Original Article/นิพนธ์ต้นฉบับ

การเปลี่ยนแปลงของความดันลูกตาภายหลังหยอดยาขยายม่านตาในผู้ป่วยต้อหินมุมเปิด

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บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาการเปลี่ยนแปลงของความดันลูกตาภายหลังหยอดยาขยายม่านตาในผู้ป่วยต้อหินมุมเปิด และความสัมพันธ์กับกายวิภาคของดวงตา

รูปแบบการศึกษา: เป็นการศึกษาแบบ prospective consecutive cases series

วิธีการ: เก็บข้อมูลผู้ป่วยต้อหินมุมเปิดที่เข้ารับการรักษาที่คลินิกต้อหิน โรงพยาบาลพระมงกุฎเกล้า ระหว่างเดือนมีนาคม-มิถุนายน 2560 โดยผ่านความเห็นชอบจากคณะอนุกรรมการพิจารณาโครงการวิจัยกรมแพทย์ทหารบก ผู้ป่วยทุกรายจะได้รับการประเมินระดับความดันลูกตาและค่ากายวิภาคของดวงตา (ocular biometry) ได้แก่ angle opening distance (AOD), trabecular iris angle (TIA), anterior chamber depth (ACD) และ pupillary distance (PD) โดยเครื่อง AS-OCT ทั้งก่อนได้รับยาขยายม่านตาและอีกครั้งที่ 1 ชั่วโมงหลังขยายม่านตาด้วยยาหยอดตา 1% tropicamide และ 2.5% phenylephrine และนำค่าที่ได้มาทำการวิเคราะห์ทางสถิติ

ผลการศึกษา: ทำการเก็บข้อมูลจำนวนทั้งหมด 75 ตาจากผู้ป่วย 57 รายคิดเป็นชาย 36 ราย (63.16%) และหญิง 21 ราย (36.84%), ทั้งหมดมีอายุระหว่าง 41-88 ปี (อายุเฉลี่ย 67.82 ปี) แบ่งตามชนิดของเลนส์ตาของผู้ป่วยได้เป็น เลนส์ตาธรรมชาติ จำนวน 38 ตา (50.67%) และเลนส์แก้วตาเทียมจำนวน 37 ตา (49.33%) มีค่าเฉลี่ยความดันลูกตาก่อนและหลังขยายม่านตาเท่ากับ 14.83±3.44 มิลลิเมตรปรอท และ 16.47±3.35 มิลลิเมตรปรอทตามลำดับ คิดเป็นค่าเฉลี่ยความดันลูกตาที่เปลี่ยนแปลงเท่ากับ 1.64±2.73 มิลลิเมตรปรอท (P<0.001) ไม่พบความแตกต่างของการเปลี่ยนแปลงค่าความดันลูกตาหลังในแต่ละชนิดของเลนส์ตาของผู้ป่วย แต่พบความสัมพันธ์ระหว่างค่าความดันลูกตาที่เปลี่ยนแปลงกับค่า AOD และ ACD เฉพาะในกลุ่มผู้ป่วยเลนส์ที่มีแก้วตาเทียมที่ P 0.028 และ 0.034 ตามลำดับ

สรุป: การใช้ยาหยอดขยายม่านตาในคนไข้ต้อหินมุมเปิด สามารถทำให้ความดันลูกตาเพิ่มขึ้นได้เฉลี่ย1.64 มิลลิเมตรปรอท (CI 1.01-2.27) **จักษุเวชสาร 2018; กรกฎาคม-ธันวาคม 32(2): 49-58.**

ผู้นิพนธ์ทั้งหมดไม่มีส่วนเกี่ยวข้องหรือผลประโยชน์ใดๆ กับผลิตภัณฑ์ที่ได้กล่าวอ้างถึงในงานวิจัยนี้

กองจักษุกรรม โรงพยาบาลพระมงกุฎเกล้า

Original Article/นิพนธ์ต้นฉบับ

Intraocular pressure alteration after pharmacologic pupillary dilatation in patients with primary open-angle glaucoma.

