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ROLE OF BEVACIZUMAB IN DIABETIC MACULAR EDEMA

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Abstract:

Objective: To evaluate the efficiency of Bevacizumab injection for the treatment of macular edema in diabetic patients.

Methods: The study was carried out at Mayo Hospital Lahore (Department of Ophthalmology) from 26 May 2017 to 25 Nov 2017. Fifty-four patients of Diabetic Macular Edema (DME) were selected for this purpose. Bevacizumab (Avastin) 1.25 mg was vaccinated 3.5 mm from the limbus. The topical anesthetic drops were used prior to start of procedure. The follow up was scheduled on the same day and after one month of the procedure. Optical Coherence Tomography (OCT) was done for each patient seven days before and after 1 month of the 1st vaccination of Avastin. The data was analyzed by using the Statistical Package for Social Sciences.

Results: The procedure results showed some improvement. A reduction of more than 10% in macula thickness was observed in 43 cases (79.6%) that were injected with Bevacizumab, ten cases delivered less than 10% decrease in macular edema (18.5%) whereas one case of increase in ocular edema (1.9%) was observed after the one month of the procedure.

Conclusions: The study concluded that the eye injection of Bevacizumab is useful and can be used for the cure/management of DME.

Key Words: *Diabetic macular edema (DME), Bevacizumab, Macular thickness.*

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INTRODUCTION:

Complete or partial visual loss in diabetic patients is more often caused by DME. The Macular edema is defined as a medical condition in which the liquid in the eye blocks the retina causing the visual loss or limited sight. The diabetes patients are likely to develop diabetic macular edema during their lifetime. The percentage for DME in diabetic patient is about 10%. Beside diabetes, vascular endothelial growth factor (VEGF) is responsible for development of macular edema [1]. DME is seen to affect the visual ability of the patients in a way which cannot be regained. VEGF causes the liquid to exude into the retina in diabetes patients hence developing the DME. Some techniques such as focal laser photocoagulation was reported to control the DME and reduction in visual loss by 50%. The laser procedure does not work in cases of cataract and require alternate measures to cure DME. Vascular endothelial growth factor (VEGF) which was exposed in 1989 was reported to increase the epithelium of retina pigment due to Hypoxia – lack of oxygen to tissues. DME Patients are often seen with higher VEGF [2]. Patients who exude more liquid have higher VEGF as compared to the patients with reduced secretions. In view of the discussion above, an alternate anti VEGF supplemental method is required for the treatment of diabetic macular edema. Avastin (Bevacizumab) is the treatment of choice in this case which prevents all isoforms of Vascular Endothelial Growth Factor. Our research was aimed at finding out the efficacy Bevacizumab eye injection in diabetes patient suffering from macular edema.

METHODS:

The sample consisted of 54 patients (54 eyes) suffering from DME. Ethical approval for this research was obtained from the Ethical committee review board of the hospital. The diabetes patients (irrespective of severity, kind and stage of the disease) who had developed DME within the age range of 25 years - 75 years were selected for the research according to inclusion criteria. The patients with disturbed BP, cardiac diseases, eye infection/disease of any other nature, previously treated through bevacizumab, pregnancies and with laser treated eyes were dropped from the study according to exclusion criteria.

Informed consent was obtained from the sample after thorough briefing about the purpose of the research to all the subjects. The activity was held at Department of Ophthalmology, Mayo Hospital Lahore. Forms were filled for each patient and basic ocular evaluation was carried out. A week before the intravitreal injection, Optical Coherence Tomography was conducted for each patient using the standard setting of 3D OCT 2000 to check out the macular specifications. The baseline ocular review suggested the injection (1.25 mg/0.05ml) after local anesthesia. After one month of the procedure, OCT was again conducted for each patient to note the difference in macular thickness prior to and after procedure. The purpose of the Tomography carried after 1 month was to verify the efficacy of the Bevacizumab intravitreal eye injection. The expenses for this study were borne by the Federal Government of Pakistan and the results were analyzed with the help of Statistical Package for Social Sciences.

