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Comparative Study on Diurnal Variation of Intraocular Pressure among Patients with Asymmetric Primary Open Angle Glaucoma and without Glaucoma at a Tertiary Eye Care Centre, Kolkata, India

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Abstract:

Background:
The Glaucomas are a group of progressive optic neuropathies associated with corresponding visual field defects where IOP is a major modifiable risk factor and is the leading cause of irreversible blindness worldwide.

Aims:
This study was conducted to compare the diurnal variation of Intraocular pressure (IOP) among patients with asymmetric primary open-angle glaucoma and without glaucoma and to determine the influence of age, sex, diabetes, hypertension, and anti-glaucoma drugs over diurnal variation of IOP.

Settings and Design:
This prospective randomized comparative study was done at the Glaucoma Clinic at the Regional Institute of Ophthalmology, Medical College and Hospital, Kolkata from January 2018 to August 2019.

Methods and Material
The patients were categorized by Cases (all asymmetric POAG patients, 80 eyes) and Control (all 80 non-glaucomatous eyes). After taking history and clinical examinations, Central Corneal Thickness (CCT) corrected IOP was measured from 7 am to 7 pm at 2 hourly intervals before starting therapy. Cases were treated with either Timolol 0.5% twice daily or Topical Travoprost 0.004%once daily (9 pm). Follow-up examinations were done at 1month and 3 months.

Statistical Analysis:
Statistical Analysis was performed with Epi Info (TM) 3.5.3 software, USA. Standard statistical tests were applied where applicable. t-test was used to compare the Mean. $p \leq 0.05$ was considered statistically significant.

Results
The mean age were 56.27±12.51 years and 56.47±15.40 years for the cases andcontrols. The mean VCDR: Diurnal variation of IOP was higher in more glaucomatous eyes ($p<0.05$). No significant

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relation between sex and diurnal variation was found. Travoprost showed a better reduction of the mean IOP in more glaucomatous eyes ($p<0.05$). In less glaucomatous eyes,reduction in mean diurnal variation and mean IOP were significantly higher in the Travoprost group ($p<0.05$).

Conclusions.

In asymmetric POAG, the more glaucomatous eye had significantly more diurnal variation of IOP. No significant association with age, sex, diabetes mellitus, or hypertension were found. The travoprost 0.004% showed more control of the diurnal variation in the less glaucomatous eye and more reduction of mean IOP both in the more and less glaucomatous eyes than timolol 0.5%.

Key Words: Asymmetric glaucoma, Diurnal variation, Timolol maleate, Travoprost.

INTRODUCTION

Glaucoma is a heterogenous group disorder of progressive optic neuropathies characterized by structural changes at the optic nerve head and corresponding visual field defects where Intra Ocular Pressure is a major modifiable risk factor. It affects more than 67 million people worldwide, of whom about 10% or 6.6 million are estimated to be blind[1]. Worldwide, 45 million people were estimated to have primary open-angle glaucoma (POAG) in 2010 and a total of 4.5 million (10%) were estimated to be blind as a result.[2] The prevalence of glaucoma in India is 11.9 million (2014) accounting to 12.8% of total blindness [3]. POAG is more common in developing countries and may cause severe visual impairment due to its silent nature[1]. The estimated risk of blindness from POAG ranges from 14.5% to 27% (unilateral) and from 7% to 9% (bilateral).[4,5]Krupin et al[6] recently reported that 27.9% of patients with open-angle glaucoma were unilaterally involved. The Vellore Eye Survey (VES) in INDIA reported the prevalence of POAG as 0.41%, Ocular hypertension (OHT) as 3.08%, and primary angle-closure glaucoma (PACG) as 4.32%. Occludable angles accounted for 10.3% of the population[7.] The Andhra Pradesh Eye Disease Survey (APEDS) reported a prevalence of 1.62% for POAG, 0.32% for OHT, 0.71% for PACG and 1.41% for Occludable angles[8]. The West Bengal Glaucoma Study reported that the prevalence of all glaucoma in people aged more than 50 years was 3.4%. Only three cases of PACG were identified, giving a crude ratio of POAG to PACG of more than 10:1[9]. Asymmetric glaucoma is a clinical condition where the vertical cup disc ratio (VCDR) difference is 0.3 or more between the two eyes or having asymmetric glaucomatous scotoma (30-2 program, Humphrey Field Analyser) and difference in mean deviation $\geq$ 8dB between the two eyes [10]. Population-based studies has shown a statistical association between increasing age and POAG[11-19]. The Barbados Eye Study [16] reported higher rates of POAG amongst males while the St. Lucia Study[17] and Blue Mountains Eye Study[18] has reported higher rates in females. A statistically significant association between diabetes and POAG has been reported in several case-control studies [20-22]. The Beaver Dam[14] and Blue Mountain studies [18] found that the odds of a diabetic having POAG were two times greater than those of a non-diabetic. The Barbados[16] and Baltimore study[22] did not find any correlation of POAG with systemic hypertension. Most studies find a positive correlation between IOP with age and systemic hypertension.[23-26] So, in this study, we would like to compare the diurnal variation of IOP in asymmetric POAG and normal patients, find the relation between the diurnal variation of IOP with age, sex, diabetes mellitus, and hypertension. This study would also assess the effect of anti-glaucoma treatment (The travoprost 0.004% and Thetimolol 0.05%) on diurnal variation of IOP. Travoprost, a highly selective and potent analogue of the prostaglandin PGF(2)(alpha), has recently been approved and marketed as a topical ocular hypotensive agent for the treatment of ocular hypertension and glaucoma. Following absorption into the eye, the free acid form of travoprost interacts with the endogenous FP prostanoid receptor to enhance aqueous humor outflow and lower intraocular pressure (IOP). Travoprost is distinguished from other marketed prostaglandin analogues in that it is a full agonist at the prostaglandin receptor. It is also highly selective with little or no affinity for other prostanoid or non-prostanoid receptors in the eye. Travoprost provides robust lowering of IOP with little diurnal fluctuation and results in low target pressures in a large percentage of patients.