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Abstract

Background: Dilated fundus examination is an essential step in glaucoma evaluation. Pharmacologic pupillary dilatation can be resulted in an alteration of intraocular pressure which would effect the progression of glaucomatous optic neuropathy, especially in advanced glaucoma patients. Magnitude of intraocular pressure alterations were varied reported.

Objective: To determine a direction and amplitude of intraocular pressure alteration after pharmacologic pupillary dilatation in patients with primary open-angle glaucoma and their correlation with ocular biometries.

Methods: A prospective consecutive cases series was conducted on primary open-angle glaucoma patients in glaucoma clinic, Phramongkutklao hospital between March 2017 to June 2017. Intraocular pressure and ocular biometry parameters were measured prior to and at 1 hour after the pharmacologic pupillary dilatation, using 1% tropicamide and 2.5% phenylephrine eye drop. An intraocular pressure alteration and correlation with other ocular biometry parameters, including angle opening distance(AOD), trabecular iris angle(TIA), anterior chamber depth(ACD), pupillary distance(PD) were also calculated.

Results: 57 consecutive patients were enrolled. 36 (63.16%) were male and 21 (36.84%) were female. The patient age was ranging from 41 to 88 years old, and mean age was 67.82 years. 75 eyes of the patients were studied. 49.33% (37 eyes) were pseudophakic. Mean pre-dilataed IOP was 14.83±3.44 mmHg and mean post-dilated IOP was 16.47±3.35 mmHg. An IOP alteration was 1.64±2.73 mmHg (P<0.001). Significant correlation of this IOP changed with AOD and ACD were found in pseudophakic eyes, P 0.028 and 0.034 respectively

Conclusions: Pharmacologic pupillary dilatation in primary open-angle glaucoma patients, using 1% tropicamide and 2.5% phenylephrine, resulted in an increasing of intraocular pressure with mean of 1.64 mmHg (CI 1.01-2.27). **Thai J Ophthalmo 2018; July-December 32(2): 49-58.**

Key word: Intraocular pressure alteration, pupil dilatation, tropicamide, phenylephrine, open-angle glaucoma

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Introduction

Dilated fundus and optic nerve examinations are essential steps in diagnosis and management of glaucoma. All glaucoma patients with open angle need to be examined for neuroretinal rim thinning, nerve fiber layer thinning or defect, optic nerve and retinal hemorrhage, together with other retinal abnormalities to exclude other conditions which can cause visual field abnormality and may misinterpret as glaucoma.

Pharmacologic pupillary dilatation may result in intraocular pressure alteration which can change optic nerve physiology and worsen the glaucoma progression.[1] However, the amplitude and direction of intraocular pressure alteration are varies and cannot be exactly predicted.[2,3,7-10] Shaw et al. reported that pharmacologic pupillary dilatation with phenylephrine 2.5% and tropicamide 1%, can cause an increasing of intraocular pressure in up to 60 percent of open-angle glaucoma subjects. Interestingly, the level of these intraocular pressure increasing at $\geq$ 5 mmHg and $\geq$ 10 mmHg were 32 percent and 12 percent respectively, with the mean changed (±SD) at 2.9±5.4 mmHg ($P<0.001$).[2] However, Cynthia et al. differently found a decreasing of intraocular pressure in up to 68.9 percent of subjects at 45 minutes after the administration of phenylephrine 5% and tropicamide 0.8%, mean(±SD) IOP decrease was -1.1±2.5mmHg OD and -0.7±2.3 mmHg OS.[3] This study was conducted to address the correlation, direction and amplitude of intraocular pressure alteration after pupillary dilatation in primary open-angle glaucoma patients.

Material and methods

This study was a prospective consecutive case series which was approved by institutional review board and the ethics committee, the Royal Thai Army medical department and conducted in the department of Ophthalmology, Phramongkutklao hospital, Bangkok, Thailand between March 2017 to June 2017. Study population size was calculated.[2] The consecutive fifty-seven subjects who visited at glaucoma clinic and required dilated fundoscopic examination were enrolled.

