Original Research Paper

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PERSPECTIVE ROLE OF INTRAVITREAL BEVACIZUMAB (AVASTIN) VS DEXAMETHASONE INTRAVITREAL IMPLANT (OZURDEX) IN MANAGEMENT OF DIABETIC MACULAR EDEMA.

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ABSTRACT The diabetic macular edema or diabetic macular edema is the complication of diabetic retinopathy. Diabetic retinopathy generally causes irreversible blindness by damaging the small blood vessels of retina. It is reported that 20% diabetic patients suffered from diabetic retinopathy. Various studies observed that that dexamethasone intravitreal implant showed faster resolution of diabetic macular edema than Bevacizumab. The purpose of present study is to determine the the efficacy & safety of intravitreal Bevacizumab (AVASTIN)and intravitreal Dexamethasone implant (OZURDEX) among patients with diabetic macular edema. In this prospective cross-sectional study A total of 50 eyes clinically diagnosed with diabetic macular edema attending the Department of Ophthalmology were included and randomly categorized into two groups. Group 1 were administered with intravitreal Avastin & Group II were administered with Dexamethasone Implant. The present study Concluded that there is significant improvement in the visual acuity, Intraocular pressure and central macular thickness with the use of intravitreal Avastin and intravitreal Ozurdex among patients with diabetic macular edema. Ozurdex was found to be more effective to reduce Central Macular Thickness than Avastin

KEYWORDS : Diabetic macular edema, Diabetic retinopathy, Diabetes, Efficacy,Intravitreal Bevacizumab and Intravitreal Dexamethasone.

INTRODUCTION

Retina is the light -sensitive tissue and macula is the part of the retina responsible for sharp, straight-ahead vision. A 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 or diabetic macular edema is the complication of diabetic retinopathy. Diabetic retinopathy generally causes irreversible blindness by damaging the small blood vessels of retina. It is reported that 20% diabetic patients suffered from diabetic retinopathy.[2]As the prevalence of diabetes is rising the diabetes related eye disorders are also increasing. About 6.8% diabetic patients suffers from diabetic macular edema.[3]

A retrospective study reported that the treatment pattern of diabetic macular edema within initial 28 days consists observation of the patient, anti-inflammatory, vascular endothelial growth factor inhibitors (anti-VEGFs) or combination of the treatment. The introduction of intravitreal pharmacological therapies in management of diabetic macular edema has made it possible to improve rather than just stabilize vision with the potential to improve patients' quality of life.4

The new gold standard treatment for diabetic macular edema is Anti–vascular endothelial growth factor (antiVEGF) agents as they are more superior over the laser photocoagulation.[5]

The study conducted by Arevalo JF, et al. (2007) demonstrated that the use of intravitreal bevacizumab (1.25 to 2.5 mg) provides stability or improvement in visual acuity, optical coherence tomography, and fluorescein angiography in diabetic macular edema at 6 months.[6]Similarly Medrano JR, et al. (2020), reported that the dexamethasone intravitreal implant in diabetic macular edema provided better functional outcomes.[7]

A comparative study showed that dexamethasone intravitreal implant showed faster resolution of diabetic macular edema than Bevacizumab.[8]

Thus, the present study was undertaken to determine the use of Intravitreal Bevacizumab (AVASTIN) vs Dexamethasone intravitreal implant (OZURDEX) in management of diabetic macular edema.

Aims And Objectives

1. To study the efficacy & safety of intravitreal Bevacizumab (AVASTIN) in diabetic macular edema.
2. To study the efficacy & safety of intravitreal Dexamethasone implant (OZURDEX) in diabetic macular edema.

MATERIAL AND METHODS

The present prospective cross-sectional studywas conducted in the Department of Ophthalmology at Acharya Shri Chander College of Medical Sciences and Hospital, Jammu, during the period of seven months (February 2022 to August 2022) after obtaining approval from the institute ethical committee.

A total of 50eyes clinically diagnosed with diabetic macular edema were involved after obtaining the informed consent from all the study participants.

Patients were randomly categorized into two groups, group I consist of 25 eyes who received Intravitreal AVASTIN and group II consist of 25 eyes who received Intravitreal OZURDEX. A detailed history (clinical history, medical and surgical past history and chief complaints) was taken and ocular examination (visual acuity, tonometry, torchlight examination, gonioscopy, slit lamp examination dilated fundus examination) and investigations (fundus photograph and OCT-3D macula) was done. All the patients (eyes) were followed up after 1 week, 1 month and 6 months later for visual acuity, intraocular pressure and central macular thickness. The post operative patients were administered with Eyedrops Gatifloxacin, Eyedrops Timolol/Dorzolamide/Prostaglandin analogue anti glaucoma drug.

Inclusion Criteria

- Patients with mild-moderate non-proliferative diabetic retinopathy (NPDR) with diabetic macular edema (DME).
- Age group 18-60 years.