MATERIALS AND METHODS

This prospective randomized controlled, single center, double-masked comparative study of diurnal variation of IOP among asymmetric POAG and non-glaucomatous patients was done at the Glaucoma

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Clinic at the Regional Institute of Ophthalmology, Medical College and Hospital, Kolkata from January 2018 to August 2019. This study conformed to the Declaration of Helsinki and clearance from the Institutional Ethical Committee. Inclusion Criteria was Asymmetric POAG patients without medication & age-matched non-glaucomatous patients. Exclusion Criteria was Age <18years, Primary angle-closure glaucoma, secondary glaucoma, Childhood glaucoma, Neo-vascular glaucoma, History of ocular trauma, Previous ocular surgery (except cataract surgery), High refractive errors (> +5 D or < -5D and astigmatism >3D) and patient on any medication for glaucoma. First 40 (80 eyes) new asymmetric POAG patients and 40 (80 eyes) normal patients were selected maintaining simple random selection criteria. New patients were diagnosed by History, Refraction, Humphrey's Visual fields (HVF), anterior segment examination, Gonioscopy, Goldmannapplanation tonometry, Fundoscopy, CCT measurement by Pachymetry. Blood sugar and Blood pressure were measured for all patients. After taking the informed consent and maintaining exclusion criteria, the patients were included in the study.

Firstly the patients are categorized by Case (80 asymmetric POAG eyes subdivided into more and less glaucomatous eyes) and Control (all 80 non-glaucomatous eyes), CCT corrected Intra-ocular pressure was measured from 7 am to 7 pm at 2 hourly intervals before starting therapy and diurnal variation was recorded. Newly diagnosed POAG cases were treated with either Topical β-blocker (Timolol 0.5%) twice daily (8 am and 8 pm) or Topical prostaglandin analogue (Travoprost 0.004%) once daily (9 pm). Follow-up examinations were done at 1month and 3 months. Both volunteered and elicited reports of side effects were collected

Statistical Analysis was performed with Epi Info (TM) 3.5.3. Under descriptive statistics Mean with Corresponding standard deviations (S.D.) were calculated. $\chi 2$ test was used to test the association between different study variables under study. Corrected $\chi 2$ test was used in case any one of cell frequency was found less than 5 in the bivariate frequency distribution. Also, One Way Analysis of variance (ANOVA) followed by a post hoc Tukey's test was performed. Test of proportion (Z-test) was used to test the significant difference between the two proportions. t-test was used to compare the Mean. $p \leq 0.05$ was considered statistically significant.

RESULTS AND ANALYSIS

The mean age (mean ± S.D.) of the cases was 56.27±12.51 years (range 31 - 81 years) and the controls were 56.47±15.40 years (range 32 - 82 years) (Table 1). t-test showed no significant difference between mean age and two groups (t_{78}=0.61; p=0.54). No significant association between sex and two groups was found (p=0.81).Thus, the cases and controls were matched for their age and sex.

