevacizumab are the commonest antiVEGF used for the treatment. It was observed that on the basis of availability and lower cost, bevacizumab is already currently in widespread clinical use for treatment of DME and it is also suggested that bevacizumab is safe and efficacious than ranibizumab.⁶

Thus, the present study was undertaken to determine the use of Intravitreal Bevacizumab vs Ranibizumab in management of diabetic macular edema.

Aim and Objective

To study the efficacy & safety of Intravitreal Bevacizumab vs Ranibizumab in management of diabetic macular edema.

Material and methods

This prospective comparative study was conducted in ASCOMS and Hospital over the period of 3 months after obtaining ethical permission from ethical committee in ASCOMS and Hospital.

A total of 50 patients were included in the study after taking informed consent from them.

Patients were randomly categorized into two groups, group-A; consist of 25 eyes who received 1.25 mg Intravitreal Bevacizumab and group-

B; consist of 25 eyes who received 0.5mg Intravitreal Ranibizumab. In group-A, one patient failed to follow-up and in group-B 2 patients failed to follow-up.

A detailed history was taken and ocular examination was performed. All the patients (eyes) were followed up for best corrected visual acuity and macular thickness before injection and after 3 months of intervention. The data was recorded in the Microsoft Excel sheet.

Inclusion criteria

- > 18 years of age patients.
- Patients diagnosed with diabetic retinopathy and diabetic macular edema.

Exclusion criteria

- Patients with any co-morbidity.
- Patients who were not willing to participate.
- Who didn't attend follow up.

Data was collected with the help of a record sheet which contains the test values and other details of all the patients. Data was tabulated, organized, analyzed and interpreted in both descriptive and inferential statistics i.e. frequency and percentage distribution, by using statistical package for social science software (SPSS), version 17.0.

Observations and Results

In our study, a total of 50 clinically diagnosed eyes of diabetic macular edema attending the Eye Outpatient Department were included and among them 3 patients failed to follow up till 3 months.

The mean age of the study patients was 45.7 ± 9.2 years in group -A and 45.4 ± 6.14 years in group-B. The majority of the patients were females with the female male ratio 1.28:1. The mean HbA1c score in group -A was 7.89 ± 1.02 and in group-B the HbA1c score was 7.72 ± 1.19 . The mean duration of diabetes mellitus in group-A was 10.13 ± 7.6 years and in group-B the mean duration was 9.34 ± 8.97 years. The mean duration of diabetic macular edema was 20.4 ± 19.4 months in group-A and in group-B the mean duration was 23.35 ± 21.12 months. The majority (57%) of the patients were from rural area followed by urban area (43%).

Table 1 Classification of Diabetic macular edema (DME)

Type of DME	Group -A		Group-B	
	No.	%age	No.	%age
Cyst	12	48	14	56

Sponge	4	16	3	12
Seris	6	24	4	16
Combined	2	8	2	8

Table 1, showed that majority (48%) of the patients in group -A has cyst diabetic macular edema followed by sponge (16%), seris (24%) and combined (8%) and patients in group-B has majority (56%) cyst diabetic macular edema followed by sponge (12%), seris (16%) and combined (8% each).⁷

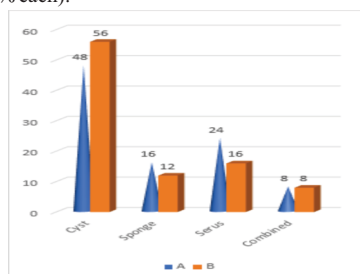


Figure 1. Classification of Diabetic macular edema (DME)

Table 2 Parameters of patients

Findings	Group-A		Group-B	
	Pre-Op	After 3 months	Post-Op	After 3 months
Best corrected visual acuity (LogMAR)	0.41±0.89	0.34±0.31	0.47±0.2	0.31±0.22
IOP (mmHg)	20.65±3.89	17±1.01	19.21±2.93	16.98±1.14
Central macular thickness (μm)	478.0±172.7	387.1±106.3	447±110.4	298.3±98.6

Table 2, depicted the best corrective visual acuity, intraocular pressure and central macular thickness of all the patients in both groups. It was observed that among both groups there was significant improvement in the patient's parameters. It was observed that ranibizumab was more effective than Intravitreal Bevacizumab.

Further, it was observed that there was significant difference in the VAS score among group-A and group-B (19.3±9.3 & 20.2±8.1 respectively). In Group-A 1 patients had vitreous hemorrhage, whereas no vitreous hemorrhage was reported in group-B.

DISCUSSION

In the present study 50 patients with diabetic macular edema was examined and treated to assess the efficacy and safety of Intravitreal Bevacizumab vs Ranibizumab in management of diabetic macular edema.

Data was analyzed and discussed with previously available literature. The mean age of the study patients was 45.7±9.2 years in group -A and 45.4±6.14 years in group-B. The majority of the patients were females with the female male ratio 1.28:1. The mean HbA1c score in group -A was 7.89±1.02 and in group-B the HbA1c score was 7.72±1.19. The mean duration of diabetes mellitus in group-A was 10.13±7.6 years and in group-B the mean duration was 9.34±8.97 years. The mean duration of diabetic macular edema was 20.4±19.4 months in group-A and in group-B the mean duration was 23.35±21.12 months. The majority (57%) of the patients were from rural area followed by urban area (43%).

The findings of our study are in accordance with the study conducted by Vader MJC et al., (2020), found that the mean age of the study patients was 63.9±11.6 years and 64.9±11.6 years in group-A and group-B. The majority of the patients were females.⁷ In another similar study conducted by Kaya M et al., (2018), categorized the patients in three groups, i.e. group-I, group-II & group-III. It was reported that patients mean age was 59.8±7.1 years, 61.8±10.4 years and 63.0±9.8 years respectively in three groups. The majority of the subjects were females. The mean duration of diabetes was 16.1±5.7 years, 14.5±6.4 years and 16.8±7.2 years respectively and mean score of HbA1c (%) was 7.6±1.1, 7.5±1.3 and 7.8±0.9 respectively.⁸

In our study majority of the patients in group-A and group-B had cyst diabetic macular edema. The results are consistent with the study conducted by Dr. Gupta E et al., (2022), reported that majority of the

study subjects had cystoid diabetic macular edema.⁹

It was reported that among both groups there was significant improvement in the patient's parameters, but, intravitreal ranibizumab was more effective than Intravitreal Bevacizumab. The findings of present study are consistent with the study conducted by Vader MJC et al., (2020) and Schauwvlieghe A. et al., (2015) reported that intravitreal ranibizumab was more effective than Intravitreal Bevacizumab.^{7,10}

The present study further founded that there was significant difference in the VAS score among group-A and group-B (19.3±9.3 & 20.2±8.1 respectively). In Group-A 1 patients had vitreous hemorrhage, whereas no vitreous hemorrhage was reported in group-B. Similarly, E Moisseiev, et al. (2014) reported there was no significant difference in VAS score among both the groups.¹¹

CONCLUSION

The diabetic macular edema results in significant impairment in vision. The present study concluded that the use of intravitreal ranibizumab was more effective than Intravitreal Bevacizumab in the treatment of diabetic macular edema.

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