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The Effect of Peripheral Laser Iridotomy on Diurnal Variation of Intra-Ocular Pressure in Primary Angle Closure Disease – A Hospital Based Longitudinal Study in a Tertiary Eye Care Centre in Kolkata, West Bengal, India

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Abstract

BACKGROUND
Primary closure angle glaucoma (PACG) bears higher risk of causing blindness and is important to detect and intervene early with various therapeutic measures. Laser iridotomy is a conventional treatment available and effect of it on IOP levels is being established in this study.

METHODOLOGY
This is a longitudinal study conducted among the subjects with primary angle closure disease (PACD) for a period of 18 months from 01/01/2018 to 30/06/2019. All the patients were

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subjected to detailed ophthalmological examination and gonioscopy and laser iridotomy using Nd:YAG laser was performed as per the standard protocol among the affected eyes of the patients. They were followed up after 1 week for patency, later at the end of 1st, 3rd and 6th month and at the end of 12 months for the diurnal variation in intraocular pressure pattern, mean diurnal IOP, peak IOP, trough IOP levels and IOP fluctuation.

RESULTS

The mean age of the study subjects was 51.94±11.35 years and majority were males (57.0%) and PACG affecting both the eyes (57.0%) was the commonest PACD. In both eyes, all the mean IOP levels - trough, peak and diurnal (mmHg) were significantly higher in both PACG and PAC group compared to PACS ($P<0.05$). Among all the groups of PACD in both eyes, the mean IOP levels significantly decreased at each follow-up visit compared to baseline except in the PAC group where only mean peak levels and diurnal variations decreased across the follow up visits compared to baseline in the right eye but only mean peak levels decreased in the PAC group in the left eye ($P<0.05$). However, the effect size within the groups was larger for peak IOP levels in both PACG and PAC groups.

CONCLUSION

Laser iridotomy was more effective in reducing peak IOP and diurnal variations of IOP in PACG and PAC groups.

KEYWORDS

Primary angle closure disease (PACD), Primary angle closure glaucoma (PACG), primary angle closure suspects (PACS), Primary Angle Closure (PAC), Intra ocular pressure, peripheral laser iridotomy, peak IOP, trough IOP, diurnal variations

Introduction

Globally, glaucoma is one of the leading causes of visual impairment.[1] It is a group of progressive optic neuropathies characterized by the degeneration of retinal ganglion cells. It results in loss of visual field because of changes in the optic nerve head.[2,] The prevalence of glaucoma among 40 to 80 years age-group is 3.54%, and is projected to increase to 111.8 million by 2040.[2,3] Glaucoma is the leading cause of irreversible blindness in India affecting a minimum of 12 million people and around 1.2 million people are blind.[3,4]

Among the different types of glaucoma, the two common types include primary open angle glaucoma (POAG), and primary angle closure glaucoma (PACG). Despite the fact that POAG is most common form, PACG has at least three times higher risk of blindness than POAG. It's early detection and management is challenging in developing countries.[5] Raised intraocular pressure is one of the major risk factors for progression of glaucoma and hence monitoring of intraocular pressure is important.[2] Among the different management options, laser iridotomy is a conventional treatment of PACG. Chun Hing Ho et al., have stated that short-term IOP fluctuation was found to be higher in PACG patients following iridotomy than normal

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individuals.[2] In the literature it is quoted that 58% subsequently required medical therapy and 32% eventually had trabeculectomy following laser iridotomy in acute primary angle closure (PAC).[5] Ai-Ling Bian et al., have also described that IOP control was not as good as expected following laser iridotomy in PACG eyes.[6] In the same background the current study was conducted to elicit the effect of the laser iridotomy on IOP levels.

Materials and Methods

This is a prospective longitudinal study conducted for a period of 18 months (01/01/2018 to 30/06/2019) among the patients with primary angle closure disease at Glaucoma clinics at Regional Institute of Ophthalmology, Kolkata. The patients with primary angle closure disease who were willing to participate and willing for follow up were included in the study. The primary angle closure disease included the primary angle closure suspects with either primary angle closure or those with early stage of primary angle closure glaucoma. The patients with previous acute angle closure, secondary angle closure due to uveitis, neovascularisation, ocular surgery or trauma, cataract, those with prior intraocular or penetrating eye injury, those taking systemic or glaucoma medication that could possibly influence IOP such as beta blockers, steroids or diuretics, those taking systemic or glaucoma medication that could possibly influence IOP such as beta blockers, steroids or diuretics, plateau iris syndrome and advanced stage of Primary Angle Closure Glaucoma were excluded from the study.

