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THE CHANGE IN IINTRAOCULAR PRESSURE AFTER INTRAVITREAL INJECTION OF ANTIVEGF

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Keywords

Intraocular pressure (IOP), Vascular endothelial growth factor, Bevacizumab, Intraocular pressure, Diabetic retinopathy.

Article History

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Abstract

Objective: *To determine the mean change in intraocular pressure at 05, 30 min, 1 and 2 weeks after intravitreal injection of anti-vascular endothelial growth factor.*

Study Design: *Quasi-Experimental*

Duration: *7th February 2024 to 6th September 2024*

Material & Methods: *This study includes a total of 100 patients, both male and female, aged >35 and <70 years. The patients included had undergone a comprehensive ophthalmic examination, which included a history, intraocular pressure using a Goldman applanation tonometer, subjective and objective refraction by autorefractometer, pinhole test, slit lamp examination of the adnexa, anterior segment examination, and fundus examination with 90D and 78D. In suspected DME, ARMD, CRVO, and BRVO patients who presented with decreased near vision and metamorphasia, we measured the thickness of the macular and retinal nerve fiber layer using OCT SD on a Heidelberg machine to validate the requirement for anti-vgef.*

Results: *One hundred participants, with an average age of 56.76 ± 12.88, were enrolled in this study. The study population, which consisted of 62 people (62%), was primarily male. Sixty-four percent of the patients, or 64 people, were older than 55. In 18% of instances, age-related macular degeneration (ARMD) was found. Intraocular pressure measurements (in mmHg) were measured at baseline, five minutes, thirty minutes, after the first week, and after the second week using repeated measures ANOVA. Statistical significance was found in the study's findings ($p<0.001^*$). In particular, the mean intraocular pressure rose from baseline to 5 and 30 minutes; nevertheless, it was noted that the intraocular pressure values considerably decreased to baseline levels at the first and second weeks.*

Conclusion: *Anti-VEGF medication IVIs are safe, although they may cause elevated intraocular pressure. IOP frequently rises quickly and temporarily after IVI, although most patients see a sharp decline within 30 minutes of the injection.*

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INTRODUCTION

Major cause of visual impairment and blindness worldwide is age related macular degeneration ARMD (196 million prevalence worldwide)[1], retinal vein occlusion RVO (16.4 million prevalence worldwide)[2], diabetic retinopathy DR (96 million prevalence worldwide).[3] The major common pathophysiology in these disease is that there is new abnormal growth of vessels due to ischemia that releases multiple metabolic factors i.e. platelet derived growth factor, endothelial growth factor, vascular endothelial growth factor and others.[4]

The recent advance treatment for these disease works on inhibiting vascular endothelial growth factor that is available in drugs form as aflibercept, ranibizumab, bevacizumab injected intravitreally.[5,6] Antivegf is most widely used treatment for (DR, ARMD and RVO). Although antivegf drugs are well proven effectively there are few systemic and ocular adverse effects of these drugs as well i.e. acute blood pressure elevation, intra ocular inflammation, ocular hemorrhage & elevated intraocular pressure.[7,8]

After searching on PubMed & Pakmedinet using keywords intraocular pressure, anivegf, many studies reported that there is an elevation of intraocular pressure post injection of intravascular endothelial growth factor. IOP rise of >20% from baseline was present in most eyes (70.4%) with persistent elevation. The more stringent requirements (>6 mmHg from baseline or an IOP rise >24 mmHg) were only met by 13 eyes (1.71%). statistics from study[9], and the increased intraocular pressure may have adverse effects on the blood flow to the retina and optic nerves due to the amount of anti-vegf.[10] Study by Mansoori et al reported the mean change in IOP after 1 day and 1 week of anti VEGF treatment was 0.29 ± 2.35 and 0.21 ± 2.85 respectively.[11] Another study reported the baseline IOP 16.16 ± 2.52 and after 5 mins of anti VEGF injection 27.44 ± 5.66.[12]

Pakistan, it is approximated that diabetic retinopathy affects around 3% cases of blindness. The rationale of this study is to validate the change in mean intraocular pressure after injection of antivegf in people of Karachi as there is very little information on it. This study will help to ophthalmologist in taking precautions against acute rise and to population in preventing any untoward effect of antivegf on optic nerve, retinal blood supply and on vision.

