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EFFECT OF AMOUNT OF ENERGY ON INTRAOCULAR PRESSURE IN PATIENTS OF PRIMARY ANGLE CLOSURE DISEASE UNDERGOING ND:YAG LASER PERIPHERAL IRIDOTOMY

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ABSTRACT

Background: The purpose of the study is to find out whether there exists a relationship between the quantum of energy used and the amount of increase in intraocular pressure in early post laser period following Nd: YAG laser peripheral iridotomy. Design is prospective observational study.

Materials and Methods: Setting - Out patient department of a tertiary care hospital in Delhi. Study Population – Patients of primary angle closure disease above 18 years of age attending outpatient department (ophthalmology) in which Nd:YAG laser peripheral iridotomy was indicated. Intervention/Observation Procedure(s) – Fifty five patients suffering from PACD (primary angle closure disease), were offered to participate in the study. Amount of laser energy used and the number of shots given for laser peripheral iridotomy were recorded. Intraocular pressure was recorded before and after the procedure. Based on the energy used, the study subjects were divided into three groups viz., Group I (< 40 mJ), Group II (40-80 mJ) and Group III (> 80 mJ). This was done with the aim to identify if the rise of IOP following YLPI was a function of amount of energy used. Main Outcome Measure(s) – Intraocular pressure.

Results: Mean of IOP at baseline, one hour, two hours, three hours, twenty-four hours, one week and one month following laser peripheral iridotomy was compared in each energy group. At baseline, just before the LPI procedure, mean IOP in all the three groups was comparable (p= 0.578). The increase in intraocular pressure in different groups at one hour, two hours, three hours, 24 hours post laser was not statistically significant with p values 0.550, 0.553, 0.565 and 0.227 respectively. The increase in intraocular pressure in different groups at one week and one month post laser was also not statistically significant (p=0.449) and (p=0.411).

Conclusion: There is no clinically significant rise of Intraocular pressure following YAG laser peripheral iridotomy among patients of primary angle closure disease irrespective of the amount of energy used upto 120 mJ. Based on the present study, we recommend that there is no need to use anti-glaucoma medication in peri-laser period for the patients undergoing YAG laser peripheral iridotomy provided the pre laser IOP is < 25 mmHg and pilocarpine is used to stretch iris immediately before laser PI. Inputs from the study may be used to design larger multi-centric trials with a larger sample size, wider pre-laser IOP range and larger energy range. If they also give similar results, the use of peri-laser ocular hypotensive drugs may be abolished saving millions of rupees every year and also to save patients from side effect of these drugs.

Keywords: Intraocular pressure, Nd: YAG laser, primary angle closure disease, peripheral iridotomy

