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Comparison between intraocular pressure spikes following intravitreal aflibercept injections between phakic and pseudophakic eyes

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Abstract

Background and objective: The quickest growth in the field of ophthalmology are intravitreal injections. Age-related macular degeneration, diabetic retinopathy and occlusive venous disease associated macular oedema include the most frequent indications of injections. Antiangiogenic agents are the most common injections. The aim of this study is to determine intraocular pressure changes following intravitreal injections between phakic and pseudophakic eyes.

Methods: A hospital based prospective cross-sectional study involved 50 patients divided into two groups; 27 phakic patients marked as group A, while 23 pseudophakic patients as group B. The study conducted in ophthalmology department of Erbil Teaching Hospital in Erbil city from July 2021 till April 2022. The participants were recruited from the outpatient clinic and planned for intravitreal anti-VEGF / aflibercept (EYLEA®) injection.

Results: The mean intraocular pressure difference pre-injection and six hours after single injection was -0.59 ± 1.21 and -0.65 ± 1.19 mmHg (higher in the post injection period) for group A and B respectively. This difference was statistically significant (*P* value was 0.018 and 0.015) for both group A and B respectively. The intraocular pressure levels reduced slightly after twenty-four hours following injection; the difference in intraocular pressure level between 6 hours and twenty-four hours was statistically significant for the phakic group (*P* value of 0.29) but insignificant for the pseudophakic group (*P* value of 0.056).

Conclusion: The status of the lens either being phakic or pseudophakic has no implication on intraocular pressure after intravitreal anti-VEGF injection. There was a statistically significant short-term increase in intraocular pressure in both groups after six hours of intravitreal injection.

Keywords: Intravitreal injections; Age-related macular degeneration; Diabetic retinopathy; Intraocular pressure; Anti–vascular endothelial growth factor.

Introduction

The quickest growth in the field of ophthalmology and medicine in general are intravitreal injections. Age-related macular degeneration, diabetic retinopathy and occlusive venous disease associated macular oedema include the most frequent indications of injections. Antiangiogenic agents (e.g., aflibercept, bevacizumab and ranibizumab) are the most common injections.[1,2]

Steroid preparations including sustained delivery instruments, antimicrobial drugs, and several medicines that will likely be accepted in clinical trials for the coming years include other intravitreal injections. Estimates from Medicare procedure codes, the number of injections in the US has raised to an estimated 6.5 million injections in 2016 compared to less than 3000 a year in 1999. As a result of ageing, new drugs are available and an expanding list of indications, this number is also rising.[2,3]

Three to four millimeters away from limbus

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injections can be done safely. Commonly used methods of administration of the anesthesia prior to intravitreal injection include anesthetic pledgets or cotton tips, topical (including viscous) preparations for the anesthetic, and subconjunctival lidocaine injection.[2,4]

The most feared complication due to intravitreal injection remains endophthalmitis; the recorded incidence ranges from 0.02% to 0.2%. While the most frequent sources of infection are the patient's own conjunctiva, eyelids and even though respiratory organisms may cause endophthalmitis via contamination from respiratory droplets. The possible inflammatory mechanisms thus involve the direct bacterial inoculation into the vitreous or subsequent contamination of the wound. [5]

Therefore, measures to minimize respiratory-droplet complications, such as minimization of the patient and provider speaking and the use of the facial masks during the operation, should be taken into consideration. Moreover, unnecessarily manipulations of the eyelid margin should be prevented to restrict the excretion of bacterially charged secretions from Meibomian glands, and intensive blepharitis treatment for patients with serious disease before injection should be considered. Endophthalmitis outbreaks in the past have led to a frequent review of pharmaceutical compounding procedures and accreditation status to minimize the likelihood of potential outbreaks. Another complication involves high intraocular pressure, either as a result of intravitreal injections of anti-VEGF agents or a typical adverse effect of steroid injections.[2]

Aflibercept (Eylea®) Aflibercept is a recombinant fusion protein which binds to VEGF-A, VEGF-B and the placental growth factor (PlGF). The clinical protocol was widely implemented after being commercially available, mainly because, as opposed to monthly injections prescribed for ranibizumab and bevacizumab, the recommended maintenance regimen consists of one injection every 2 months. Some patients are more likely needed to be injected more than once; every 2 months. The normal dose is 2 mg per 0.05 ml; three injections are administered at monthly intervals as an induction course.[6,7]

Ranibizumab (Lucentis®). A humanized monoclonal antibody fragment developed particularly for use in the eye, but derives from the same parent mouse antibody as bevacizumab. It binds and inhibits non-selectively all VEGF-A isoforms.[8]