MATERIALS AND METHODS:

The Ophthalmology department, Liaquat National Hospital Karachi carried out this quasi-experimental study from 7th February 2024 to 6th September 2024. Patients having age in between 35-70 yrs diagnosed as diabetic retinopathy (presence of neovascularization on disc or elsewhere with or without central macular edema according to ETDRS classification of diabetic retinopathy confirmed on clinical, oct or ffa (severe NPDR WITH CSME, CSME or PDR is an indication of antivegf), retinal vein occlusion (occlusion of central, branch or hemi retinal vein characterized by arterial narrowing, tortious veins, cotton wool spots and hemorrhages leading to decrease perfusion of retina increasing tendency of angiogenesis (NVE or NVI at any stage is indication of antivegf)or (CME, diagnosed on oct as central macular thickness greater than 250microns)), age related macular degeneration (presence of drusens, intraretinal hemorrhages, pigment epithelial detachment, choroid neovascularization diagnosed on clinical, Oct or FFA is an indication of antivegf) and undergoing 1st intravitereal injection of antivegf were included. Sample size was calculated by using G-power. By using the mean baseline IOP 16.16 ± 2.52 and IOP after 5 mins of injection 27.44 ± 5.66[12], assuming correlation 0.5, power 95% and confidence level 95%. The calculated sample size is 5 but we enrolled 100 patients. Patient who had already intravitreal antivegf injection or different dose & type of antivegf, undergone any ocular surgery during injection of antivegf doses or known glaucoma and ocular hypertension and on steroids or iop lowering agent (intravitereal, topical or oral) were excluded.

After approval by REC, sample has been collected through consecutive non probability sampling from outpatient department of ophthalmology department liaquat national hospital on routine basis. Those patients included had undergone complete ophthalmic examination including history, subjective and objective refraction by autorefractometer,

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pinhole test, slit lamp examination of adnexa, anterior segment examination and fundus examination with 90D and 78D along with intraocular pressure on Goldman applanation tonometer. We had obtained macular and retinal nerve fiber layer thickness by OCT SD on Heidelberg machine in suspected patients of DME, ARMD, CRVO and BRVO having presenting compliant of decrease near vision, metamorphasia for confirming the need of antivegf. We had explained the whole procedure to patient and after informed written consent has been taken for this study. A questionnaire about variables i.e. age, gender, previous ocular surgery, previous intravitreal injection, any medication history has been self-interviewed.

Collected data has been entered and analyzed through IBM SPSS Statistics version 26.00. Normality was checked by Shapiro wilk test. Mean and standard deviation or Median and interquartile range has been used for quantitative variable such as age, intraocular pressure at baseline, at 05 minutes, at 30 min, after 1st week and after 2nd week. Frequency and percentage reported for gender, diabetes mellitus, hypertension, asthma, any ocular surgery and lens status, history of any previous intravitreal injection and history of any antiglaucoma drug usage. Mean comparison of IOP at baseline line has been done with IOP at 05 min, at 30 min, after 1st week and after 2nd week by Repeated measure ANOVA. Stratification has been done and mean comparison was done for stratified categories of age, gender, diabetes mellitus, hypertension, asthma, any ocular surgery, lens status, history of any previous intravitreal injection and history of any antiglaucoma drug usage. Post stratification independent t-test / Mann Whitney U test been applied taken P-value less than or equal to 0.05 has been considered significant.

RESULTS:

This study involved the enrollment of 100 participants, with a mean age of 56.76 ± 12.88. The study population exhibited a predominance of males, comprising 62 individuals (62%). A majority of the patients, constituting 64 individuals (64%), were aged more than equal to 55 years or older. The median intraocular pressure (IOP) levels were recorded at baseline, 05 minutes, 30 minutes, after the first week, and after the second week, with values of 16 (range: 17.5 - 14), 38 (range: 44 - 30), 32.5 (range: 40 - 28), 20 (range: 24 - 19), and 17 (range: 18 - 14), respectively. (Table-I)

Hypertension (HTN) stands out as the predominant comorbid condition, affecting 59 individuals (59%). Following closely, diabetes mellitus (DM) emerges as the second most prevalent, with 55 cases (55%), while only 14 individuals (14%) experienced asthma. Out of the total observed, 38 individuals (38%) had undergone ocular surgery. Further stratification based on lens status revealed that 38 (38%) were pseudophakic, having artificial lenses, while 62 (62%) were observed to be phakic, retaining their natural lenses. A total of 14 individuals (14%) were noted to have a history of prior intravitreal injections. Ten patients (10%) were noted to have observed antiglaucoma treatment. Age-related macular degeneration (ARMD) was observed in 18% of the total cases.