INTRODUCTION

Glaucoma is the leading cause of global irreversible blindness. Angle closure disease is responsible for nearly half of the world's blindness due to glaucoma.[1]The spectrum of primary angle closure disease (PACD) includes: Primary angle closure suspect (PACS), Primary angle closure (PAC), Primary angle closure glaucoma (PACG) and Acute angle closure crisis.[1,2] The magnitude of the disease and its amenability to treatment, if detected early, makes it imperative for all to follow evidence-based protocols for the management of the disease.[2] There is high prevalence of angle closure glaucoma in Indian sub-continent.[3-7] India accounts for approximately 11.2 million persons aged 40 years and older with glaucoma.[8] Primary angle closure glaucoma constitutes almost half of all glaucoma patients among Indians.[9-12] Those with any form of primary angle closure disease comprise 27.6 million persons.[8] Laser peripheral iridotomy (LPI) is a standard treatment modality in the treatment of primary angle closure disease.[13,14] It is indicated in primary angle closure where pupillary block is the mechanism. This is a quick and effective outpatient procedure for the prophylactic treatment of all types of angle closure glaucoma. It's safety and the effectivity in angle closure disease has been well documented.[13,14] Neodymium: Yttrium Aluminium Garnet (Nd: YAG) laser works on the principle of photo disruption. It is the mechanical force produced by disruption and emission of electrons within the nuclei that causes breakdown of iris. It is believed to act by bypassing relative block at the pupil, which results in a significant increase in angle width. Short term rise in intra ocular pressure (IOP) is one of the commonly reported complications of Nd: YAG laser peripheral iridotomy,[16,17,18] and other anterior segment laser procedures.[19,20] Occasional studies in the literature have shown none or insignificant rise of IOP in similar procedures.[21] A study was performed at our institute to identify the most effective medicine, among those available in India, which would best prevent post laser IOP spikes following various anterior segment laser procedures. However, it was observed that if energy delivered remained within 50 mJ, there was no rise of IOP even when no medication was used.[21] With this observation in mind, another study was designed to observe changes in IOP following laser capsulotomy with titrated doses of energy. It was observed that the IOP rise was proportional to the amount of energy used and that there was no rise of IOP if the energy was limited to 40 mJ (under publication). On searching the literature, very few studies were found which studied the amount of rise of IOP as a function of the quantum of energy used. Presently, most prevalent practice is to use some kind of anti-glaucoma medication in the peri-laser period as a blanket treatment for all patients undergoing anterior segment Nd: YAG laser procedures. In the light of above two studies, it seems practical to avoid use of these anti glaucoma drugs as a blanket treatment. However, there was not enough scientific evidence in literature to prove the hypothesis. This study, was thus, designed to observe rise of IOP, if any, following Nd: YAG laser peripheral iridotomy (PI) among patients of primary angle closure disease (PACD) and relate this rise to quantum of energy used. It has been observed that a moderate rise of IOP among patients of glaucoma can result in a significant damage to the optic nerve head.[22] However, in the background of the two studies performed at our institute, as mentioned above, a sufficient confidence had been developed that, if performed under strict vigil, it is possible to perform this kind of study among the patients of PACD as well. To avoid any damage caused by chance, despite strict vigil, appropriate exclusion criteria were included.

MATERIALS AND METHODS

The Institutional Ethics Committee recommended and approved the protocol titled "effect of amount of energy on intraocular pressure among patients of primary angle closure disease undergoing ND:YAG laser peripheral iridotomy". The approval was obtained prior to the commencement of the study i.e, on 27/Sep/2016.

Patients included were primary angle closure disease patients with age > 18 yrs, gonioscopically proven primary angle closure disease in which peripheral iridotomy was indicated. Indications for peripheral iridotomy included: all cases of PACG, PAC, patients of Primary angle closure suspect (PACS) with Critically narrow angles, fellow eyes of patients suffering from PACG, diabetic patients requiring repeated dilation, patients who cannot come for follow up due to any reasons, those willing to participate in study and ready to sign a written informed consent were included in the study. Patients excluded from study were those with baseline IOP > 28 mm of Hg, patients of secondary angle closure disease, those who had undergone any intraocular surgery, patients during acute attack of angle closure glaucoma, patients using any ocular hypotensive drugs, patients with active ocular inflammations, any corneal abnormality or any physical or mental limitation of the patient preventing reliable applanation tonometry, patients with known allergy to any of the drugs or any systemic contraindications to any of the drug to be used in the procedure, any patient with visual field defect in central 100 resulting from glaucoma were excluded in the study. Study period was 1.11.2016 to 31.03.2018 and sample size was calculated assuming the prelaser PI Intraocular pressure based on previous study done in our institution to be 12.1 mm Hg as mean, and a 0.5 SD decrease in IOP post laser PI at the latest follow up which equates to 1.6 mm Hg decrease in mean IOP. The required sample size came out to be 50 using Statcalc software for pre and post analysis and after

adding 10% as non-response rate the final sample size came out to be 55. This calculation assumes 90% power of study.