Bevacizumab (Avastin®). Bevacizumab, unlike ranibizumab, was originally formulated as a complete antibody developed to target the growth of blood vessels in metastatic cancer deposits. The use in AMD and other indications is ‘off label’. it is very much cheaper than ranibizumab and aflibercept. Treatment methods are similar to ranibizumab in AMD. Usually 1,25 mg/0,05 mL is the bevacizumab dose.[6,9]

Pegaptanib (Macugen®). The first approved anti-VEGF agent for ocular therapy was Pegaptanib sodium; the findings are close to results with PDT, and its use is now extremely reduced.[6,10]

The importance of this study is to know the comparison between intraocular pressure spikes following intravitreal injections between phakic and pseudophakic eyes. This study was conducted to demonstrate that numerous people experience increases in intraocular pressure following intravitreal injections, which, if not adequately managed and treated, could result in blindness. The aim of this study is to determine intraocular pressure (IOP) changes following intravitreal injections between phakic and pseudophakic eyes.

Methods

Study design and setting

The study was a hospital based prospective longitudinal study which involved 50 patients which had been divided into two groups; phakic patients were marked as group A while

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pseudophakic patients marked as group B. The study was conducted in ophthalmology department of Erbil Teaching Hospital in Erbil city from July 2021 till April 2022. The participants were recruited from the outpatient clinic and planned for intravitreal anti-VEGF / aflibercept (EYLEA®) injection. Participant should have the following criteria in order to be involved in the study: Wet AMD or macular edema due to DM or RVO, patients with normal cornea on biomicroscope and CCT of between 520 and 555 µm, participants with open and normal anterior chamber angle on gonioscopy. And patients with uneventful phacoemulsification surgery with hydrophilic foldable IOL implanted in the capsular bag for the pseudophakic group.

Any participant with any of the following settings has been excluded from the study: Participants with orbital disease such as thyroid, history of previous ocularor refractive surgery (exceptpatients with uneventful phacoemulsification surgery with hydrophilic foldable IOL implanted in the capsular bag for the pseudophakic group) or with ocular diseases, participants with ocular inflammation or rubeosis, patients with primary open-angle glaucoma (POAG), chronic primary angle closure glaucoma (CACG), normal tension glaucoma (NTG) or secondary glaucoma.

Study participants' assessment

Full ophthalmological evaluations based on clinical history and examination, including best corrected visual acuity (BCVA) using Snellen charts, slit-lamp bio microscopy, gonioscopy and dilated fundus examination using condensing lenses were performed.

IOP was evaluated using a slit lamp-mounted Goldmann applanation tonometer, (Figure 1, 2). Tetracaine eye drop had been used to numb participants' eyes and sterile fluorescence were used to stain the tear. The IOP measurement was carried out before intravitreal injection for every eye. After intravitreal injection, two other measurements took place at six and twenty-four hours post injection. Subjects have been made aware never to squeeze their eyes or hold their breath. The measured IOP were adjusted to CCT measurement for each patient.

IOP spike is defined as an IOP level of more than 30 mmHg or an elevated IOP of 5 mmHg more than the recorded baseline level.

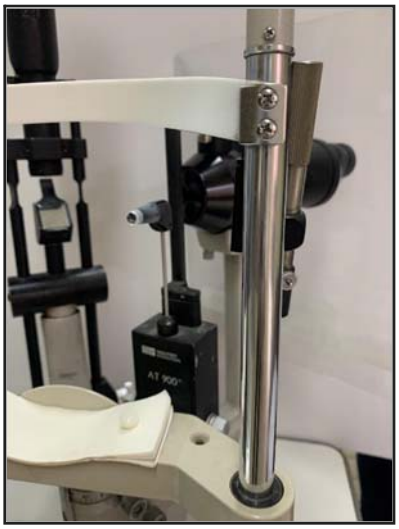

Figure 1 Goldmann applanation tonometer.

Figure 2 Ultrasonic pachymeter. TOMEY SP-100HAAG-SREIT INTERNATIONAL AT900.

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Single intravitreal injections were given in operating theater with optimal sterile conditions. The eye is anesthetized with sterile tetracaine drops, povidone iodine 5% is instilled into the eye and used to sterile the skin around the eye then a drape is placed over the patients' eye with a speculum being inserted. Using a caliber (4mm from limbus for phakic/3.5mm from limbus for pseudophakic patients), 2mg/0.05mL of aflibercept (EYLEA® vial) were injected intravitreally through 30-gauge × ½-inch sterile injection needle. A sterile cotton swap was applied on the injection site to prevent medication reflux. Only antibiotics drops had been prescribed for the patients for 4 days.

Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) version 26 was used for data analysis. Quantitative continuous variables were presented as mean, median and standard deviation. Qualitative nominal and ordinal data presented as frequencies and per-cent. Shapiro-Wilk test was used to test for normality. Correlated samples were compared using paired sample t test. Mann-Whitney U test was applied to correlate independent variables outside normal distribution. Fisher's exact test was applied to correlate between different categorical data. *P* – value less than 0.05 was appraised to be significant.