Repeated measures ANOVA was conducted to assess intraocular pressure readings (in mmHg) at various time points: baseline, 5 minutes, 30 minutes, after the 1st week, and after the 2nd week. The study findings revealed statistical significance. Specifically, the mean intraocular pressure increased from baseline to 5 and 30 minutes; however, it was observed that at the 1st and 2nd weeks, the intraocular pressure values significantly returned to levels similar to the baseline readings. (Table-II)

The Mann-Whitney U test was employed across distinct time points: baseline, 5 minutes, 30 minutes, after the 1st week, and after the 2nd week. No significant differences in medians were noted at these time points ($p > 0.05$). Similarly, the median differences related to gender, asthma, having undergone ocular surgery, and a history of any previous intravitreal injection were found to be insignificant at these various time points ($p > 0.05$). Interestingly, diabetes patients had higher eye pressure before the injection at the beginning and at the 2nd-week follow-up, showing significant differences (P=0.010* and P=0.049*). Similarly, hypertension patients at the beginning and at the 2nd-week follow-up, showing significant differences (P=0.027* and P=0.006*). It was surprising to observe a significant decrease in patients with

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antiglaucoma treatment at different time points: baseline, 5 minutes, 30 minutes, after the 1st week, and after the 2nd week (P < 0.05*), respectively. (Table-III & IV).

Table I: Descriptive Statistics of the patient's characteristics

Study Parameters	Shapiro-Wilk (Test of Normality)		
	Measurement	Sig.	Descriptive
Age in (Years)	Mean ± SD	0.0800	56.76 ± 12.88
IOP Preinjection	Median [IQR]	0.0000	16 [17.5 -14]
IOP Preinjection at 5min	Median [IQR]	0.0030	38 [44 -30]
IOP Preinjection at 30min	Median [IQR]	0.0360	32.5 [40 -28]
IOP Preinjection at 1stweek	Median [IQR]	<0.001*	20 [24 -19]
IOP Preinjection at 2ndweek	Median [IQR]	<0.001*	17 [18 -14]

Table 1: Mean comparison of IOP at baseline line has been done with IOP at 05 min, at 30 min, after 1st week and after 2nd week by Repeated measure ANOVA

Multivariate Testsa						
Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	0.918	269.371b	4	96	<0.001*
	Wilks' Lambda	0.082	269.371b	4	96	<0.001*
	Hotelling's Trace	11.224	269.371b	4	96	<0.001*
	Roy's Largest Root	11.224	269.371b	4	96	<0.001*

Mauchly's Test of Sphericity[a]							
Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
factor1	*0.015*	*411.845*	*9*	*<0.001**	*0.34*	*0.343*	*0.25*

a. Design: Intercept

Within Subjects Design: factor1

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Tests of Within-Subjects Effects						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
factor1	Sphericity Assumed	*40022.800*	*4*	*10005.700*	*663.784*	.000
	Greenhouse-Geisser	*40022.800*	*1.360*	*29420.487*	*663.784*	.000
	Huynh-Feldt	*40022.800*	*1.373*	*29154.682*	*663.784*	.000
	Lower-bound	*40022.800*	*1.000*	*40022.800*	*663.784*	.000
Error(factor1)	Sphericity Assumed	*5969.200*	*396*	*15.074*		
	Greenhouse-Geisser	*5969.200*	*134.677*	*44.322*		
	Huynh-Feldt	*5969.200*	*135.905*	*43.922*		

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	Lower-bound	*5969.200*	*99.000*	*60.295*		

Tests of Between-Subjects Effects					
Transformed Variable:	**Average**				
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Intercept	*311750.450*	*1*	*311750.450*	*2465.799*	*.000*
Error	*12516.550*	*99*	*126.430*		

Table III: Median comparison with IOP at 05 min, at 30 min, after 1st week and after 2nd week for stratified categories of age, gender, diabetes mellitus, hypertensioN