Fifty-five patients, suffering from PACD (primary angle closure disease), requiring Nd: YAG laser peripheral iridotomy were offered to participate in the study after obtaining written informed consent. Patients were evaluated prior to procedure as given below. Amount of laser energy used and the number of shots given for laser peripheral iridotomy were recorded. Intraocular pressure was recorded before and after the procedure as explained in the following sections. Pre-laser workup was done by taking meticulous history and systemic workup were done to rule out exclusion criteria. Patients who met the eligibility criteria were informed about the potential risks and benefits of the procedure and written informed consent were taken. Patients participating in the study underwent baseline ophthalmic examination prior to laser peripheral iridotomy. If both eyes were found to be eligible for the study participation, one eye was included in the study in random fashion by envelope technique. Detailed general ophthalmic examination was carried out in each case: detailed anterior segment evaluation was done using slit lamp bio microscopy, posterior segment examination was done without dilatation using direct ophthalmoscope. Specific examination included: Visual acuity (VA): - visual acuity was recorded by Snellen‘s chart at six meters. The refraction and assessment of best corrected visual acuity (BCVA) was done prior to the procedure. If a patient was not able to read the whole line then number of letters read in that line was noted. Intraocular pressure readings were taken using a well calibrated Goldmann Applanation Tonometer. At least two baseline intraocular pressure readings were taken prior to recruitment and once one hour before the procedure, gonioscopy was done using two mirror Goldmann type gonioscope (Ocular instruments Inc., USA) using 2% Hydroxypropyl methyl cellulose as coupling medium. Differentiation of appositional and synechial closure was done using four mirror Sussaman gonioscope, detailed slit lamp and fundus examination was carried out to rule out secondary glaucoma, visual fields were done of every patient (24-2) using Carl Zeiss meditech HFA II 745/750. Nd: YAG laser peripheral iridotomy (PI) was performed using Visulas YAG Plus II [Carl Zeiss]. Both eyes underwent procedure in the same sitting unless contraindicated. However, only one eye was taken for study as explained above. Pupil was constricted using 2% Pilocarpine eyedrops every 15 minutes, three times starting one hour before the procedure. A non-reacting pupil was ensured before performing peripheral iridotomy. The location to perform PI was decided based on following criteria: - Supero nasal quadrant was the most preferred quadrant, radially the preferred site was junction of central two- third and peripheral one – third. Area of arcus, pannus or any another corneal haze was avoided. A crypt was the most preferred site. If a crypt was not present in the above region, then any other site with crypts was preferred. The energy of 4-6 mJ per shot was used. In case of total absence of crypts, PI was done in the location as described above but would be preceded by drumstick pattern photocoagulation to stretch the iris using double frequency Nd: YAG laser mode of the same machine. Parameters of double frequency Nd: YAG laser if required: Spot size: 100 µm, Duration: 100 mS; Power: 200 mW. Post-laser IOP was recorded at 1, 2, 3 hours and one day as well as one week after the procedure. One-week post laser visual acuity (VA) testing, slit lamp examination to check patency of PI and signs of inflammation, intra ocular pressure (IOP), anterior chamber depth (ACD), gonioscopy was done to assess the opening and other details of the angle of anterior chamber, pupils were dilated using Tropicamide 1% eye drops for detailed fundus examination and/ or fundus photography, mid dilated IOP was also recorded, intraocular pressure was also recorded at one month following laser if a significant increase was observed at one-week study point. Rise of IOP was classified as mild if any elevation of IOP up to or less than 5 mm Hg above the baseline. This rise was considered clinically insignificant and hence this was clubbed with no rise of IOP for all considerations including data analysis. Moderate rise of IOP defined as a rise of more than or equal to 5 mm Hg but less than 10 mm Hg above the baseline was designated as moderate rise of IOP. Severe rise of IOP defined as a rise of more than or equal to 10 mm Hg above the baseline. All patients were prescribed Loteprednol etabonate 0.5% eye drops four times per day for one week starting immediately following laser. At any point of time, if there was a moderate to severe rise of IOP, then the patient was given appropriate treatment to lower the IOP to a level considered safe for each individual patient. In case patient required treatment for control of IOP then the IOP was measured every two hours till it came down to normal range and next reading was taken after 12 hours (effect of ocular hypotensive drug is over). If IOP still remained in moderate to severe range, then treatment was appropriately modified and monitoring continued. Otherwise no further treatment was given. Prostaglandin analogues were not used for treatment in this study as they increase ocular inflammation and because of their long duration of action which does not permit enough drug free period for precise monitoring of IOP rise as a function of the intervention. At one-week assessment, if IOP was found to be still high, appropriate long-term therapy was instituted and reassessment was done at one month. Mid dilated IOP was recorded at one-week study visit. Those patients who developed significant rise of IOP on dilation, intraocular pressure was controlled using appropriate drugs including intravenous Mannitol if required. These cases were advised long term Pilocarpine therapy (along with other drugs if required) or surgery depending on the merit of each case.

