

## Research Article

### Effects of Diagnostic Mydriasis with Tropicamide and Phenylephrine on Intraocular Pressure

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#### Abstract

**Purpose:** To determine the effects of diagnostic mydriasis using 1% tropicamide and 2.5% phenylephrine on the intraocular pressure of patients attending the Eye Clinic of University of Port Harcourt Teaching Hospital.

**Methods:** This was an interventional 'within-patient' comparative hospital-based study conducted over 3 months, in which the right eyes of 137 subjects requiring diagnostic mydriasis received 1% tropicamide and 2.5% phenylephrine. The left eyes served as control.

**Results:** There were 137 study participants: 86 males (62.8%) and 51 females (37.2%). The mean age of participants was 44.87±15.94 years. The baseline IOPs were 12.34±3mmHg for the Right Eye (RE) and 12.09±2.64mmHg for the Left Eye (LE). The mean post dilatation IOP at 30, 45, 60, 90 and 120 minutes in the RE were higher than baseline. The maximum mean post dilatation IOP in the RE was 13.75±2.99mmHg and this occurred at 45 minutes. In the control undilated LE, the mean post dilatation IOPs were lower than base-

line at all the follow up periods except at 45 minutes where it was slightly higher (12.11±2.87mmHg). These differences in mean IOP change were statistically significant ( $p<0.05$ ). At all the follow-up periods, 8.8%-14.6% of participant's right eyes had large IOP elevations (>5mmHg but <10mmHg). Multiple linear regression analysis showed that pre dilatation IOPs were positively correlated to post dilatation IOPs.

**Conclusion:** There is need to recheck IOP post dilatation preferably at 45 minutes in all patients who have had diagnostic mydriasis to prevent damage to the optic nerve. Diagnostic mydriasis could safely be done using small concentrations of tropicamide and phenylephrine.

**Keywords:** Diagnostic mydriasis; Intraocular pressure; Mydriasis; Phenylephrine; Tropicamide

#### Introduction

Intraocular Pressure (IOP) is the tissue pressure within the eye which is determined by the balance between aqueous humor production and outflow, which under normal circumstances is nearly equal. The normal distribution of IOP within the general population is 11-21mmHg [1]. Intraocular pressure can be affected by a range of factors like time of the day, heartbeat, respiration, exercise, fluid intake, posture, blinking, eye movements, valsalva manoeuvres and medications; including those used for pupillary dilatation [2-4]. Racial differences in the effects of diagnostic mydriasis on IOP have been suspected to exist. Asians have been thought to have a higher risk of developing angle closure following diagnostic mydriasis however, this has not been proven conclusively [5,6].

Pupillary dilatation (mydriasis) is routinely done for ophthalmological examinations to aid diagnosis (diagnostic mydriasis), treatment and follow up of a wide range of ocular disorders. It facilitates the examination of the peripheral lens, ciliary body, and retina producing better diagnostic and therapeutic outcomes compared to the natural undilated pupil [7-9]. It is also used in the treatment of iritis by preventing the formation of posterior synechia and relieving pain caused by ciliary spasm [10].

Diagnostic mydriasis is usually achieved by the use of mydriatics which are either parasympatholytics or sympathomimetic agents. The parasympatholytics cause pupillary dilatation and accommodation paralysis. The sympathomimetics potentiate or mimic the action of adrenaline by stimulating the dilator pupillae muscle. Examples of parasympatholytics include atropine, homatropine, cyclopentolate and tropicamide. Examples of sympathomimetics include phenylephrine, ephedrine and hydroxyamphetamine [11].

The onset of action of tropicamide is 15-30 minutes with duration of action of 3-8 hours [12]. Phenylephrine achieves maximum mydriasis within 60-90 minutes with recovery after 5-7 hours [13].

Diagnostic mydriasis using these pharmacological agents is not without consequences. Many studies have shown that pupillary dilatation can cause a change in IOP, most supporting an increase in IOP

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in normal eyes and also abnormal eyes notably those that are glaucomatous [14-22] and others showing no significant change [23,24].

A significant change in IOP that persists and remains untreated serves as a risk factor for glaucoma development and progression. Diagnostic mydriasis which is routinely done in most eye clinics has the potential to increase IOP. It is therefore important to know if this occurs in Nigerian subjects and by how much. Other effects of this intraocular pressure rise include retinal vascular occlusion, anterior ischemic optic neuropathy which could be sight threatening and ocular pain [25,26]. Recognition of susceptible individuals, adequate monitoring and prompt treatment of this elevation of IOP when it occurs are very important.

