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RESEARCH ARTICLE

Comparative study of efficacy of latanoprost (0.005%) and dorzolamide (2%), in primary open-angle glaucoma patients, as monotherapy

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ABSTRACT

Background: Glaucoma is the second most common cause of blindness worldwide and also in India and its prevalence is increasing. Raised intraocular pressure (IOP) is most important and directly related to development of primary open-angle glaucoma (POAG). Hence, the present study carried out to compare the efficacy between latanoprost and dorzolamide for reducing IOP in POAG as monotherapy. **Aims and Objectives:** The objectives are as follows: (i) To compare the efficacy between topical latanoprost (0.005%) and topical dorzolamide (2%) in POAG as monotherapy, and (ii) to evaluate the adverse effects of latanoprost and dorzolamide. **Materials and Methods:** The present prospective, open-labeled study was conducted in 80 patients males and females which were selected randomly with POAG diagnosis and divided into two groups. One group received latanoprost (0.005%) topical eye drops once a day and other group received dorzolamide (2%) eye drops 3 times a day. All participants were followed up for three visits at 2 weeks, 4 weeks, and 8 weeks. Before starting on treatment baseline, IOP was recorded by Perkins Hand Held Tonometer. Again during each follow-up visit, IOP was recorded to know the response of drugs. The informed consent was taken from all patients and ethical clearance was taken from institution. **Results:** The mean IOP reduction for latanoprost group was 9.5 ± 3.56 and dorzolamide group was 7.89 ± 3.56. Both drugs were effective in reducing IOP. The difference in IOP reduction between latanoprost and dorzolamide was statistically significant ($P = 0.02$). Both drugs were well tolerated during study period, maximum side effects seen in latanoprost group ($n = 9$) compared to dorzolamide group ($n = 7$). **Conclusion:** The present study concludes that both latanoprost (0.005%) and dorzolamide (2%) topical eye drops effectively reduce IOP in POAG. The latanoprost is more efficacious compared to dorzolamide in reducing IOP.

KEY WORDS: Glaucoma; Intraocular Pressure; Latanoprost; Dorzolamide

INTRODUCTION

Glaucoma is a chronic progressive optic neuropathy caused by a group of ocular conditions which lead to damage of the optic nerve with loss of visual function.[1]

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Glaucoma is the second most common cause for blindness next to cataracts in worldwide and also in India.[2] It is estimated that around 65 million people throughout the world are affected by glaucoma.[2-4] In India, it is estimated that 11.2 million patients are suffering from glaucoma.[5] It is estimated in the United State that 2.25 million peoples are affected with primary open-angle glaucoma (POAG) over the age of 40 years.[6]

POAG is a more prevalent condition among other different types of glaucoma.[5] A proposed definition of POAG (modified from the American Academy of Ophthalmology Preferred Practice Pattern Guidelines, 2005) is a multifactorial

optic neuropathy in which there is characteristic atrophy of the optic nerve.[7] PAOG is a type of glaucoma which affects 6.48 million populations in India.[5] The incidence of POAG increases with increase in age and its prevalence may increase to 16 million by 2020.[5]

Treatment for POAG is mainly to reduce the intraocular pressure (IOP), as it is the most important risk factor for glaucoma and progression of glaucoma.[8] Presently, many drugs are available to reduce the IOP such as cholinergic agonists, adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors, and prostaglandin analogs.[7] Prostaglandin analogs are used as monotherapy and also in combination therapy.[7] Among these drugs, latanoprost has more efficacy and longer action and also decrease the fluctuation in diurnal IOP.[9] In Gupta *et al*. study showed that prostaglandin analogs are first-line drugs for POAG.[3]