RESULTS

Fifty five subjects with primary angle closure disease attending out patient department (ophthalmology) of a tertiary care hospital in Delhi were enrolled in the study. All of them completed the study i.e. a drop out rate of 0%. Laser peripheral iridotomy was performed using Abraham iridotomy lens (Oculus Inc.) using 2% hydroxypropyl methyl cellulose as coupling agent. Visulas YAG plus II (Carl Zeiss) laser was used for the procedure. Record of the amount of energy delivered and number of shots required to achieve an optimum iridotomy was kept.

Post laser evaluation was carried out as pre defined study protocol. The intraocular pressure was recorded at one hour, two hours, three hours, one day and one week. Mean intraocular pressure distribution at different intervals in the study subjects is given in [Table 3 and Figure 1]. Among the study subjects, mean of IOP at baseline, one hour, two hours, three hours, twenty-four hours, one week and one month following laser peripheral iridotomy was compared, using ANOVA, in each energy group. At baseline, just before the LPI procedure, mean IOP in all the three groups was comparable (p= 0.578). Mean IOP in Group I being 17.95 ± 4.2mm Hg ±, in Group II being 18.74 ± 3.4 mm Hg and in Group III being 19.56 ± 4.3 mm Hg. At one hour, mean IOP in Group I was 18.74 ± 4.0 mm Hg, in Group II was 19.22 ± 3.4 mm Hg and in Group III was 20.44 ± 4.5 mm Hg. The increase in intraocular pressure in different groups at one hour post laser was not statistically significant (p=0.550).

At two hours, with mean IOP in Group I was 18.21± 3.7 mm Hg, in Group II was 18.56 ± 3.5 mm Hg and in Group III was 19.89 ± 4.8 mm Hg. The increase in intraocular pressure in different groups two hours post laser was not statistically significant (p=0.553).

At three hours, with mean IOP in Group I was 18.37 ± 3.7 mm Hg, in Group II was 18.70 ± 3.5 mm Hg and in Group III was 20.00 ± 4.6 mm Hg. The increase in intraocular pressure in different groups three hours post laser was also not statistically significant (p=0.550).

At 24 hours, mean IOP in all the three groups was comparable (p= 0.227), with mean IOP in Group I was 17.74 ± 3.5 mm Hg, in Group II was 18.22 ± 3.4 mm Hg and in Group III was 20.11± 4.4 mm Hg. At one-week post YLPI, mean IOP in Group I was 17.74 ± 3.3 mm Hg, in Group II was 17.96± 3.2 mm Hg and in Group III was 19.44 ± 4.0 mm Hg. The increase in intraocular pressure in different groups at one week post laser was also not statistically significant (p=0.449).

At one month post laser peripheral iridotomy, mean IOP in Group I was 17.63 ± 3.1 mm Hg, in Group II was 17.96 ± 2.5 mm Hg and in Group III was 19.22 ± 3.5 mm Hg.

Mean intraocular pressure distribution at different intervals in the study subjects is given in [Figure 1]. Among the study subjects, mean of IOP at baseline, one hour, two hours, three hours, twenty-four hours, one week and one month following laser peripheral iridotomy was compared, using ANOVA, in each energy group. At baseline, just before the LPI procedure, mean IOP in all the three groups was comparable (p= 0.578). Mean IOP in Group I being 17.95 ± 4.2mm Hg ±, in Group II being 18.74 ± 3.4 mm Hg and in Group III being 19.56 ± 4.3 mm Hg.

