COMPARISON OF INTRAVITREAL BEVACIZUMAB AND TRIAMCINOLONE ACETONIDE WITH INTRAVITREAL BEVACIZUMAB ALONE IN MACULAR EDEMA SECONDARY TO CENTRAL RETINAL VEIN OCCLUSION

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METHODS

The study was approved by the ethical review committee of Hayatabad Medical Complex, Peshawar, Pakistan and adhered to the tenets of the declaration of Helsinki (Ref. no. 094/HEC/PICO/18). It was a quasi-experimental study conducted at the Department of Ophthalmology, Hayatabad Medical Complex (HMC), Peshawar from June 2018 to December 2018. This trial was registered with https://clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT04812977). The sample size for this study was calculated by a two-sample comparison of percentages calculator in which post-injection percentages were used. The SCORE study had shown that 3-line visual acuity gain was 30 percent from the baseline while another study conducted in India had shown that 3-line gain of visual acuity in 85 percent of patient15. For a 2-sided confidence level of 95% and power of 80%, the total sample size of 30 subjects with 15 in each group was calculated by using an online calculator. The subjects were recruited from the out-patient department (OPD). The written informed consent was taken from all subjects. Non-random sampling technique was used. Subjects were assigned to the treatment groups based on their presentation sequence; odd numbers were sent to group A and even numbers to group B. The CONSORT 2010 flow diagram is shown in figure 1. Subjects of either gender, age greater than or equal to 40 years, having ME secondary to CRVO, Best-corrected visual acuity (BCVA) of less than or equal to 0.3 on Log MAR chart (Snellen equivalent of 6/12), Central foveal thickness CFT greater than or equal to 250 microns on Heidelberg Spectralis Spectral Domain Optical coherence tomography (SD-OCT) and clinical diagnosis of CRVO by consultant vitreo-retina were included in this study. Subjects excluded from the study were those who previously received laser treatment and/or intravitreal injection of any Anti-VEGF agent, having one eye, diagnosed case of glaucoma, family history of glaucoma, young patient, and anyone who has received any treatment for CRVO before presenting to us. The slit lamp biomicroscopic examination was performed and clinically diagnosis of the presence of ME due to CRVO were documented. For each subject baseline (BCVA) was recorded on the Log MAR visual acuity chart. Base-line SD-OCT was done to record central foveal thickness (CFT).

Combination Therapy

A single injection of triamcinolone acetonide (Kenacort-A®). (2mg/0.05ml) and intravitreal bevacizumab (Avastin®) (1.25mg/0.05ml) was given at the start of the treatment whereas intravitreal bevacizumab (1.25mg/0.05ml) was repeated monthly for 3 months. Group A received combination therapy of IVB (1.25mg/0.05ml) and IVT (2mg/0.05ml) injection while group B received IVB (1.25mg/0.05ml) alone. All subjects were observed by a vitreo-retina consultant. The main outcome of the study was an improvement in visual acuity and central foveal thickness CFT on SD-OCT from baseline to the sixth month. At each subsequent visit at 3, 6 months post-injection, patient visual acuity (VA in Log-MAR), and central foveal thickness (on SD-OCT) were measured.

Statistical Analysis:

The data were analyzed by using SPSS version 24. The post-injection visual acuity and central foveal thickness were used to calculate results and student t-test were applied on these two variables of group A and group B. The with-in the groups and between the groups' comparisons were done to check for any statistical difference between the outcome at baseline and follow-up. A p-value of < 0.05 was taken as significant.