Ethical Consideration

Data will be anonymous and no personal, or identifiable information are required as a part of this study. An informed consent and information sheet had been given to the patients according to his/her language, either English, Kurdish or Arabic before involving them into the research.

Results

Fifty patients with fifty eyes who have been recruited from the outpatient clinic and planned of intravitreal aflibercept injection had been involved in this research. Patients have been split into two categories; group A of phakic patients (27 patients) and group B of pseudophakic patients (23 patients).

The demographic data of the study group are examined and illustrated in Table 1. The mean age of participants was 62.06 ± 9.41 years. The average age of study group A was 60.11 ±8.73 years while group B was 64.35 ± 9.85 years. Although group B had a higher mean of age; this distinction lacked statistical significance (*P* value: 0.114).

In terms of gender, group A had 15 male and 12 female patients while group B had 11 males with 12 female patients. Again, these differences were not statistically significant (*P* value: 0.777).

Table 1 Demographic data of the Study groups

	Group A (Phakic)	Group B (Pseudophakic)	Total	*P*-value
Age (years)		**Mean ± STD**		
	60.11 ±8.73	64.35 ± 9.85	62.06 ± 9.41	0.114*
Gender		**No. (%)**		
Male	15 (55.56%)	11 (47.82%)	26 (52%)	0.777**
Female	12 (44.44%)	12 (52.18%)	24 (48%)	
Total	27 (100.0)	23 (100.0)	50 (100.0)	

* Independent t sample test used to estimate *P* value
** Fisher's exact test applied to estimate *P* value

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The study groups' general characteristics are examined and illustrated in Table 2. Regarding medical comorbidities, 84% of patients had diabetes with 46% in group A and 38% in group B. Fifty-eight percent of participants had hypertension with 28% and 30% in group A and B respectively. In terms of side of eye involved, the right eye represented 62% while the left represented 38%. As a result of diabetic macular edema (DME), wet age-related macular degeneration (wet AMD), and retinal vein occlusion (RVO), with a frequency of 39, 4, and 7 patients correspondingly, participants had been scheduled for intravitreal injections.

Because the p value was more than 0.05, the difference between groups A and B was not statistically significant in terms of medical comorbidities, involved side of eye, and the diagnosis.

The mean IOP measured with Goldmann applanation was 14.56 ± 2.3 and 14.57 ± 2.39 before intravitreal injection, 15.15 ± 2.28 and 15.22 ± 2.29 mmHg six hours after single injection, and 14.59 ± 2.08 and 14.7 ± 2.54 mmHg twenty-four hours after injection for group A and B respectively. The difference between group A and B was not significant as the p value was more than 0.05 as illustrated in Table 3.

The mean IOP difference pre-injection and six hours after single injection was -0.59 ± 1.21 and -0.65 ± 1.19 mmHg (higher in the post injection period) for group A and B respectively. This difference was statistically significant (*P* value was 0.018 and 0.015) for both group A and B respectively. The IOP levels reduced slightly after twenty-four hours following injection; the difference in IOP level between 6 hours and twenty-four hours was statistically significant for the phakic group (p-value of 0.029) but insignificant for the pseudophakic group (*P* value of 0.056).

For both group A and B, no IOP spikes (IOP level higher than 30 mmHg or IOP level of 5 mmHg than the recorded baseline level) had been recorded throughout the study.

Table 2 General characteristics of the study groups

	Group A (Phakic) No.(%)	Group B (Pseudophakic) No.(%)	Total	*P*-value*
Medical History				
DM	23 (85.18)	19 (82.6)	42 (84)	0.552
HTN	14 (60.86)	15 (65.21)	29 (58)	0.253
Side				
OD	15 (55.56)	16 (69.56)	31 (62)	0.385
OS	12 (44.44)	7 (30.43)	19 (38)	
Diagnosis				
DME	23 (85.18)	16 (69.56)	39 (78)	0.103
Wet AMD	0	4 (17.39)	4 (8)	
RVO	4 (14.81)	3 (13.04)	7 (14)	
Total	27	23	50	

* Fisher's exact test used to estimate *P* value

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Table 3 IOP changes following intravitreal injection

IOP (mmHg)		Group A (Phakic)	Group B (Pseudophakic)	*P*-value*
Before injection	Mean ± STD	14.56 ± 2.3	14.57 ± 2.39	0.988
	Min/Max	12/20	11/19	
6 hours post injection	Mean ± STD	15.15 ± 2.28	15.22 ± 2.29	0.916
	Min/Max	10/19	12/19	
24 hours post injection	Mean ± STD	14.59 ± 2.08	14.7 ± 2.54	0.876
	Min/Max	12/18	12/18	
P*–value*		0.023	0.019	0.701
IOP (pre-injection- 6 hours post injection)	Mean ± STD	-0.59 ± 1.21	-0.65 ± 1.19	0.136
	P-value***	0.018	0.015	
IOP (6 hours - 24 hours post injection)	Mean ± STD	0.55 ± 1.25	0.52 ± 1.23	0.038
	P-value***	0.029	0.056	