Inclusion criteria

1. Primary open-angle glaucoma patient
2. Able to receive a complete eye examination, including
    a. Intraocular pressure measurement using Goldmann applanation tonometer
    b. Gonioscopy using the 4-mirror goniolens
    c. Ocular biometry evaluation using the anterior segment optical coherence tomography (AS-OCT, Casia SS-1000, Tomey Corporation, Nagoya, Japan)[4]

Exclusion criteria

1. Any angle-closure glaucoma or other secondary glaucoma patient
2. Pseudoexfoliation and pigmentary glaucoma patient
3. History of previous filtering surgery and glaucoma drainage device implantation
4. Obvious presence of iris atrophy with/without irregular dilatation
5. History of previous corneal surgery, laser refractive surgery
6. Active corneal disease, ectatic disease or corneal scar that effect the intraocular pressure measurement
7. Contraindicated for pupil dilatation or allergy to medications were used (tropicamide and phenylephrine)

All subjects received the study information and signed the consent. Glaucoma status and patients' current anti-glaucoma medications were reviewed. All studied patients underwent complete eye examination including an ETDRS visual acuity testing, slit lamp biomicroscopic examination, intraocular pressure evaluation, gonioscopy, dilated fundus examination using tropicamide 1% and phenylephrine 2.5% eye drops and anterior segment optical coherent tomography(AS-OCT) evaluation. We gave single drop of tropicamide 1% and phenylephrine 2.5% alternately every 10 minutes apart for 3 consecutive times. The applanated intraocular pressure(IOP) measurements were done prior and at 1 hour after the pharmacologic pupillary dilatation, by single observer (Auraya Pruttiphong). Two applanated intraocular pressure values were recorded at every measurement both pre and post pharmacologic pupillary dilatation, but the average IOP was used for statistical analysis. Anterior segment optical coherence tomography (AS-OCT, Casia SS-1000, Tomey Corporation, Nagoya, Japan) was used to measure the ocular biometry parameters. Again the AS-OCT was done before and at 1 hour after pharmacologic pupillary dilatation. We had also evaluated the anterior chamber angle to obtain the angle parameters, including angle opening distance (AOD), trabecular iris angle (TIA), and the anterior segment parameters including anterior chamber depth (ACD), central corneal thickness (CCT) and pupil diameter (PD). All manual measurements were done twice and average value was used for analysis.

Definitions

An alteration of IOP (ΔIOP) is a different between pre and post dilatation IOP value, calculated by postdilatation IOP – predilatation IOP.

Angle parameters

- Scleral spur identification on AS-OCT image: the point where there is a change in curvature of the inner surface of the angle wall, often appearing as a highly reflective region and inward protrusion of the sclera.
- Angle opening distance at 500 μm from the sclera spur (AOD500) is defined as the perpendicular distance between the trabecular meshwork and the iris at 500 μm anterior to the sclera spur.
- Trabecular Iris Angle at 500 μm from the scleral spur (TIA500) is defined as an angle measured with the apex in the iris recess and the arms of the angle passing through a point on the trabecular meshwork 500 μm from the scleral spur and the point on the iris perpendicularly.
- Average AOD is defined as an average of AOD500 that measured in the horizontal plane at 0 and 180 degrees of cornea.
- Average TIA is defined as an average of TIA500 that measured in the horizontal plane at 0 and 180 degrees of cornea.
- An alteration of AOD (ΔAOD) is a different between pre and post dilatation AOD value, calculated by postdilatation AOD – predilatation AOD.
- An alteration of TIA (ΔTIA) is a different between pre and post dilatation TIA value, calculated by postdilatation TIA – predilatation TIA.

Anterior chamber parameters

- Anterior chamber depth (ACD) is defined as the distance from the corneal endothelium to the anterior surface of the lens.
- Central corneal thickness (CCT) is defined as the distance from the corneal epithelium to the corneal endothelium.