A significant association between DM and two groups of patients was found ($\chi 2$ =11.25, p=0.0007). A significant association was found between Hypertension and two groups of patients (χ^2=5.20, p=0.02). Asymmetric glaucoma was more common in the right eye (55.0%) than left (45.0%) but it was not statistically significant (Z=1.41; p=0.15). The mean VCDR: Diurnal variation of IOP were 0.83±0.08:9.22±1.54, 0.45±0.09:7.75±1.30, and 0.28±0.06:3.50±1.62 mm Hg for more, less, and non-glaucomatous eyes respectively. The VCDR and diurnal variation of IOP was significantly higher in more glaucomatous eyes than less glaucomatous eyes than non-glaucomatous eyes (Tukey's Test followed by ANOVA, p<0.05). The Pearson correlation coefficient between VCDR and diurnal variation of IOP were 0.64, 0.52, 0.39 for more glaucomatous, less glaucomatous, and non-glaucomatous eyes respectively which was statistically significant (p<.05) (Table 2). VCDR: peak level of IOP (mean ±SD) were 0.83±0.08:26.48±3.47, 0.45±0.09:22.79±1.07, 0.28±0.06:16.65±1.68 for more glaucomatous, less glaucomatous, and non-glaucomatous eyes respectively. One-way ANOVA test was applied and showed a significant difference in mean VCDR ($F_{2,159}$= 3.08; p=0.04) and mean peak level of IOP ($F_{2,159}$ =5.13; p=0.0069) with the severity of glaucoma So, glaucomatous cupping was found to be associated with higher peak intraocular pressure and higher diurnal variation. Mean diurnal variation of IOP of all the three kinds of eyes increases with the age of the patients (p<.05) irrespective of the severity of glaucoma (Table 3 & Fig 1). Mean diurnal variation of IOP between males and females in three kinds of eyes showed no statistical

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significance ($p>0.05$) (Table 4). The mean diurnal variation of more glaucomatous eyes was significantly higher than the less glaucomatous eyes which were again higher than the non-glaucomatous eyes in both sexes ($p<0.05$). There was no significant association between mean diurnal variations of IOP with Hypertension and Diabetes Mellitus in three kinds of eyes ($p>0.05$). Table 5showed that there was no significant difference between mean Diurnal variation of IOP of Travoprost group and Timolol Group at follow-ups in More glaucomatous eyes ($p>0.05$). But, it was significant in less glaucomatous eyes ($p<0.01$). The reduction of IOP (%) at the follow-up visits was significantly higher in the travoprost group than the timolol group for both more and less glaucomatous eyes ($p<0.0001$) (Table 6). Hyperemia was experienced at rates of 28.94% (11 of 38) for travoprost 0.004%, and 9.52% (4 of 42) for timolol. Iris pigmentation changes were noted in 2.6% (1of 38) of patients receiving travoprost 0.004% with no changes noted in the thetimolol group. In the timolol group a decrease in pulse and systolic blood pressure were observed.

Table-1: Descriptive data on POAG

Mean age	
cases	56.27±12.51 years (range 31 - 81 years)
controls	56.47±15.40 years (range 32 - 82 years).
Male	
Cases	24
Controls	25
Female	
Cases	16
Controls	15
Diabetes Mellitus (DM)	
Cases	28
Controls	13
Hypertension	
Cases	21
Controls	11
Laterality of more glaucomatous eyes	
Right	22
Left	18
Vertical cup disc ratios	
More glaucomatous eye	0.83±0.08
Less glaucomatous eye	0.45±0.09
Non glaucomatous eye	0.28±0.06
Diurnal variation of IOP (mm in Hg)	
More glaucomatous eye	9.22±1.54
Less glaucomatous eye	7.75±1.30
Non glaucomatous eye	3.50±1.62
Peak level of IOP (mm in Hg)	
More glaucomatous eye	26.48±3.47
Less glaucomatous eye	22.79±1.07
Non glaucomatous eye	16.65±1.68

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Table-2: Correlation between VCDR and diurnal variation of IOP of the patients

Eye	Pearson correlation coefficient	P value
More glaucomatous	0.64	<0.0001*
Less glaucomatous	0.52	0.0006*
Non glaucomatous	0.39	0.0003*

*Statistically significant

Table-3: Distribution of Age and diurnal variation of IOP among different grades of glaucoma

Age in yrs	More glaucomatous eye (n=40)	Less glaucomatous eye (n=40)	Non glaucomatous eye (n=80)
30-39	8.50±1.00	7.75±0.50	2.82±0.87
40-49	8.71±0.95	7.57±1.13	2.50±0.71
50-59	9.18±1.60	7.91±1.51	3.20±1.03
60-69	9.33±1.92	7.33±1.56	3.70±1.57
≥70	10.00±1.26	8.33±0.82	4.71±1.70
ANOVA	$F_{4.159} = 8.29$	$F_{4.159} = 7.71$	$F_{4.159} = 3.23$
P VALUE	**<0.0001**	**<0.0001**	**0.04**