Sampling and Sample Size

100 patients of Primary Angle Closure Disease satisfying all the inclusion and exclusion criteria were included in the study. Considering the prevalence of Primary Angle Closure Diseases (p) as 1.54% ≈ 1.5% as per the literature[7], q=100-p i.e., 98.5%, and with an absolute precision of 2.5% (d), z value being 1.96 at 95% confidence interval, the total sample size was estimated to be 90.7≈ 91 based on the formula, $n=z^2(pq/d^2)$. Considering 10.0% of the estimated sample size i.e., 9 as the anticipated proportion of loss to follow up, a total sample size of 100 was calculated.

Procedure of Data Collection

Once the ethical clearance was obtained from the institutional committee and after taking the written informed consent, the patients were included under the study. Demographic details, clinical history, history on previous treatments and the current complaints were obtained. The patients were further subjected to the detailed ophthalmological examination with best corrected visual acuity, testing visual fields, slit lamp examination of anterior segments with gonioscopy and measurement of IOP by applanation tonometer were also conducted along with examination of optic nerve head and CCT measurement by pachymetry. Blood examination for FBS, PPBS, and Blood pressure measurement was done for every patient. The newly diagnosed patients with primary angle closure disease were categorized into PAC, PACS and PACG accordingly. Based on the inclusion and exclusion criteria, the study subjects were admitted in our institute for 24 hours. Then the patients were examined for peak IOP, trough IOP and

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diurnal variation of IOP before and after laser peripheral iridotomy, where the IOP was measured by the applanation tonometry from 8am on the day of admission to 8am next day morning with 2 hour interval (e.g. 7am, 9am, 11am, lpm, 3pm, 5pm, 7pm).

After appropriate preparation for conducting tonometry with calibrated dial of the tonometer being set at 10 mmHg and the magnification of the slit lamp set at 10x, the local anaesthetic drops were instilled and the fluorescein stain was applied. It was made sure that the slit beam was shining onto the tonometer head from the patient's right side for measuring IOP in the patient's left eye, and from the patient's left side for measuring the IOP in the right eye. Then the patient was asked to look straight ahead, open both eyes wide, and keep perfectly still. The patient's upper eyelid was gently held up with the thumb, taking care not to put any pressure on the eye. The blue light was directed from the slit lamp onto the prism head. The tonometer head was made perpendicular to the eye, tonometer was moved forward slowly until the prism rests gently on the centre of the patient's cornea. The calibrated dial on the tonometer was turned forward with the other hand until the two fluorescein semi-circles in the prism head that was seen to meet and form a horizontal `S' shape. The correct end point was when the inner edges of the two fluorescein semi-circle image just touched. The reading was noted on the dial and recorded in the notes. The prism from the corneal surface was withdrawn and its tip was wiped with a clean dry swab. The procedure was repeated for the other eye. The prism was wiped with a clean dry swab and replaced in receptacle with just its tip touching the disinfectant. The tonometer was checked for calibration errors on monthly basis. A single observer performed all the tonometry measurement using same Goldmann Applanation instrument. The mean of 3 consecutive IOP reading was recorded as the final IOP.

Laser peripheral iridotomy (LPI) was performed using Neodymium:yttrium-aluminum-garnet (Nd:YAG) laser peripheral iridotomy (Carl Zeiss Meditec, Visulas YAG III, Germany) on all eyes with topical anesthesia of one drop of proparacaine 0.5% using a Goldmann gonioscopy after administrating 3 drops of 2% pilocarpine with most preferred superonasal location. Pilocarpine 2% eye drops were instilled every 15 mins, four times starting 1 hour before iridotomy. Abraham iridotomy lens were used along with 2 % methyl cellulose as coupling agents. With energy set at 3mJ for Nd:YAG laser, LPI was performed in the superonasal quadrant after identifying iris crypts over an area covered by lids and maximum energy was ensured to be less than 90mJ. Patients were examined for the presence or the absence of iris crypts. Patency and completion of iridotomy was considered to be achieved when a gush of aqueous flowed out from behind, clear red glow was seen without iris strands or ciliary processes were seen through iridotomy. Total number of shots or energy in the presence of crypts patency was achieved using single pulse. Few more shots were given to obtain optimum size of opening.

Post laser low potential steroid was given for a week. Brimonidine, the alpha agonist were used as the most effective ocular hypotensive agents used for post laser spikes. Pilocarpine 2% BD was prescribed for 5 days to keep the pupil stretched to maintain patency.

Patients were then followed up after 1 week and patency of iridotomy was checked. Later they were followed up for 1 year for the diurnal variation in intraocular pressure pattern, mean

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diurnal IOP, peak IOP, trough IOP and IOP fluctuation at the end of 1 month, 3 months, 6 months and 12 months.