- Pupil diameter (PD) is defined as the distance between the margin of pupillary border or pupil size.
- An alteration of ACD (ΔACD) is a different between pre and post dilatation ACD value, calculated by postdilatation ACD – predilatation ACD.
- An alteration of pupil diameter (ΔPD) is a different between pre and post dilatation PD value, calculated by postdilatation PD – predilatation PD.

Statistical analysis

All differences (ΔIOP, ΔAOD, ΔTIA, ΔACD, ΔPD) are compared by T-test. Paired t-test is used for pre/post dilatation data of total study eyes and independent t-test for subgroup analysis of phakic and pseudophakic data. A correlation of intraocular pressure alteration and other ocular biometry parameters were calculated, using Pearson correlation coefficient. P-values <0.05 were considered statistically significant.

Results

Fifty-seven consecutive primary open-angle glaucoma patients were enrolled, 36 patients (63.16%) were male and 21 patients (36.84%) were female. The patients' age was ranging from 41 to 88 years old, mean 67.8 years. Seventy-five eyes of the enrolled patients were studied, 50.67% of the studied eyes were phakia and another 49.33% were pseudophakia. The number of anti-glaucoma medications which were used in each individual were ranging from 1 to 4, with the median of 2. (Table 1) An average central corneal thickness was 524.1 μm (range 449-597). The mean pre-dilatation intraocular pressure was 14.83±3.44 mmHg (range 8-22). The mean post-dilatation IOP was 16.47±3.35 mmHg (range 11-28). The mean difference of IOP change was 1.64±2.73 mmHg. (P<0.001) (Table 2)

The pre-dilatation and post-dilataion IOP in phakic group were 15.87±3.34 mmHg and 17.58±3.05 mmHg. The mean difference of IOP change in this phakic group was 1.71±2.72 mmHg. (P<0.001) (Table 2, 3)

The pre-dilatation and post-dilataion IOP in pseudophakic group were 13.76±3.25 mmHg and 15.32±3.31 mmHg. The mean difference of IOP change in this pseudophakic group was 1.57±2.78 mmHg. (P=0.002) (Table 2, 3)

The angle opening distance (AOD) value was 0.56±0.22 mm before dilatation and 0.57±0.20 mm after dilatation. The mean AOD changed was 0.01±0.15 mm. (P=0.687) For phakic patient, the mean AOD value was 0.41±0.15 mm before dilatation and 0.49±0.16 mm after dilatation, with mean change of 0.07±0.12 mm. (P=0.001) In pseudophakia, The mean AOD was 0.72±0.17 mm before dilatation and 0.66±0.21 mm after dilatation, with the mean change of -0.06± 0.15 mm. (P=0.014) (Table 2, 3)

The mean trabecular iris angle (TIA) before and after pupil dilatation were 47.91±13.56 degrees and 47.91±11.47 degrees respectively. The mean TIA change was 0.00±9.87 degrees. (P=0.998) The mean TIA in phakic patients was 38.31±10.93 degrees before dilatation and 42.72±10.02 degrees post dilatation, with the mean TIA change of 4.41±8.84 degrees. (P=0.004) (Table 2, 3)

The mean TIA in pseudophakic patients was 57.77±7.63 degrees before dilatation and 53.24±10.47 degrees post dilatation, with the mean TIA change of -4.53±8.85 degrees. (P=0.004) (Table 2, 3)

The mean pre-pupil dilatation ACD was 3.05±0.48 mm and post pupil dilatation ACD was 3.14±0.47 mm. The mean change of ACD was 0.09±0.17 mm. (P<0.001) In phakic group, the average ACD was 2.71±0.42 mm in pre dilatation and 2.84±0.42 mm in post dilatation.

Table 1. A comparison of baseline characteristics of phakic and pseudophakic study group.