- **Statistically significant**

Fig 1
Distribution of Age and Diurnal Variation in different grades of Glaucoma

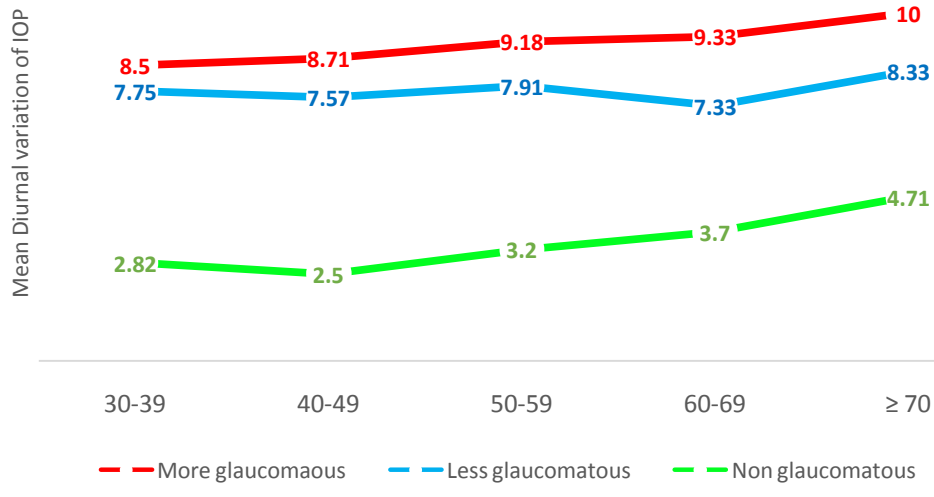

Table-4: Relationship between sex and diurnal variation of IOP

Eye	Male (n=49) Means± SD	Female (n=31) Means± SD	t_{78}	p value

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More glaucomatous eye (n=40)	9.20±1.20	9.18±1.60	0.06	0.95 Not significant
Less glaucomatous (n=40)	7.70±1.19	7.75±1.48	0.16	0.87 Not significant
Non glaucomatous eye (n=80)	2.88±1.53	3.91±1.09	1.12	0.26 Not significant

Table-5: Comparison of diurnal variation of IOP at follow up visits in between Travoprost and Timolol group

Treatment	Diurnal variation of IOP at 1st visit (Mean±SD)		Diurnal variation of IOP at 2nd visit (Mean±SD)		Diurnal variation of IOP at 3rd visit (Mean±SD)	
	More Gluaomatous	Less Gluaomatous	More Gluaomatous	Less Gluaomatous	More Gluaomatous	Less Gluaomatous
Travoprost n=38	9.62 ± 1.34	7.50±1.57	4.99 ±1.57	3.58±1.05	2.83±1.04	2.72±0.98
Timolol n=42	8.85±2.31	7.88±1.09	5.33±1.33	4.86±1.33	3.42±0.99	3.85±0.48
t_{38} test	1.27	0.88	1.43	3.39	1.83	4.55
p value	0.21	0.38	0.16	**0.0014***	0.07	**<0.0001***

*** statistically significant**

Table-6: Reduction of IOP (%) at follow up visits in Travoprost and Timolol group

Treatment	**Reduction of IOP at 2nd visit (%) (Mean ± SD) (in %)**	**Reduction of IOP at 3rd visit (%) (Mean ± SD) (in %)**

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	More glaucomatous eye	**Less glaucomatous eye**	**More glaucomatous eye**	**Less glaucomatous eye**
Travoprost n=38	25.64 ± 3.84	22.68±3.21	33.79± 4.76	30.19±3.96
Timolol n=42	17.86± 2.46	17.46±2.47	22.87± 3.86	22.44±3.23
t_{38} test	9.82	5.72	7.91	6.74
p value	**< 0.0001***	**<0.0001***	**<0.0001***	**<0.0001***

DISCUSSION

This is a prospective randomized comparative study of diurnal variation of IOP among asymmetric POAG and non-glaucomatous patients. In POAG some patients have bilateral asymmetric progression characterized by the VCDR difference 0.3 or more[10] or asymmetric glaucomatous scotoma (difference in mean deviation ≥ 8Db) in 30-2 program, Humphrey Field Analyzer[15]. Here we have taken the criteria VCDR for asymmetric POAG.