## Materials and Methods

This was an interventional ‘within-patient’ comparative hospital-based study in which the right eyes of 137 subjects requiring diagnostic mydriasis received 1% tropicamide and 2.5% phenylephrine. The left eyes served as control. IOP was measured with Perkins tonometer. It was conducted over a three-month period lasting from November 2016 to January 2017. Time of instillation of the first drop was taken as 0 and IOP was rechecked at 30, 45, 60, 90 and 120 minutes. Pulse rates and blood pressures were rechecked at 55 minutes. Ocular discomfort grading and blurred vision assessments were done at 125 and 130 minutes respectively. Data was analysed using the Statistical Package for Social Sciences (SPSS) version 20.0 at significant level of  $p < 0.05$ .

Inclusion criteria was adult patients (aged 18 years and above) visiting the eye clinic of UPTH whose eyes required diagnostic mydriasis with normal open angles as seen on gonioscopy. An angle was considered to be normal and open when on gonioscopy, Shaffer’s grade 3 or 4 angles without abnormalities such as new vessels, pigments, pseudoexfoliative materials was found. Exclusion criteria were high IOP  $> 21$  mmHg on the visit before dilatation or the day of dilatation, pre-existing ocular pathology such as uveitis, high myopia or glaucoma, patients with one eye and prior use of ocular medications that could influence IOP level.

The details of research were made known to the subjects. Subsequently, their approval and signed informed consent was obtained before inclusion into the study. The approval of the Ethical Committee of the University of Port Harcourt Teaching Hospital to carry out this research was sought and obtained.

## Results

Table 1 shows the age and sex distribution of study participants. There were 78 (56.9%) males and 59 (43.1%) females with a male to female ratio of 1.32:1. The mean age of participants was  $44.87 \pm 15.94$  years (Range 19-83 years). Majority of the participants were 41 years and above (87 out of 137). The sex distribution of the various age categories showed that there was an overall male preponderance. The differences in proportion of the age categories by sex of participants were statistically significant ( $p = 0.0001$ ).

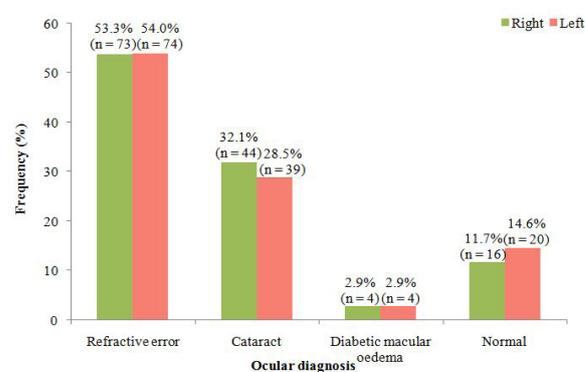
Figure 1 shows the frequency of ocular diagnosis in the right and left eyes of study participants. The highest proportion of participants had refractive errors (53.3% and 54.0% in the right and left eyes respectively). This was followed by cataract which was present in 32.0% and 28.9% of participant’s right and left eyes respectively.

Normal ocular findings were present in 11.7% and 14.6% of participant’s right and left eyes respectively. Diabetic macular oedema occurred in 2.9% of participants right and left eyes.

Age Groups (Years)	Sex		Total Number (%)
	Male Number (%)	Female Number (%)	
18-40	30 (60.0)	20 (40.0)	50 (100.0)
41-83	48 (55.2)	39 (44.8)	87 (100.0)
Total	78 (56.9)	59 (43.1)	137 (100.0)

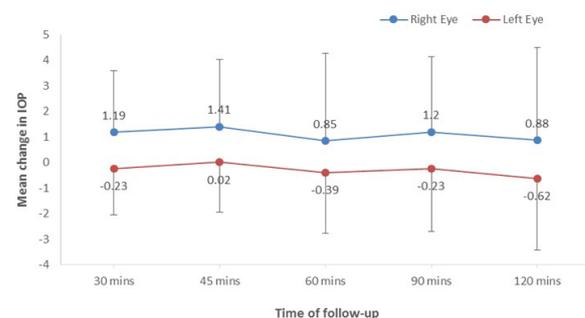
**Table 1:** Age and Sex Distribution of Study Participants.