Baseline characteristics	Phakic n(%)	Pseudophakic n(%)	p-value
Gender			0.076
Male	17(53.13)	19(76)	
Female	15(46.88)	6(24)	
Age (yrs.) Mean±SD(Min-Max)	64.88±10.1(41-88)	71.6±9.41(49-84)	0.013*
Central corneal thickness(μm)	530.95±29.57	517.14±36.80	0.077*
Median of med no.(Min-Max)	2(1-4)	2(1-4)	0.773†

Chi-Square test

* Independent t-test

† Mann-Whitney U test

Table 2. Comparison of intraocular pressure and ocular biometry parameters by lens status.

Study group	Dilatational status/ P-value	IOP Mean±SD (mmHg)	Average AOD Mean±SD (mm)	Average TIA Mean±SD (degree)	ACD Mean±SD (mm)	Pupil diameter Mean±SD (mm)
All study eyes	Pre dilatation	14.83±3.44	0.56±0.22	47.91±13.56	3.05±0.48	3.39±0.82
	Post dilatation	16.47±3.35	0.57±0.20	47.91±11.47	3.14±0.47	6.04±1.18
	P-value	<0.001	0.687	0.998	<0.001	<0.001
Phakic eyes	Pre dilatation	15.87±3.34	0.41±0.15	38.31±10.93	2.71±0.42	3.69±0.71
	Post dilatation	17.58±3.05	0.49±0.16	42.72±10.02	2.84±0.42	6.63±0.88
	P-value	<0.001	0.001	0.004	<0.001	<0.001
Pseudophakic eyes	Pre dilatation	13.76±3.25	0.72±0.17	57.77±7.63	3.40±0.21	3.09±0.82
	Post dilatation	15.32±3.31	0.66±0.21	53.24±10.47	3.45±0.26	5.43±1.15
	P-value	0.002	0.014	0.004	0.179	<0.001

Paired t-test

Table 3. The difference in intraocular pressure and ocular biometry parameters in comparison of phakic and pseudophakic eyes.

Parameters	Phakic Mean±SD	Pseudophakic Mean±SD	p-value
ΔIOP(mmHg)	1.71±2.72	1.57±2.78	0.823
ΔAOD(mm)	0.07±0.12	-0.06±0.15	<0.001
ΔTIA(degree)	4.41±8.84	-4.53±8.85	<0.001
ΔACD(mm)	0.13±0.10	0.05±0.21	0.033
ΔPupil diameter(mm)	2.94±0.96	2.34±0.94	0.007

Independent t-test

The mean change of ACD in phakic group was 0.13±0.10 mm. (P<0.001) In pseudophakic group, the average ACD was 3.40±0.21 mm in pre dilatation and 3.45±0.26 mm in post dilatation. The mean change of ACD in pseudophakic group was 0.05±0.21 mm. (P=0.179) (Table 2, 3)

The mean pupil diameter(PD) in this studied group was 3.39±0.82 mm before dilatation and 6.04±1.18 mm post dilatation. The mean PD change was 2.65±0.99 mm. (P<0.001) In phakic group, the mean PD pre dilatation was 3.69±0.71 mm and post dilatation was 6.63±0.88 mm with the mean PD change in this group was 2.94±0.96 mm. (P<0.001) In pseudophakic group, the mean PD pre dilatation was 3.09±0.82 mm and post dilatation was 5.43±1.15 mm, with the mean PD change in this group was 2.34±0.94 mm. (P<0.001) (Table 2, 3)

The correlation coefficient(r) of the IOP alteration and all angle parameters including ΔAOD, ΔTIA, ΔACD, ΔPD were -0.196, -0.033, -0.217, and +0.069 respectively. Subgroup analysis of these correlation in phakic eyes were -0.084, -0.051,-0.016, 0.168 respectively, and in pseudophakic eyes were found to be -0.362, -0.051, -0.350, -0.043, respectively. (Table 4)

Discussion

The intraocular pressure alteration after pupillary dilatation is important especially in the management of glaucoma. In narrow angle or angle closure glaucoma, the intraocular pressure (IOP) is highly elevated

Table 4. The correlation between intraocular pressure and other ocular biometry parameters.