	IOP Preinjection	P-value	IOP Preinjection at 5min	P-value	IOP Preinjection at 30min	P-value	IOP Preinjection at 1stweek	P-value	IOP Preinjection at 2nd week	P-value
	Median [IQR]		Median [IQR]		Median [IQR]		Median [IQR]		Median [IQR]	
Age Groups										
<55 Years	15 [17 - 14]	0.283	33 [42 - 30]	0.183	30 [40 - 26]	0.2	20 [24 -18.5	0.554	16 [18 - 14.5]	0.518
>=55 Years	16 [18 - 13]		38 [45 - 30]		33.5 [40.5 -29]		20 [24 - 19]		17 [19 - 14]	
Gender										
Female	16 [18 - 15]	0.122	38 [45 - 32]	0.331	34.5 [42 - 28]	0.407	20.5 [24 - 19]	0.421	17 [19 - 15]	0.072
Male	15 [17 - 13]		36.5 [43 - 30]		32 [40 - 28]		20 [24 - 19]		16 [18 - 14]	
Diabetes Mellitus (DM)										
Yes	16 [18 - 15]	0.011*	40 [44 - 30]	0.435	34 [40 - 27]	0.595	20 [24 - 19]	0.989	17 [19 - 15]	0.049*
No	15 [16 - 13]		34 [44 - 30]		32 [40 - 28]		20 [24 - 18]		16 [18 - 14]	
Hypertension (HTN)										
Yes	16 [18 - 14]	0.027*	40 [46 - 30]	0.089	34 [42 - 30]	0.014*	22 [24 - 20]	0.006*	17 [19 - 15]	0.017*
NO	15 [17 - 13]		34 [42 - 30]		30 [37 - 24]		19 [21 - 18]		16 [18 - 14]	

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Table IV: Median comparison with IOP at 05 min, at 30 min, after 1st week and after 2nd week for stratified asthma, any ocular surgery, lens status, history of any previous intravitreal injection and history of any antiglaucoma drug usage.

	IOP Preinjection	P-value	IOP Preinjection at 5min	P-value	IOP Preinjection at 30min	P-value	IOP Preinjection at 1stweek	P-value	IOP Preinjection at 2nd week	P-value
	Median [IQR]		Median [IQR]		Median [IQR]		Median [IQR]		Median [IQR]	
Asthma										
Yes	16 [19 -14]	0.701	41 [48 - 30]	0.266	38 [44 - 27]	0.228	20.5 [24 - 20]	0.443	17.5 [19 -16]	0.402
NO	16 [17 -14]		37 [44 - 30]		32 [40 - 28]		20 [24 - 19]		17 [18 - 14]	
Any Ocular Surgery										
Yes	16 [18 -12]	0.627	36 [44 - 29]	0.378	32.5 [40 - 28]	0.733	20 [22 - 19]	0.32	17 [19 - 14]	0.96
NO	16 [17 -14]		38.5 [44 - 30]		33 [40 - 28]		20.5 [24 - 19]		16 [18 - 15]	
History of any previous intravitreal injection										
Yes	16 [18 -12]	0.689	34 [42 - 29]	0.232	31 [33 - 24]	0.164	20 [20 - 18]	0.133	16.5 [19 -12]	0.491
No	16 [17 -14]		38 [44 - 30]		34 [40 - 28]		20 [24 - 19]		17 [18 - 15]	
Anti glucoma										
Yes	10.5 [17 - 10]	0.048*	25 [30 - 25]	0.001*	23 [29 - 22]	0.002*	18 [19 - 18]	0.008*	13 [17 - 12]	0.016*
No	16 [18 -14]		38.5 [44 - 30]		34 [40 - 28]		20 [24 - 19]		17 [19 - 15]	
Age related macular degenration (ARMD)										

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Yes	18 [19 -16]	0.011*	39 [44 - 30]	0.663	34 [40 - 28]	0.815	20 [24 - 19]	0.615	17 [18 - 16]	0.473
No	15 [17 -13]		38 [44 - 30]		32 [40 - 27]		20 [24 - 19]		16.5 [18 -14]	

DISCUSSION:

Injections of intravitreal anti-VEGF are now a recognized therapy option for a variety of choroidal and retinal disorders. For this, a wide variety of anti-VEGF injections are utilized. Bevacizumab is used off-label, while the three licensed ones are ranibizumab, aflibercept, and pegaptanib. Bevacizumab is frequently utilized in underdeveloped nations despite being off-label because of its accessibility and affordability.

Our study results involved the enrollment of 100 participants, with a mean age of 56.76 ± 12.88. The study population exhibited a predominance of males, comprising 62 individuals (62%). A majority of the patients, constituting 64 individuals (64%), were aged more than equal to 55 years or older. The median intraocular pressure (IOP) levels were recorded at baseline, 05 minutes, 30 minutes, after the first week, and after the second week, with values of 16 (range: 17.5 - 14), 38 (range: 44 - 30), 32.5 (range: 40 - 28), 20 (range: 24 - 19), and 17 (range: 18 - 14), respectively.