Amount of laser energy required for performing peripheral iridotomy is given in [Figure 2]. The eyes were fractionated into three groups based on the energy required in Nd: YAG peripheral iridotomy, viz., Group I (< 40 mJ), Group II (40-80 mJ) and Group III (> 80 mJ). Majority of study eyes {27 (49.1%)} fell in Group II. In Group I and Group III there were 19 (34.5%) and 9 (16.4%) eyes respectively.

Diagnosis wise distribution of study subjects is given in [Figure 3]. Majority of study subjects {32 (58.2%)} were primary angle closure suspects. Only 5 (9.1%) of subjects had Primary angle closure glaucoma.

Table 1: Diagnosis wise distribution of study subjects (N=55)

Diagnosis	Number	Percentage (%)
Primary angle closure suspects	32	58.2%
Primary angle closure	18	32.7%
Primary angle closure glaucoma	5	9.1%
Total	55	100%

Diagnosis wise distribution of study subjects is given in [Table 1]. Majority of study subjects {32 (58.2%)} were primary angle closure suspects. Only 5 (9.1%) of subjects had Primary angle closure glaucoma.

Table 2: Amount of laser energy required for performing peripheral iridotomy (N=55)

Groups	Amount of energy (mJ)	Number	Percentage (%)
I	<40	19	34.5%
II	40-80	27	49.1%
III	>80	9	16.4%
	Total	55	100%

Amount of laser energy required for performing peripheral iridotomy is given in table 2. The eyes were fractionated into three groups based on the energy required in Nd: YAG peripheral iridotomy, viz., Group I (< 40 mJ), Group II (40-80 mJ) and Group III (> 80 mJ). Majority of study eyes {27

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Mean intraocular pressure distribution at different intervals in the study subjects is given in [Table 3]. Among the study subjects, mean of IOP at baseline, one hour, two hours, three hours, twenty-four hours, one week and one month following laser peripheral iridotomy was compared, using ANOVA, in each energy group. At baseline, just before the LPI procedure, mean IOP in all the three groups was comparable (p= 0.578). Mean IOP in Group I being 17.95 ± 4.2mm Hg ±, in Group II being 18.74 ± 3.4 mm Hg and in Group III being 19.56 ± 4.3 mm Hg.

Table 3: Mean intraocular pressure at different post laser periods in study subjects (N=55)

IOP	Groups*			P-value**
	Group I (<40 mJ) Mean ± SD	Group II (40-80 mJ) Mean ± SD	Group III (>80 mJ) mean± SD	
Baseline	17.95 ± 4.2	18.74 ± 3.4	19.56 ± 4.3	0.578
1 hour	18.74 ± 4.0	19.22 ± 3.4	20.44 ± 4.5	0.550
2 hours	18.21 ± 3.7	18.56 ± 3.5	19.89 ± 4.8	0.553
3 hours	18.37 ± 3.7	18.70 ± 3.5	20.00 ± 4.6	0.565
24 hours	17.74 ± 3.5	18.22 ± 3.4	20.11 ± 4.4	0.227
1 week	17.74 ± 3.3	17.96 ± 3.2	19.44 ± 4.0	0.449
1 month	17.6 ± 3.1	17.96 ± 2.5	19.22 ± 3.5	0.411

* Amount of energy delivered, mJ = milli Joules; SD = standard deviation; IOP = Intraocular pressure
** ANOVA

DISCUSSION

Neodymium Yttrium Aluminum Garnet (Nd: YAG) laser peripheral iridotomy (LPI) is a well- established modality for the treatment of primary angle closure glaucoma. It may prevent recurrence of acute episodes and eliminate the risk of acute attacks in fellow eyes. After LPI, the pressure between the anterior and posterior chambers comes to equilibrium due to flow of aqueous directly through the iridotomy opening. Short term rise in intra ocular pressure (IOP) is one of the commonly reported complications of Nd: YAG laser peripheral iridotomy.[20,27,30,31,32]