Study group	r	p-value
Total (N=75)		
ΔAOD	-0.196	0.092
ΔTIA	-0.033	0.777
ΔACD	-0.217	0.062
ΔPD	0.069	0.558
Phakic (N=38)		
ΔAOD	-0.084	0.614
ΔTIA	-0.051	0.761
ΔACD	-0.016	0.922
ΔPD	0.168	0.313
Pseudophakic (N=37)		
ΔAOD	-0.362	0.028
ΔTIA	-0.051	0.766
ΔACD	-0.350	0.034
ΔPD	-0.043	0.799

Pearson Correlation coefficient

due to angle crowding and angle biometry parameters changes as identified during provocative test.[5,6] However in primary open-angle glaucoma (POAG), the amplitude and direction of pressure alteration vary and inconclusive. Most of POAG patients had an increase of intraocular pressure after pharmacologic pupillary dilatation using phenylephrine 2.5% and tropicamide 1% reported by Joon Mo Kim et al. and Shaw et al., including reported by Hancox et al. using cyclopentolate 1%.[2,7,8] Whereas Cynthia et al. reported a decrease of IOP after pharmacologic pupillary dilatation with phenylephrine 5% and tropicamide 0.8% in non-glaucomatous subjects. Interestingly, Eray et al. reported no statistically significant IOP alteration using phenylephrine 10% and tropicamide 1%.[3,9]

The proposed hypothesis to explain IOP elevation after pupillary dilatation in open-angle glaucoma patient was a reduction in trabecular meshwork outflow by an increase of pigment liberation leading to the obstruction of trabecular meshwork. Secondly, ciliary muscle paralysis by cycloplegic agents result in a reduction of pulling force on trabecular meshwork.[10-12] On the other hand, an increasing of uveoscleral outflow from pharmacologic relaxation of ciliary muscle can cause a reduction of IOP after pupillary dilatation.[13] Therefore phenylephrine 2.5% and tropicamide 1% were used in this study to lessen the cycloplegic effect. The angle parameters including ACD, AOD, TIA and PD were also observed to address the mechanism of a pharmacologic induced IOP alteration. Regarding the reported maximal mydriatic effect of phenylephrine 2.5% and tropicamide 1% were ranged between 20-40 minutes and 15-60 minutes, respectively.[14] As a result this study are designed to measure IOP for determining the alteration at 60 minutes after administration of medications. We also concerned the effect of pigment dispersion after pupillary dilatation which may lead to an IOP elevation episode so we excluded all patients with pigment dispersion and pseudo-exfoliation and re-evaluated the anterior chamber cell after dilatation using standard SUN criteria[15] but found no significant changed.

In this study, the IOP alteration after pharmacologic pupillary dilatation were found in all directions including increasing, decreasing and even unchanged. The majority of the studied eyes were found to have IOP increasing in up to 65.33% (49/75), while 20% (15/75) of studied eyes had decreased IOP. Interestingly 14.67% (11/75) were stable. Four-fifths (81.63%) of an IOP increasing eyes were in 1-4 mmHg range. Pseudophakic eyes seemed to be susceptible to IOP increasing post dilatation than phakic eyes. There were 70.27% of pseudophakic eyes and 60.53% of phakic eyes had an IOP increasing. In contrast to the result from Cynthia et al. showed phakic eyes were susceptible to have IOP alteration post-dilatation than pseudophakic eyes.[3] However, 21.05% of phakic eyes and 8.11% of pseudophakic eyes had no IOP change. In comparison, the magnitude of these IOP alteration in both phakic and pseudophakic eyes was not statistically significant (P=0.823). Interestingly, the IOP increasing of more than 6 mmHg was also found in 2 from 75 eyes (2.67%) which may need intensive monitor especially in advance glaucomatous cases. (Figure 1)

An association of IOP changes with all angle parameters post pharmacologic pupillary dilatation using phenylephrine 2.5% and tropicamide 1%, were also analyzed. Our study showed no correlation of all these angle parameters with IOP changes. However AOD and ACD changes were statistically significant in pseudophakic eyes (P=0.028, 0.034 respectively) (Table