The mean age of the cases was 56.27 years and control was 56.47 years, 60% of cases and 62.5% of controls were male. 70% of the cases and 32.5% of the control were diabetic patients (Z=5.30; p<0.0001). A significant association between DM and POAG cases was found (p=0.0007).[20-22] Proportion of Hypertension was significantly higher in cases (52.5%) than controls (27.5%) (Z=4.05; p<0.0001). A significant association was found by the Chi-square test between Hypertension and POAG patients (p=0.02).[23-26] In asymmetric POAG, 55% of more glaucomatous eye was the right eye. The Pearson correlation coefficient between VCDR and diurnal variation of IOP were 0.39, 0.52, 0.64 for non-glaucomatous, less glaucomatous, and more glaucomatous eyes respectively with p<0.001. The mean VCDR: Mean Diurnal variation of IOP were 0.28±0.06:3.50±1.62, 0.45±0.09:7.75±1.30, 0.83±0.08:9.22±1.54 for non-glaucomatous, less glaucomatous, and more glaucomatous eyes respectively with p<0.05. Thus, the diurnal variation was found to be more in more glaucomatous eyes than in less glaucomatous eyes. Drance SM et al[27] reported the diurnal variation of IOP in the normal population as 3.7±1.8 mmHg, which is similar to our study (3.50±1.62 mm Hg). So, the glaucomatous changes were more in the eyes with the high peak level of IOP and high diurnal variation.

The mean diurnal variation of IOP had also been increased with age (p<0.05). Weak positive correlations were found between age and diurnal variation of IOP of the patients in more glaucomatous eyes. These findings were consistent with Jean Diaz Jiet al[28] but contradicted by David R et al[29]and Jonathan S Pointer[30]. We found no significant relation between the diurnal variation of IOP and sex(p>.05) [29] but Jonathan SPointer[30]had documented more fluctuation of diurnal variation of IOP in male. In our study, we found no significant difference between the mean diurnal variation of IOP and the presence of HTN and DM among three kinds of eyes (p>.05)though the mean value was a little higher in diabetics.

The results revealed that glaucomatous cupping was greater in the eye with higher intra ocular pressure and higher diurnal fluctuation of IOP which were supported by previous scientific literatures by Cartwright MJ et al, [31]Crichton A et al [32] &Bengtsson B.[24]

We found no significant difference between mean Diurnal variation of IOP in patients treated with the Travoprost (0.004%) and the Timolol (0.5%) at follow up visits in more glaucomatous eyes (p>.05) but it was significant in the less glaucomatous eyes (p<.05). Reduction of Mean IOP in the

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Travoprost group was significantly higher than the Timolol group ($p<0.0001$) in both more glaucomatous and less glaucomatous eyes at follow ups.[33-35]

The timolol is the beta-adrenoceptor antagonist which decreases aqueous production. Travoprost 0.004% was an effective anti glaucoma agent offering an additional 5 - 7 mmHg IOP reduction in patients inadequately controlled on timolol 0.5%. Travoprost is a very stable compound following exposure to extremely low and high temperatures, repeated freezing and thawing and exposure to light. Travoprost was found to be safe and well-tolerated with very few (< 5%) discontinuations due to adverse events. Travoprost 0.004% is a clinically significant advance for the treatment of glaucoma and ocular hypertension. It helps in better IOP reduction and diurnal control, in a safe, well-tolerated, stable formulation.[35]Throughout the clinical trial, travoprost was found to be safe and well-tolerated with few (< 5%) discontinuations due to side effects.

The limitations of our study were small number of patients in both groups, shorter follow-up and single centre study. In our study IOP just after awakening couldn't be measured as it was an OPD based study.

CONCLUSION(S)

In the present study, we evaluated the changes in diurnal variation of IOP among asymmetric POAG and non-glaucomatous controls. The more glaucomatous group had significantly higher diurnal variation than the less glaucomatous group which was also significantly higher than the non-glaucomatous subjects. No significant associations were found between the diurnal variation of IOP with age, sex, diabetes mellitus, and hypertension though there is weak positive correlation between diurnal variations of IOP with age.

Among treated asymmetric POAG patients, the travoprost 0.004% once daily showed more control of diurnal variation of IOP with more reduction of IOP than the timolol 0.5% twice daily in the less glaucomatous eyes,. The reduction of IOP was also greater in the more and the less glaucomatous eye in the travoprost group than the timolol group. Therefore the asymmetric progression of optic neuropathy (cupping of disc) in POAG patients may have occurred due to the asymmetry of diurnal variation of IOP and Mean IOP which could be prevented and deferred by treatment with the Travoprost (Prostaglandin analogue) in better way.

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