Increased IOP is the most important causative factor for glaucoma and its fluctuation influences progression of glaucoma.[8] Latanoprost is prostaglandin analogs drug decrease the IOP by improving the uveoscleral outflow and this is due to relaxation of ciliary muscle and remodeling of the extracellular matrix of ciliary muscle.[7] Latanoprost also prevent diurnal fluctuation in the IOP.[10] Dorzolamide is a carbonic anhydrase inhibitor, it reduces the IOP by reducing the aqueous formation, and this is due to limiting the generation of bicarbonate ion in the ciliary epithelium.[7] Hence, its mechanism of action differs from the latanoprost. Some studies showed that dorzolamide reduces IOP by 22.8% of raised IOP.[11,12] Its efficacy is equivalent to pilocarpine and having less adverse effects.[11] Thomas *et al*. study and Singh and Shrivastava study showed that latanoprost reduces IOP near normal value significantly and stabilizes the diurnal curve in variation of IOP.[8,10] Hence, we selected comparative study to know the efficacy in reducing IOP between latanoprost and dorzolamide by topical route of administration in POAG.

Objectives of the Present Study

The objectives are as follows:
1. To compare the efficacy between topical latanoprost (0.005%) and topical dorzolamide (2%) as monotherapy in patients with POAG
2. To evaluate the adverse effects of latanoprost (0.005%) and dorzolamide (2%) topical eye drops in POAG patients.

MATERIALS AND METHODS

The study was prospective type, open-labeled, randomized study, conducted on patients with POAG. The local Ethics Committee approval was taken. The patients were selected from outpatient Department of Ophthalmology, McGann Teaching Hospital, and Shimoga Institute of Medical Science (SIMS), Shivamogga. The study was done over 19 months from November 2012 to May 2014.

Inclusion Criteria

The following criteria were included in the study:
1. Mean IOP above 21 mmHg
2. Patients with POAG and ocular hypertension involving either or both eyes
3. Patients age 40 years and above of both sexes.

Exclusion Criteria

The following criteria were excluded from the study:
1. Narrow angle or presence of peripheral anterior synechiae
2. Ocular surgery or argon laser trabeculoplasty carried out <6 months before the study
3. Corneal abnormalities or any condition preventing reliable Perkins Tonometer used to measure IOP
4. Active eye disease other than open-angle glaucoma
5. Known hypersensitivity to any component of the study drugs (latanoprost or dorzolamide)
6. Use of any drug (e.g., pilocarpine and neostigmine) known to affect the IOP
7. Pregnant or nursing women
8. History of noncompliance or unreliability or inability to adhere to the protocol
9. Normal-tension glaucoma (IOP <21 mmHg).

Materials

1. Drugs-latanoprost 0.005% eye drops and dorzolamide 2% eye drops
2. Perkins Hand Held Tonometer
3. Snellen's chart
4. Slit lamp
5. Ophthalmoscope-direct and indirect
6. Gonioscopy
7. Pro forma.

Methodology

The study was conducted on 80 patients of POAG. All patients were selected based on inclusion and exclusion criteria. An informed consent was taken from each patient after explaining to them about details of the study, in their local language. The sample size was calculated based on the previous study.[9]

Patient Evaluation

A standard case protocol was maintained which includes a complete detailed history and thorough clinical examination.

Each patient was evaluated as follows.

History

A detailed history was obtained from the patient regarding general and ocular complaints such as diminution of vision,

difficulties in reading or doing near work, ocular allergies, history of ocular surgeries within 6 months of prior, drug allergy, history of hypertension, h/o of diabetes, h/o of chronic obstructive pulmonary disease, asthma and liver dysfunction, h/o of smoking and alcohol consumption, h/o other medication, family h/o of glaucoma, and condition which increases the intracranial pressure such as meningitis, brain tumor, and space-occupying lesions.

Examination

In general examination – physical appearance, pulse rate, blood pressure, and respiratory rate were noted.

In the systemic examination, clinical examination of cardiovascular system, respiratory system, endocrine system, and central nervous system were done.

For ocular examination, the following parts of the eye were examined in detail.

- Eyebrow, eyelashes, conjunctiva, cornea, anterior chamber, iris, pupil, lens, and visual acuity

All the detailed history and examination were recorded in pro forma.