Repeated measures ANOVA was employed to analyze intraocular pressure readings (in mmHg) at various time points: baseline, 05 minutes, 30 minutes, after the 1st week, and after the 2nd week. The results revealed a significant decrease ($p<0.001$*) in intraocular pressure after the second week of observation. The repeated measurement graph initially showed an increase at 5 minutes and 30 minutes, followed by a significant reduction at the 1st and final follow-up in the 2nd week. This pattern suggests an initial rise in measurements at the earlier time points, followed by a notable decrease during the subsequent observations in the 1st week and the final follow-up in the 2nd week. Since the use of anti-VEGF injections has become widespread, there is constant worry about the potential negative effects on the eyes. LoBue SA. et al., examined the ocular side effects of intravitreal bevacizumab injections in eyes with choroidal or retinal neovascularization.[13] After 12 weeks, only two of these eyes showed a negligible increase in intraocular pressure. Numerous investigations using intravitreal bevacizumab to detect long-term ocular hypertension have produced inconsistent results. Ocular hypertension is thought to be caused by a number of causes, including silicone microdroplets, autoimmune reactions, protein aggregation, trabecular congestion, trabecular changes following repeated injections, and chronic trabeculations.[14]

The current study looked into the immediate rise in IOP after the first-time Intravitreal injection of bevacizumab. In this study, the IOP The median intraocular pressure (IOP) levels were recorded at baseline, 05 minutes, 30 minutes, after the first week, and after the second week, with values of 16 (range: 17.5 - 14), 38 (range: 44 - 30), 32.5 (range: 40 - 28), 20 (range: 24 - 19), and 17 (range: 18 - 14), respectively. According to published research, IVTs of anti-VEGF medications are often followed by brief rises in IOP.[15-17] A study of the literature on the effects of different anti-VEGF drugs (bevacizumab, ranibizumab, aflibercept, and pegaptanib) on intraocular pressure was carried out by Hoguet et al.[18] They came to the conclusion that while research on the short-term changes in intraocular pressure (IOP) after IVTs varied in design, all of them consistently demonstrated an instantaneous increase in IOP, which was seen in 100% of eyes within one minute after injection. Within 30 minutes following the surgery, 92% to 97% of subjects showed an IOP below 30 mm Hg, indicating that this peak was temporary. The analysis, according to the same authors, showed that the mean IOP ranged from 28.3 to 55.2 mm Hg within 1 minute after the injection. After that, the mean IOP gradually decreased at subsequent time points, falling from 24.5±11.7 mm Hg to 28.3±4.2 mm Hg at 10 minutes, from 17.6±5.0

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mm Hg to 20.6±9.5 mm Hg at 30 minutes, and between 31.4±14.4 mm Hg and 34.1±2.7 mm Hg at 5 minutes.[18]

After searching on PubMed & Pakmedinet using the keywords intraocular pressure, and anivegf, many studies reported that there is an elevation of intraocular pressure post injection of intravascular endothelial growth factor. IOP rise of >20% from baseline was present in most eyes (70.4%) with persistent elevation. The more stringent requirements (>6 mmHg from baseline or an IOP rise >24 mmHg) were only met by 13 eyes (1.71%). statistics from study[9], and the increased intraocular pressure may have adverse effects on the blood flow to the retina and optic nerves due to the amount of anti-vegf.[10] The study by Mansoori et al reported the mean change in IOP after 1 day and 1 week of anti-VEGF treatment was 0.29 ± 2.35 and 0.21 ± 2.85 respectively.[11] Another study reported a baseline IOP of 16.16 ± 2.52 and after 5 mins of anti-VEGF injection 27.44 ± 5.66.[12]

After IVI, an abrupt increase in the volume of the closed vitreous cavity due to the injected medication induces an intraocular pressure rise. The aqueous outflow is changed by this volume effect, which causes an instantaneous, temporary rise in IOP. It is more debatable, nevertheless, how persistent IOP elevation occurs. An extended rise in IOP may result in reduced blood supply to the juxta-papillary retina and optic nerve head, harming the RNFL irreparably.[19,20]

CONCLUSION:

Anti-VEGF medication IVIs are safe, although they may cause elevated intraocular pressure. IOP frequently rises quickly and temporarily after IVI, although most patients see a sharp decline within 30 minutes of the injection.

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