Exclusion Criteria

- Study participants who were not willing to participate.
- Patients with optic nerve pathologies, any other fundus pathology, previous history of laser photocoagulation,cryotherapy,scleral buckling,intravitreal injection.
- Patients with severe & very severe non-proliferative diabetic retinopathy and with proliferative diabetic retinopathy(PDR)
- Patients with hazy ocular media.

Data was collected and tabulated in a excel sheet, it was analysed 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. Categorical variables were expressed as number and percentage.

OBSERVATIONS AND RESULTS

In the present study, 50 clinically diagnosed eyes of diabetic macular edema attending the Eye Outpatient Department were included. The mean age of the study patients was 61.7±11.2 years in group I and 63.9±12.04 years in group II. The majority of the patients were females with the female male ratio 1.38:1. The mean HbA1c score in

group I was 7.12±1.22 and in group II the HbA1c score was 7.27±1.39. The mean duration of diabetes mellitus in group I was 8.95±6.7 years and in group the mean duration was 11.5±7.97 years.The mean duration of diabetic macular edema was 22.4±27.9 months in group I and in group II the mean duration was 25.03±28.9 months.

Table 1 Type Of Diabetic Macular Edema (DME)

Type of DME	Group I		Group II	
	No.	%age	No.	%age
Cystic	13	52	11	44
Sponge	2	8	4	16
Serous	5	20	3	12
Combined	5	20	7	28

Table 1, showed that majority (52%) of the patients in group I has cystic diabetic macular edema followed by sponge (8%), serous & combined (20% each) and patients in group II has majority (44%) cyst diabetic macular edema followed by sponge (16%), serus (12%) and combined (28% each).

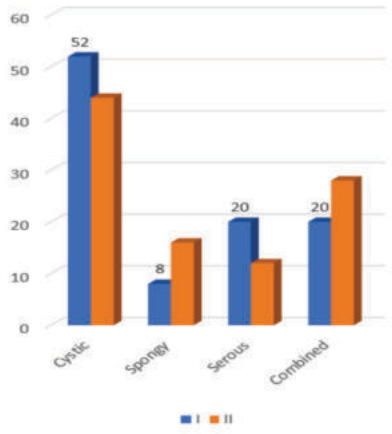

Figure 1. Type of Diabetic macular edema (DME)

Table 2 Group I findings (Intravitreal AVASTIN)

Findings	Pre-op	1 week	1 month	6 months
Visual acuity (LogMAR)	0.41±0.28	0.38±0.31	0.37±0.3	0.34±0.12
IOP (mmHg)	18.65±1.89	18.02±0.3	17.61±2.34	16.02±. 2.07
Central macular thickness (µm)	387.0±182.8	381.1±118.3	320±120.4	275.7±108.

Table 3 Group II findings (Intravitreal OZURDEX)

Findings	Pre-op	1 week	1 month	6 months
Visual acuity (LogMAR)	0.39±0.29	0.32±0.12	0.28±0.26	0.27±0.22
IOP (mmHg)	19.65±2.89	19.01 ±1.1	18.01 ±2.39	18.01 ±1.07
Central macular thickness(µm)	367.0±112.8	353.1±121.3	290±110.3	265.7±98.01

The present study revealed that there was significant improvement in the visual acuity, Intraocular pressure and central macular thickness with the use of intravitreal Avastin and intravitreal Ozurdex among patients with diabetic macular edema. It was observed that Ozurdex was more effective to reduce Central Macular Thickness than Avastin as depicted in table number 2 and table number 3.

Table 4 Comparison of the AVASTIN and OZURDEX

Parameters	Group I	Group II
Pain (mean±SD)	18.5±11.3	20.7±18.4
Subconj h'ge	1	2
Vitreous h'ge	2	2
Cataract	1	3
Uveitis	0	0
Retinal detachment	0	0
Endophthalmitis	0	0

Table 4, depicted that the mean VAS score of group I and group II was 18.5±11.3 and 20.7±18.4 respectively, 1 patient in Group 1 Had subconjuntival hemorrhage 2 Patients in Group II Had Subconjunctival Hemorrhage. 2 patients had vitreous hemorrhage in group I and 2 patient had Vitreous hemorrhage in group II, 1 patient in group I had cataract and 3 patients in group II had cataract

DISCUSSION

In the present study 50 patients with diabetic macular edema was involved to assess the efficacy and safety of intravitreal AVASTIN and OZURDEX. Data was analysed and discussed with literature.