Statistical Analysis

Statistical Analysis was performed with help of SPSS version 20.0. All the data were entered into Microsoft Excel sheet and the data were expressed in means and proportions. The improvement from the baseline to the different time points during the follow up was estimated using repeated measures ANOVA and significance at each levels was elicited using either Tukey's or Bonferroni's post hoc test. A P-value of <0.05 was considered to be statistically significant.

RESULTS

Overall the mean age of the study subjects was 51.94±11.35 years which ranged from 28 to 81 years with majority being males (57.0%) and commonest primary angle closure diseases being primary angle closure glaucoma affecting both the eyes (57.0%).

The mean age of the study subjects and mean vertical cup disc ratio (VCDR) in both the eyes were significantly higher in PACG group compared to other groups (P<0.05). The distribution of males and females did not differ significantly across the groups of primary angle closure diseases (P>0.05). [Table/Fig-1]

In the right eye, the mean trough, peak and diurnal IOP levels in mmHg were significantly different and they were significantly higher in both PACG group and PAC group compared to PACS and at the baseline and also throughout the follow up (P<0.05), however, the mean IOP levels did not differ significantly between PACG and PAC group anytime during the study including the baseline (P>0.05). [Table/Fig-2]

Among PACG group, the mean trough IOP levels also decreased significantly from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(1.689, 108.123)=62.37; P<0.05); the mean peak IOP levels also decreased from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(1.673, 107.077)=265.582; P<0.05), however the significance was also seen among the IOP levels between each month of follow up to the last follow up of 12^{th} month and additionally the difference was also significant between 1^{st} month and 3^{rd} month of follow up (P<0.05); the mean diurnal IOP levels decreased across the follow up visits compared to baseline (F(2.666, 170.650)=111.314; P<0.05). [Table/Fig-2]

Among PAC group, the mean trough IOP levels also decreased significantly from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(1.650, 31.344)=21.101; P<0.05); the mean peak IOP levels also decreased from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(1.903, 36.158)=85.801; P<0.05); the mean diurnal IOP levels decreased across the follow up visits compared to baseline (F(2.855, 54.237)=29.581; P<0.05). [Table/Fig-2]

Among PACS group, the mean trough IOP levels did not differ significantly from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(2.396, 33.545)=2.82; P>0.05); the mean peak IOP levels also decreased from baseline to 1^{st}, 3^{rd}, 6^{th} and 12^{th} month of follow up (F(2.147, 30.054)=23.090; P<0.05); the mean diurnal IOP levels decreased from baseline to the last

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follow up of 12th month but the difference also was significant from baseline to 1st month (F(2.453, 34.345)=3.937; P<0.05). [Table/Fig-2]

In the left eye, among the PACD groups, the mean trough, peak and diurnal IOP levels in mmHg were significantly different and they were significantly higher in PACG group compared to PACS and at the baseline and also throughout the follow up (P<0.05), however, it was not significantly more compared to PAC group anytime during the study including the baseline (P>0.05). [Table/Fig-3]

Among PACG group, the mean trough IOP levels also decreased significantly from baseline to 1st, 3rd, 6th and 12th month of follow up, however the IOP levels also decreased significantly from 1st month to 12th month of follow up (F(1.680, 412.628)=62.813; P<0.05); the mean peak IOP levels also decreased from baseline to 1st, 3rd, 6th and 12th month of follow up (F(2.175, 139.195)=343.279; P<0.05), however the significance was also seen among the IOP levels between each month of follow up to the last month of follow up at 12th month except between 3rd month and 6th month of follow up (P<0.05); the mean diurnal IOP levels decreased across the follow up visits compared to baseline (F(2.101, 134.459)=114.871; P<0.05) and also from 1st month to 12th month (P<0.05). [Table/Fig-3]

Among PAC group, the mean trough IOP levels also decreased significantly from baseline to 1st, 3rd, 6th and 12th month of follow up (F(1.711, 32.509)=44.779; P<0.05) and also between 1st and 6th month of follow up (P<0.05); the mean peak IOP levels also decreased from baseline to 1st, 3rd, 6th and 12th month of follow up (F(1.452, 27.579)=184.588; P<0.05); the mean diurnal IOP levels decreased across the follow up visits compared to baseline (F(2.124, 40.357)=62.098; P<0.05). [Table/Fig-3]