Fisher’s exact test = 36.713;  $p$ -value = 0.0001\* \*Statistically significant



**Figure 1:** Ocular diagnosis of study participants.

Figure 2 shows the mean changes in IOP from baseline in the dilated right eye and undilated left eye over the various follow up times. At all the follow up times, there was an increase in the mean change in IOP from baseline in the RE with the highest recorded at 45 minutes (1.41 mmHg) and the least value recorded at 60 minutes (0.85 mmHg).



**Figure 2:** Mean changes in IOP from baseline in the dilated right eye and undilated left eye over the follow up period.

The control LE on the other hand, experienced a reduction from baseline at all the follow up times except at 45 minutes where there was a slight increase of 0.02 mmHg. The greatest reduction was noticed at 120 minutes (-0.62 mmHg).

Table 2 compares the changes in mean IOP between the dilated RE and undilated LE across the different times of follow up. At all the

times of follow up, the mean changes in IOP were higher in the dilated RE with the least change in IOP being  $+0.85\pm 3.44$ mmHg recorded at 60 minutes and the greatest change being  $1.42\pm 2.63$ mmHg recorded at 45 minutes. The control LE on the other hand had slight changes with the least being a slight increase  $0.02\pm 1.95$ mmHg recorded at 45 minutes and the greatest being a reduction of  $-0.62\pm 2.79$ mmHg recorded at 120 minutes.

Time of follow up	Right Eye Mean IOP change± S.D	Left Eye Mean IOP change± S.D	Paired t-test	p-value
30 mins	1.19±2.40	-0.23±1.81	6.812	0.0001*
45 mins	1.42±2.63	0.02±1.95	6.651	0.0001*
60 mins	0.85±3.44	-0.39±2.38	5.124	0.0001*
90 mins	1.20±2.94	-0.21±2.46	6.732	0.0001*
120 mins	0.88±3.63	-0.62±2.79	7.184	0.0001*

**Table 2:** Comparison of the changes in mean IOP from baseline between the dilated RE and undilated LE across the different times of follow up.

\*Statistically significant

S.D - Standard Deviation

These differences in the changes in mean IOP from baseline at all the follow-up times between the RE and LE were statistically significant ( $p=0.0001$ ).

Table 3 compares Post-dilatation IOP (mmHg) between males and females. Males had a slightly higher mean post dilatation IOP ( $13.93\pm 2.68$ mmHg) compared to females ( $13.45\pm 3.44$ mmHg). This difference was however not statistically significant ( $p=0.366$ ).

	Sex		t	p-value
	Male mean ± SD	Female mean ± SD		
Post dilatation IOP (mmHg)	13.93±2.68	13.45±3.44	0.908	0.366

**Table 3:** Comparison of mean Post-dilatation IOP (mmHg) between males and females.

SD - Standard Deviation

Table 4 shows IOP changes above 5mmHg in the dilated RE and control LE across the follow-up period. At all the follow-up times, between 8.8% to 14.6% of participants right eyes had IOP elevations above 5mmHg while only 2.9% of left eyes had same. No participant had elevations above 10mmHg.

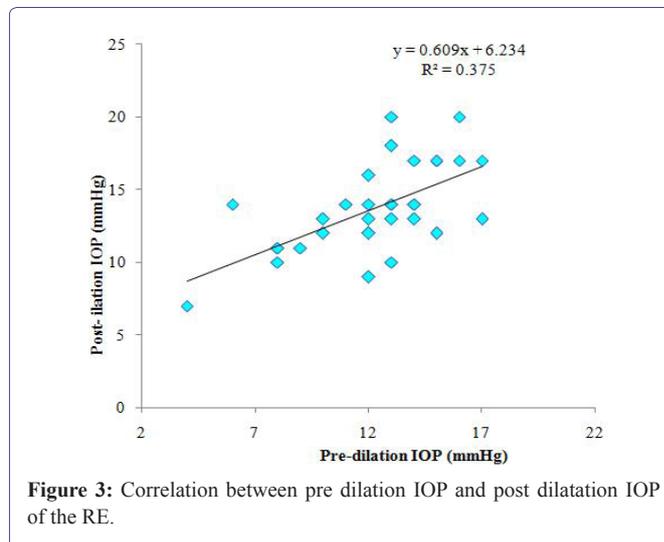
Follow-up period	Right Eye n (%)	Left Eye n (%)
30 mins	16 (11.7)	4 (2.9)
45 mins	12 (8.8)	0 (0.0)
60 mins	16 (11.7)	4 (2.9)
90 mins	20 (14.6)	0 (0.0)
120 mins	15 (10.9)	0 (0.0)

**Table 4:** IOP changes >5mmHg in dilated RE & control LE across follow-up period.

\*None of the patients had IOP change greater than 10mmHg across the follow-up period.