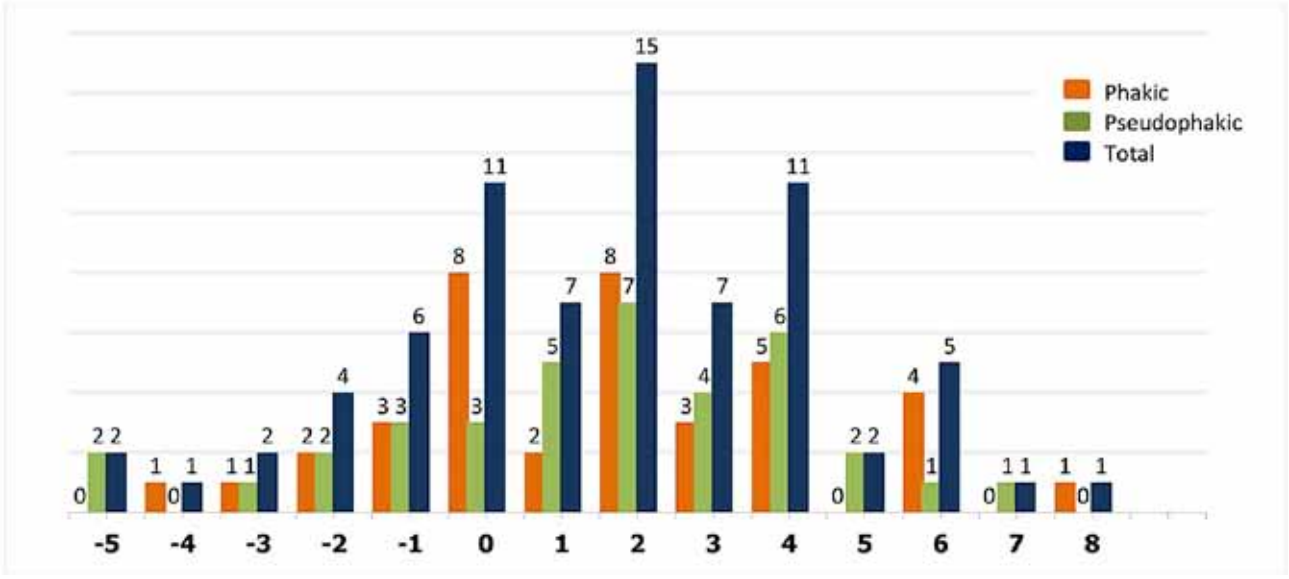

Figure 1. *Show number of eyes in each ranges of intraocular pressure alteration. (See Color figure on page 115)*

4), and interestingly the majority of pseudophakic eyes demonstrated an increasing of IOP post dilatation, so we analyzed this possible correlation and found that 73.1% of pseudophakic eyes with increasing post-dilated IOP had the decrease in AOD values. Even we cannot explained why AOD was decreasing after dilatation in pseudophakic eyes but we believed that AOD might be a major factor in IOP increasing in this particular group.

In our study, there were few limitations which need to be discussed. The first one was related to the image plane of anterior segment OCT. We chose to make an AS-OCT scan only at the horizontal plane (0 and 180 degrees) due to its reliability, most repeatability and may not be interfered by lid position. The second limitation was lacking of good technology and computer software to help identify the scleral spur so we identified and manually double marked the scleral spur using the standard criteria on Casia SS-1000 AS-OCT images which gave 2D high resolution images and allowed best reproducible measurement.[16]

Conclusion

Two-thirds of eyes with primary open-angle glaucoma (65.33%) have an intraocular pressure elevation after pharmacologic pupillary dilatation using tropicamide 1% and phenylephrine 2.5%, with mean IOP changed at 1.64 mmHg (CI 1.01-2.27). Angle opening distance alteration is an important parameter in determining of IOP increasing especially in pseudophakic eyes.

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