Occasional studies in the literature have shown none or insignificant rise of IOP in similar procedures as well.[24,25,28,29] A randomized clinical trial was done at our institute to identify the most effective medicine among those available in India, which would best prevent post laser IOP spikes following various anterior segment laser procedures. However, it was observed that in cases where energy used was <50 mJ, there was no rise of IOP even in control subjects where no medication was used.[21] With this observation in mind, this study was designed to observe rise of IOP, if any, following Nd: YAG laser peripheral iridotomy (PI) among patients of primary angle closure disease (PACD) and relate this rise to quantum of energy used.[26] In the present study, based on the energy used in Nd: YAG peripheral iridotomy, the study subjects were divided into three groups viz., Group I (<40 mJ), Group II (40-80 mJ) and Group III (> 80 mJ). This was done with the aim to identify if the rise of IOP following YLPI was a function of amount of energy used. The results obtained were studied in the light of available literature.

Present study was designed to see whether there existed any relationship between quantum of laser energy delivered for YAG Laser PI and post laser intra ocular pressure spikes. The results of study showed that not even a single subject among any of the three energy groups had clinically significant rise (5 mmHg or more) of intraocular pressure (maximum energy delivered in group III being 112 mJ). Many studies have reported similar results e.g., Anterior segment Nd: YAG Laser procedures by Singh MD et al (2015) who reported significant rise of IOP only in one patient (n=28) when < 50 mJ energy was used.[21] Singh MD, Aggarwal P and Sharma N (2015) conducted a study on comparison of two laser iridotomy techniques in 40 patients of primary angle closure disease (PACD) with absent iris crypts.[26] They reported fall in IOP irrespective of the amount of energy used and interpreted this as having been caused by opening of the angle of anterior chamber. Reza M et al (2015) also conducted a study on changes in ocular biometry and anterior chamber parameters among 21 primary angle closure suspect (PACS) patients before and after laser peripheral iridotomy and found that peripheral iridotomy had no significant effect on intraocular pressure (IOP).[23] Similarly, Ramani et al (Sep 2009) conducted a study primarily to determine the morphologic changes in the anterior segment of primary angle closure suspects (PACS) who underwent laser peripheral iridotomy (LPI).[29] None of the subjects developed increased intraocular pressure after laser iridotomy. Another study conducted by How A et al (2012) on changes in anterior segment morphology after laser peripheral iridotomy in Singapore among 176 patients with PACS showed that significant fall in mean IOP occurred in subjects who underwent peripheral iridotomy which was attributed to opening up of angle of anterior chamber after peripheral iridotomy.[24] However, many authors have reported increase in IOP in early post laser period.[20,27,30-32] Kam J P, Zepeda E M, Ding L (2017) conducted a study where mean total power used was 78.2±68.7 mJ per eye.[25] They reported IOP spikes (>8 mm Hg) in 5.1% (10/196). Jiang Y et al (2012) observed a significant IOP rise in 9.8% of cases at one hour. The differences in these studies could be because of

difference in patient profile and whether pilocarpine was used or not in the peri laser period, technology & techniques used, method of IOP recording and the period of study.[27]

Robin AL et al (1984) conducted a study on comparison of Nd: YAG and argon laser iridotomies. Immediate postoperative intraocular pressure elevation greater than 10 mmHg was seen in seven (35%) argon and six (30%) Nd: YAG-treated eyes.[20] It may be noted that this is very old study and many factors, including technology and techniques may have changed after this period. Studies like this may have resulted in making of protocol, in certain institutions, to use alpha agonists or other ocular hypotensive drugs in all cases of YLPI as a standard modality. However, in view of present study and with support of above mentioned studies it is strongly felt that such a practice is not indicated, although use of pilocarpine eye drops is considered essential to stretch the iris.

CONCLUSION

The findings of present study conclude that there is no clinically significant rise of Intraocular pressure following YAG laser peripheral iridotomy among patients of primary angle closure disease irrespective of the amount of energy used upto 120 mJ. There is no need to use ocular hypotensive drugs in peri-laser period among patients of primary angle closure disease undergoing laser PI provided pilocarpine is used to stretch iris immediately before laser PI.

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