Figure 3 shows the correlation between Pre dilatation IOP and post dilatation IOP of the RE. There was a positive correlation between Pre dilatation IOP and Post dilatation IOP of the RE; as pre-dilatation IOP

increases, post dilatation IOP increases. This was statistically significant ( $p=0.0001$ ).



**Figure 3:** Correlation between pre dilatation IOP and post dilatation IOP of the RE.

## Discussion

Pupillary dilatation for dilated fundus examination (diagnostic mydriasis) is a very important aspect of ophthalmic practice. Diagnostic mydriasis has the ability to cause both ocular and systemic effects [14-22,27-30].

In our study, all participants were adults with a mean age of  $44.87\pm 15.94$  years. This mean age is similar to that reported in other studies [14,15,24]. Hung et al., and Tsai et al., did a similar study but in children [17,23]. This mean age of patients needing diagnostic mydriasis may be a reflection of disorders that cause visual impairment in our environment such as cataracts, age-related macular degeneration and diabetic retinopathy; which are all age-related.

In our series, eyes with normal open angles as seen on gonioscopy were used. The most common ocular diagnosis was refractive error which accounted for the highest proportion. Others were cataract and diabetic macular oedema. Some studies also used patients without glaucoma [14,31]. On the other hand, other studies used eyes with glaucoma [16,32,33] or a mixture of both glaucomatous and non-glaucomatous [15].

In the present study, the mean baseline pre-dilatation IOP was similar in both eyes. However, the mean post dilatation IOP was significantly higher in the dilated right eye than the undilated left eye. Kim et al., and Velasco et al., whose study population was similar to this, reported similar findings [14,31]. Shaw & Lewis and Siam et al., also reported higher post dilatation IOPs but their studies included patients with glaucoma [16,33]. Other studies with similar results were those of Hung et al., and Shihadeh et al., but these studies were on children and patients with pseudoexfoliation respectively [17,19]. On the other hand, Pukrushpan et al., reported no significant difference in mean IOP pre and post dilatation even though their study population was similar to that of this study [24]. This difference in findings may be because of the use of a single agent and the fact that IOP was rechecked only once at 30 minutes after dilatation therefore, elevations which may have occurred thereafter might have been missed.

In this study, post dilatation IOP was checked 5 times as such, the tendency of changes being missed was reduced to the barest minimum. In the same vein, Tsai et al., whose study was in children noted no significant, difference between mean pre and post dilatation IOPs [23]. Their study population being children and the fact that IOP was rechecked just once, at 45 minutes may have been responsible for this difference.

Throughout the study period in our study, the IOPs never returned to the baseline. Kim et al., however noted a return to baseline IOP after about 4 hours and Velasco et al., near baseline at 5 hours; in their study, Velasco et al., noted complete return to baseline after 24 hours [14,31]. This study lasted for just 2 hours, and that may be the reason why the IOPs did not return to pre-dilatation levels in the right eye. It is therefore unknown whether the post dilatation IOPs would have returned to baseline levels, had the study lasted longer.

In the dilated right eye, the peak IOP change was noted at 45 minutes. This is similar to a study in Spain where a maximum rise in IOP was achieved at 45 minutes [31]. On the other hand, a Korean study reported maximum IOP rise at 150 minutes post dilatation [14]. This difference may not be unconnected to the fact that in their study, the first post dilatation IOP was checked at 30 minutes and the next at 150 minutes, giving a wide gap between the first and second and it is likely that the IOP may have peaked before then.

At all follow-up periods, 8.8%-14.6% of participant's right eyes had large IOP elevations (>5mmHg but <10mmHg). This range was chosen because the mean diurnal fluctuations of IOP in normal persons do not exceed 5mmHg [1,34]. Shaw & Lewis however, reported a rise above 5mmHg in 32% of their study participants and more than 10mmHg in 12% of subjects [16]. These changes were noted one-hour post dilatation and may be because the study population included glaucoma patients. Hung et al., whose study population were children, reported much lower percentages with only 3.3% of participants having IOP fluctuations greater than 5mmHg [17].

## Conclusion

There is need to recheck IOP post dilatation preferably at 45 minutes in all patients who have had diagnostic mydriasis. This is because IOP elevations can potentially damage the optic nerve.

## Financial Disclosure

None.

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