RESULTS:

The sample of 54 patients was given the Intravitreal Injection of Bevacizumab during the time period of the research. The sample constituted of both females (23) and males (31). The age range of the sample was from 25 to 75 years with a mean age of 55.44 years. The mean value for the duration of diabetes was calculated to be 10.15 years (± 3.21 years). Out of 54 patients, 10 patients were using insulin for diabetes whereas 44 were non-insulin dependent. Moreover, diabetes control through medicine was observed in 63% patients (34 cases) whereas no control was observed in 37% patients (20 cases) by use of anti diabetic medication.

Prior to procedure mean value for macular thickness was 384.38 (± 40.51) micrometers as compared to the macular thickness at follow up after 1 month of procedure recorded as 323.19 (±32.58) micrometers. Fifty-three cases have shown positive results for intravitreal injection except one case in which macular thickness has increased.

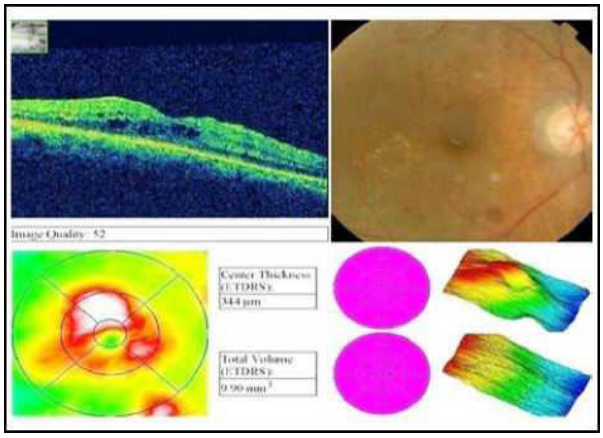


Fig.lA: Pre avastin OCT of a patient.

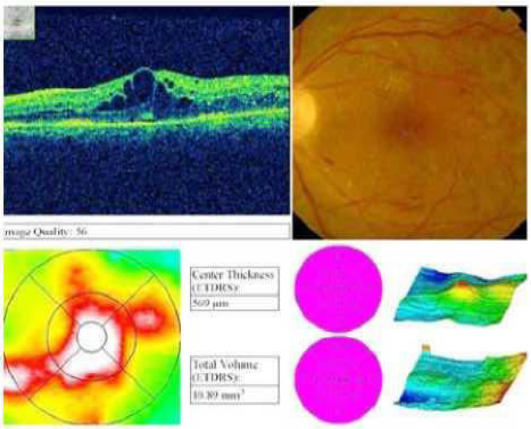
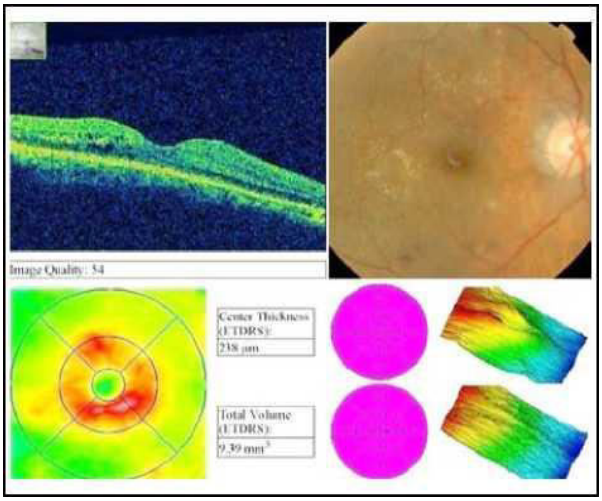
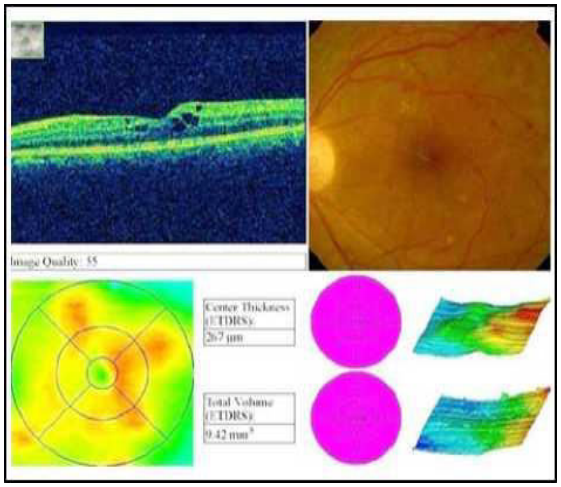