*Mann Whiteny U test conducted to evaluated *P* value

**Friedman test conducted to evaluated *P* value

***Paired sample t test conducted to evaluated *P* value

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Discussion

The injection of intravitreal anti vascular endothelial growth factor has become recently a leading modality of treatment in various ocular disease such as diabetic retinopathy and maculopathy, choroidal neovascularization and retinal venous occlusive disease.[11–13]

It is expected to have an increase in intraocular pressure post intravitreal injections for short periods and in occasional cases for long periods; still the phakic or lens status of the eye is not studied well regarding this concern.[14]

Despite the short-term transient increase in intraocular pressure following intravitreal injections that was found in this study, the lens status of either being phakic or pseudo phakic has no implications on changes of intraocular pressure. The difference at baseline, six hours and twenty-four hours between the phakic and pseudophakic groups were statistically not significant as the *P* value were 0.988, 0.916 and 0.876 for the three periods respectively. This finding agrees with Gismond*et al.,*[15] Hoang *et al.,*[16] El Chebab *et al.,*[17] and Lemos-Reis *et al.*[18]

In contrast to this study, Hoang et al. used ranibizumab and bevacizumab intravitreal injections for only wet age-related macular degeneration and the follow up period of IOP was on the longer run (two consecutive visits on alternate days) when compared to our study. On the other hand, El Chebab*et al.* discussed the short-term change in intraocular pressure following intravitreal injection but it differs from this study as it included AMD patients treated with ranibizumab and measured IOP pre injection in supine position using Perkins applanation tonometry while the measurement following injection were made in sitting position; it is a well-defined fact that the IOP measurement differs with different body posture.[19] Lemos-Reis *et al.* evaluated the change in IOP levels post intravitreal bevacizumab injection immediately after two minutes; while it was six hours in this study.

On the other hand, Cui *et al.*[20] stated that pseudophakic patients started IOP lowering medications significantly less than phakic patients following intravitreal anti-VEGF injections. Although Cui et al included more than 17 thousand patients with AMD or RVO; it evaluated the long-term changes in intraocular pressure. In the same context, Foss *et al.*[21] (a randomized controlled clinical trial) stated that the spikes in intraocular pressure following injection of bevacizumab or ranibizumab were less in aphakic or pseudophakic patients when compared to phakic patients. Demirel *et al.*[22] has concluded the same results. In contrast to this study, those three studies evaluated IOP changes in patients receiving multiple injections of anti-VEGF (single injection of aflibercept in this study) it is postulated that the short-term rise in IOP following repeated intravitreal injections may impact the angle and trabecular meshwork.[23]

This study has shown that no IOP spikes had occurred at six- or twenty-four-hours following injection as the highest recorded IOP was 20 mmHg and none of the patients had a rise in IOP of 5 mmHg or more from baseline recorded level.

The mean IOP levels six hours after injection was higher than baseline IOP levels; this difference was statistically significant as the *P* value was 0.018 and 0.015 for phakic and pseudophakic patients respectively. After 24 hours following injection, the IOP level declined near baseline levels. The MARINA and ANCHOR trials had both found that there will be a transient increase in IOP following intravitreal anti-VEGF injections.[24,25]

Despite the controversy regarding the effect of lens status on IOP levels following intravitreal injection, it is well known that being pseudophakic or aphakic will deepen the anterior chamber making the angle wide and open; hence decreasing the intraocular pressure; in other terms, mechanical effect of increased volume in closed space.[26] Zamani *et al.*[27] stated that

the expansion and stabilization of the anterior chamber structures was accountable for this long-term outcome, as evidenced by the fact that the reduction in IOP 10 years following phacoemulsification with IOL implantation was as significant as at 1-year post-procedure.

The strengths of this study can be illustrated in few points; intravitreal injections by the same surgeon, patients with no previous intravitreal injections which may have a long-term impact on IOP, pseudophakic patients using a single type of in the bag IOL. Limitations of this study is the small sample size.

Conclusion

The status of the lens either being phakic or in the bag pseudophakic has no implication on intraocular pressure after intravitreal anti-VEGF injection. There was a statistically significant short-term increase in intraocular pressure in both groups after six hours of intravitreal injection.

Further studies with larger sample size are needed to studythe long-term impact of anti-VEGF upon intraocular pressure, the difference with other types of IOL such as sulcus or iris fixed IOL, the effect of repeated intravitreal injections and the impact of different types of anti-VEGF on IOP.

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Competing interests

The authors declare that they have no competing interests.

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