Among PACS group, the mean trough IOP levels did not differ significantly from baseline to 1st, 3rd, 6th and 12th month of follow up (F(1.908, 26.717)=2.784; P>0.05); the mean peak IOP levels also decreased from baseline to 1st, 3rd, 6th and 12th month of follow up (F(2.498, 34.971)=14.177; P<0.05); the mean diurnal IOP levels also did not decrease significantly from baseline to the last follow up of 12th month (F(2.536, 35.509)=3.073; P>0.05). [Table/Fig-3]

The effect sizes for peak IOP levels were more than 0.8 in PACG and PAC groups in both the eyes and it was more than 0.6 for diurnal variations of IOP in PACG and PAC groups**.**

Variables	**PACG (n=65)**	**PAC (n=20)**	**PACS (n=15)**	**Chi-square value/F-value (*P*-value)**
Age (Mean±SD) in years†	56.51±10.28	44.60±6.59	41.93±9.32	21.67 (<0.001)*
Gender‡ n (%)				
Males	40 (61.5)	11 (55.0)	06 (40.0)	2.35 (0.31)
Females	25 (38.5)	09 (45.0)	09 (60.0)	
VCDR RE§ (Mean±SD)	0.66±0.13	0.39±0.15	0.31±0.08	69.69 (<0.001)*
VCDR LE§ (Mean±SD)	0.63±0.15	0.35±0.15	0.32±0.08	52.12 (<0.001)*

Table 1: Socio-Demographic and Vertical Cup Disc Ratio (Vcdr) among the Study Subjects

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*indicates statistical significance at P<0.05; †One-way ANOVA applied & Tukey's post-hoc test was applied (F-value); § One-way ANOVA applied & Bonferroni's post-hoc test was applied (F-value); ‡Chi-square test applied (Chi-square-value)

Variables	PACG (n=65)	PAC (n=20)	PACS (n=15)	F-value (*F*(2,97))	*P*-value
Trough IOP†					
Baseline	18.37±3.49	19.10±3.14	12.80±2.24	19.95	<0.001*
1st month	15.35±2.74	15.30±1.98	12.27±1.98	9.59	<0.001*
3rd month	15.17±2.87	15.30±1.98	11.87±2.07	10.41	<0.001*
6th month	14.95±2.92	15.40±1.96	12.27±1.67	7.57	0.001*
12th month	14.83±2.87	15.30±2.27	11.73±1.83	9.71	<0.001*
Effect size	0.49*	0.53*	0.17	--	
Peak IOP†					
Baseline	26.43±4.12	27.00±3.34	16.93±3.37	39.59	<0.001*
1st month	20.31±3.43	20.70±2.36	14.67±2.35	21.81	<0.001*
3rd month	19.91±3.53	20.30±2.77	14.67±2.35	17.37	<0.001*
6th month	19.75±3.70	20.30±2.99	14.53±2.20	16.08	<0.001*
12th month	19.32±3.68	20.00±2.90	14.27±2.49	15.42	<0.001*
Effect size	0.81*	0.82*	0.62*	--	
Diurnal Variations of IOP†					
Baseline	8.06±1.77	7.90±1.52	4.13±1.77	32.64	<0.001*
1st month	4.92±1.33	5.40±1.60	2.40±1.12	24.93	<0.001*
3rd month	4.74±1.48	4.90±1.52	2.80±1.27	11.78	<0.001*
6th month	4.80±1.57	4.90±1.52	2.80±2.37	9.05	<0.001*
12th month	4.52±1.51	4.70±1.17	2.53±1.19	13.40	<0.001*
Effect size	0.64*	0.61*	0.22*	--	

Table 2: Comparison of Trough, Peak and Diurnal Variations of IOP Levels at Different Follow UPS and between the Groups of PACD in the Right Eye

*indicates statistical significance at P<0.05; †One-way ANOVA & Repeated Measures ANOVA tests were used and Tukey's post-hoc test applied

Variables	PACG (n=65)	PAC (n=20)	PACS (n=15)	F-value (*F*(2,97))	*P*-value
Trough IOP†					
Baseline	17.69±3.30	18.50±2.50	12.40±2.41	21.23	<0.001*
1st month	15.20±2.44	15.50±2.04	11.47±1.92	17.57	<0.001*
3rd month	14.98±2.45	15.00±2.20	11.47±1.77	14.73	<0.001*
6th month	14.80±2.39	14.80±2.19	11.33±1.95	13.49	0.001*
12th month	14.83±2.87	15.30±2.27	11.73±1.83	14.62	<0.001*
Effect size	0.49*	0.70*	0.17	--	
Peak IOP†					