Fig.lB: Post avastin OCT of same patient after one month.





The results of intravitreal injection were encouraging in 79.6% case (43 patients with more than 10% decrease in macular edema). Only 18.5% (10 patients) showed less than 10% decrease in macular edema and in one patient the thickness was increased.

Table: Reduction in Macular thickness following single intravitreal injection of Avastin at one month follow up

Reduction in Macular Thickness	**Frequency**	**Percentage**
Yes > 10%	43	79.6
Yes < 10%	10	18.5
Increased	1	1.9
Total	54	100

DISCUSSION:

In cases of cataract or vitreous hemorrhage patients, laser grid is not always effective. Furthermore, other related eye complications such as glaucoma with hyphemia hinders the full laser procedure [3]. In some cases, the macular edema is not controlled by laser treatment. The present cure of edema (Bevacizumab) has shown comparatively better results for control of macular edema in less time [4]. A sample of 54 patients was selected for the evaluation of intravitreal injection which comprised of 23 females and 31 males with a mean age of (55.44 ± 7.38) years (age range 25 – 75 years) [5]. Most of the patients were 40 years and above. The subjects were from lower middle class and presented themselves to the government hospital during the period of the study [6]. The patients were less concerned about the quality health care, routine follow ups and diabetes control. The duration of the diabetes in most of the patients in our set up was longer enough to develop other related complications arising from the disease [7]. Another study directed by Mason reported the mean age of the sample as (47.7 ± 12.5) years (age range 26 – 63 years). Another research by Avery et al reported the sample of thirty-two patients mean age of 58 years (age range 27 - 82 years) [8]. Arevalo JF evaluated the sample of 33 patients (44 eyes) with a mean age of 57.2 years in his study. Different studies carried out at different locations on retinopathy among diabetic patients have variations in age groups [9].

El Haddad in his study showed that age of the patient is directly related to the retinopathy, further evaluation revealed that it was linked with longer diabetes duration [10]. The duration of diabetes in our set up was (10.15 ± 3.2) years as compared to Mason's study 18.4 years. Longer duration is strongly associated with DME. In non-insulin dependent patients, the discovery of diabetes is often deferred [11].

DME is the major cause of partial or complete visual loss among upper age people irrespective of the gender [12]. Our study reported 18.5% insulin dependent and 81.5% non-insulin dependent cases of diabetes patients suffering from macular edema. Similarly, Studies by Arevalo et al, El Haddad and Mason et al reported 69.7%, 17% and 43.3% IDDM and 31.3%, 83% and 56.7% NIDDM respectively. In our sample 34 patients were having effective diabetic control by the use of medication and 20 patients were not feeling any improvement after the use of anti diabetes medication. Interestingly, insulin dependent patients have showed better diabetic control in all subjects whereas fluctuations in diabetes control were recorded for NIDDM patients. Pre-operative macular thickness was calculated to be (384.38 ± 40.51) um which reduced to (323.19 ± 32.58) um after one month of the intravitreal injection of Bevacizumab (Avastin). Haritoglou et al have reported even better results with the reduction of up to 33% in macular thickness. Pre-procedure thickness was (498.96 ± 123.99) pm (Baseline) that reduced to (334.40 ± 121.76) pm after one month.

CONCLUSION:

The study concluded that the eye injection of Bevacizumab is useful and can be used for the cure/management of DME.

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