It was observed that the mean age of the study patients was 61.7±11.2 years in group I and 63.9±12.04 years in group II. The majority of the patients were females with the female male ratio 1.38:1. The mean HbA1c score in group I was 7.12±1.22 and in group II the HbA1c score was 7.27±1.39. The mean duration of diabetes mellitus in group I was 8.95±6.7 years and in group the mean duration was 11.5±7.97 years. The mean duration of diabetic macular edema was 22.4±27.9 months in group I and in group II the mean duration was 25.03±28.9 months. In similar study conducted by Rosenblatt A. et al. (2020), found that the mean age of the study participants was 66.3±9.3 years and most of the patients were males, mean HbA1c score was 7.69±1.18 & 7.67±1.21, mean duration of diabetes was 14.16±9.54 &14.43±9.04, mean duration of diabetic macular edema was 24.3±28.8 27.0±32.1.[9]

The present study observed that there was significant improvement in the visual acuity, Intraocular pressure and central macular thickness with the use of intravitreal Avastin and intravitreal Ozurdex among patients with diabetic macular edema. In similar study conducted by Aroney C, et al. (2016) found that there was significant improvement in vision related quality of life among patients with diabetic macular edema after receiving the intravitreal Avastin and intravitreal Ozurdex.[10] In another study conducted by Shah SU, et al. (2016) and Laine I, et al. (2017) observed that that intravitreal Ozurdex showed more efficacy that intravitreal Avastin among patients with diabetic macular edema.[5,8]

Further it was observed thatthe mean VAS score of group I and group II was 18.5±11.3 and 20.7±18.4 respectively. 1 patient in Group 1 Had subconjuntival hemorrhage 2 Patients in Group II Had Subconjunctival Haemorrhage. 2 patients had vitreous hemorrhage in group I and 2 patient had Vitreous Haemorrhage in group II, 1 patient in group I had cataract and 3 patients in group II had cataract In similar study conducted by Moisseiev E, et al. (2014) reported the mean VAS score 20.8±20.3. in in patients and there was no significant difference in pain among both groups.[11]

CONCLUSION

The present study Concluded that there is significant improvement in the visual acuity, Intraocular pressure and central macular thickness with the use of intravitreal Avastin and intravitreal Ozurdex among patients with diabetic macular edema. Ozurdex was found to be more effective to reduce Central Macular Thickness than Avastin

REFERENCES

1. Macular edema. *National Eye Institute*. 2019. Available at: https://www.nei.nih. gov/learn-about-eye-health/eye-conditions-and-diseases/macular-edema.
2. Yau JWY, Rogers SL, Kawasaki R, et al. Global prevalence and major risk factors of diabetic retinopathy. *Diabetes Care*. 2012;35(3):556e564.
3. Hemal Mehta, Mark Gillies, Samantha Fraser-Bel. Perspective on the role of Ozurdex (dexamethasone intravitreal implant) in the management of diabetic macular oedema. *Therapeutic Advances in Chronic Disease*. 2015; 6(5):234–245.
4. Cantrell R. A., Lum F., Chia Y., et al. Treatment patterns for diabetic macular edema: an intelligent Research in sight (IRIS) registry analysis. *Ophthalmology.* 2020;127(3): 427–429.
5. Sanket U. Shah, Ashley Harless, Laura Bleau, Raj K. Matur. Prospective randomized subjectmasked study of intravitreal bevacizumab monotherapy versus dexamethasone implant monotherapy in the treatment of persistent diabetic macular edema. *Retina, The Journal of Retinal And Vitreous Diseases*. 2016; 36 (10):1986-1996.
6. Arevalo JF, Fromow-Guerra J, Quiroz-Mercado H, Sanchez JG, Wu L, Maia M, Berrocal MH, Solis-Vivanco A, Farah ME; Pan-American Collaborative Retina Study Group. Primary intravitreal bevacizumab (Avastin) for diabetic macular edema: results from the Pan-American Collaborative Retina Study Group at 6-month follow-up. *Ophthalmology*. 2007 Apr;114(4):743-750.
7. Ruiz-Medrano J, Rodríguez-Leor R, Almazán E, et al. Results of dexamethasone intravitreal implant (Ozurdex) in diabetic macular edema patients: Early versus late switch. *European Journal of Ophthalmology*. 2021;31(3):1135-1145.
8. Laine I, Lindholm JM, Ylinen P, Tuuminen R. Intravitreal bevacizumab injections versus dexamethasone implant for treatment-naïve retinal vein occlusion related macular edema. *Clin Ophthalmol*. 2017;11:2107-2112.
9. Amir Rosenblatt, Patricia Udaondo, José Cunha-Vaz, et al. A Collaborative Retrospective Study on the Efficacy and Safety of Intravitreal Dexamethasone Implant (Ozurdex) in Patients with Diabetic Macular Edema. *Ophthalmology.*2020; 127:377-393.
10. Aroney C, Fraser-Bell S, Lamoureux EL, Gillies MC, Lim LL, Fenwick EK. Vision-related quality of life outcomes in the BEVORDEX study: a clinical trial comparing

Ozurdex sustained release dexamethasone intravitreal implant and bevacizumab treatment for diabetic macular edema. Invest *Ophthalmol Vis Sci.* 2016;57:5541–5546.
11. E Moisseiev, M Regenbogen, T Rabinovitch, et al. Evaluation of pain during intravitreal Ozurdex injections vs intravitreal bevacizumab injections. *Eye*. 2014; 28: 980–985.