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Baseline	25.35±3.68	25.90±3.14	16.00±2.73	48.26	<0.001*
1st month	19.88±2.89	20.10±2.19	14.40±1.88	28.01	<0.001*
3rd month	19.38±3.08	19.60±2.39	14.27±1.83	21.69	<0.001*
6th month	19.20±3.16	19.50±2.42	14.13±1.77	20.66	<0.001*
12th month	18.92±3.10	19.60±2.39	13.87±2.07	21.86	<0.001*
Effect size	0.84*	0.91*	0.50*	--	
Diurnal Variations of IOP†					
Baseline	7.66±1.89	7.40±1.14	3.60±1.55	34.66	<0.001*
1st month	4.68±1.29	4.60±1.31	2.93±1.28	11.39	<0.001*
3rd month	4.40±1.51	4.60±1.14	2.80±1.01	9.24	<0.001*
6th month	4.40±1.51	4.70±1.17	2.53±0.92	13.01	<0.001*
12th month	4.18±1.26	4.40±1.05	2.53±1.19	12.83	<0.001*
Effect size	0.64*	0.77*	0.18	--	

Table 3: Comparison of trough, peak and diurnal variations of IOP levels at different follow ups and between the groups of PACD in the left eye

*indicates statistical significance at P<0.05; †One-way ANOVA & Repeated Measures ANOVA tests were used and Tukey's post-hoc test applied.

Discussion

Nd: YAG laser iridotomy has major significance in the treatment of PACG[8] and there is no much data to determine if the current treatment would sustain IOP levels in the long-term after initial PI to prevent vision loss in patients who present with good visual acuity.[9]

Ritu Shree MS et al., have recorded a mean age of 50.5 ± 9.6 years among their study subjects similar to ours where the mean age was 51.9 years.[10] Though some studies have reported majority as females our study reports males as the majority.[10,11] Ramnani V and Damle V and Ichhpujani P et al., have reported PACG as the commoner angle closure diseases similar to ours.[12,13] It has been noted that the mean VCDR was around 0.6 in both right and left eyes and they were significantly higher in PACG compared to PAC and PACS and naturally as PACG marks the severe end of the spectrum indicating the progress through the stages of PACS to PAC and lastly PACG, the mean VCDR is expected to be higher. Though the difference in mean VCDR levels was not significant in PAC compared to PACS in this study, it was observed to be slightly higher in PAC.[14]

Ichhpujani P et al., noted that the three stratified groups of PACS, PAC and PACG differed significantly among their mean IOP, similar to our study finding with the highest IOP recorded was found among PACG followed by PAC and PACS of 21.06, 17.24 and 15.92 mmHg respectively but the IOP was highest among PAC in our study and did not differ when compared to PACG and the peak IOPs in PACG, PAC and PACS were 26.43, 27.00 and 16.93 mm Hg respectively in RE and 25.35, 25.90 and 16.00 mm Hg in LE respectively. The IOP levels were more in our study finding when compared to the study by Ichhpujani P et al., as the IOP levels vary and the time of the day when maximum IOP occurs cannot be predicted.[13,15]

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Reddy R et al., have also found that 92.2% of PAC, 71.4% of PACG and 100.0% of PACS eyes and the fellow eyes with prophylactic laser iridotomy had good IOP control throughout the follow up similarly, there was effective reduction in the peak IOP levels and diurnal variations of IOP among PACG and PAC groups in both the eyes. Though there was significant reduction in IOP levels in PACS group, the effect size was slightly lesser in PACS group and that may be due to the reason that the baseline IOP levels itself was significantly lesser as compared to PAC and PACG groups throughout the follow-up.[16] Improvement in the IOP levels might also vary due to different study settings, different age group distributions and gender. However, laser peripheral iridotomy (LPI) increases the angle width of anterior chamber in primary angle closure suspects (PACS) and primary angle closure (PAC) and deepens the anterior chamber and hence LPI is an effective treatment option in PACS to prevent acute angle closure glaucoma and Gupta V and Dada T have stated that such parameters would not change significantly in PACG.[11,17] As discussed above the results might vary based on the different study settings and also the stage at which the PACG patients are treated. There are not many literatures on long term follow up and this study is one of its kinds where the study subjects were followed up till 1 year post laser peripheral iridotomy. More similar studies in larger settings among the representative samples with the matched control groups are recommended to establish the association and generalize the outcome.

Conclusion

Peripheral Laser Iridotomy is an effective treatment option in reducing peak IOP levels in PACG, PAC and PACS groups and additionally it effectively reduced the diurnal variations of IOP in PACG and PAC groups throughout the follow up. Hence an early intervention with peripheral laser iridotomy would be effective to control the IOP levels and progression of disease.

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