Following Investigations were done for each Patient

1. IOP measurement was taken at baseline and during follow-up period using Perkins Hand Held Tonometer. Three readings were taken at the same time and these reading were converted to mean IOP
2. Gonioscopy to examine the iridocorneal angle to rule out angle-closure glaucoma
3. Fundus examination by direct ophthalmoscope.

Individual Patients were Received following Drugs during the Study Period

The patients were randomly divided into two groups.

- Group 1: Forty patients with POAG received latanoprost (0.005%), topical eye drops for both eyes, and one drop at night time (around 8 pm) for 8 weeks
- Group 2: Forty patients with POAG received dorzolamide (2%), topical eye drops, one drop, 3 times daily at 7 am, 4 pm, and 11 pm for 8 weeks.

Then, all patients were followed at 2 weeks, 4 weeks, and 8 weeks. During each follow-up visit, IOP measurement was done using Perkins Hand Held Tonometer.

Statistical Analysis

Statistical analysis involved quantitative variables summarized through mean and standard deviation. Difference between mean of the two groups was tested using student's unpaired test, where significance of $P < 0.05$. Mann–Whitney U-test is applied to compare the difference in IOP reduction between latanoprost group and dorzolamide group.

RESULTS

The present study was conducted in the Department of Ophthalmology, McGann Teaching Hospital, SIMS, Shivamogga during the period of 19 months from November 2012 to May 2014. POAG patients aged above 40 years were included in the study to compare the efficacy between latanoprost and dorzolamide drug solutions as topical monotherapy. A total of 80 participants were included in the study out of which 72 participants completed the study, remaining eight participants dropped out of the study. Out of eight drops out participants, two participants were lost for follow-up, four participants went for combination therapy, one changed the drug solution because of cost and one participant underwent eye surgery (trabeculoplasty).

A comparison of demographic data for both latanoprost and dorzolamide groups was performed with the Statistical Package for the Social Sciences software. Efficacy analyses were conducted per-protocol population.

For the efficacy variables, the descriptive statistics (mean, standard deviation, and median) were calculated for each treatment group at baseline and third follow-up. Difference between mean IOP reductions between latanoprost and dorzolamide groups was calculated using Mann–Whitney U-test.

Demographic Profile of the Participants

Tables 1 and 2 give the demographic profile of the participants. A total of 80 patients with age above 40 years, with both males and females, were enrolled for study based on inclusion and exclusion criteria. Mean age for latanoprost group was 63.11 ± 10.46 and for dorzolamide group was

Table 1: Age distribution in study groups

Age in years	Dorzolamide group no of patients=40	Latanoprost group no of patients=40
41–50	4	7
51–60	9	10
61–70	17	13
71–80	10	10

Table 2: Gender distributions in latanoprost and dorzolamide group

Gender	Latanoprost group *n*=40	Dorzolamide group *n*=40	Total *n*=80
Male	19	23	42
Female	21	17	38

65.61 ± 9.44. In both groups, maximum patients belong to the age group between 61 and 70 years.

Gender distribution in the latanoprost group consisted of 19 males and 21 females, whereas in dorzolamide group 23 were males and 17 were females [Table 2]. In the study population, total numbers of males were 42 and 38 were females.

Table 3 shows the associated risk factors with POAG. In the present study, 14 patients had diabetes mellitus, 25 were hypertensive patients, and 12 patients had smoking history.

Calculation of Efficacy of Individual Drugs in Present Study

The baseline means IOP for latanoprost group was 29.78 ± 5.1 and for dorzolamide group was 30 ± 4.06. Thus, baseline mean IOP for both drug groups was comparable. During the third follow-up, the mean IOP for latanoprost group was 20.28 ± 2.45 and for dorzolamide was 22.11 ± 2.83. The differences between baselines mean IOP and third follow-up mean IOP were indicator for efficacy of the drugs. The difference between baseline mean IOP and third follow-up mean IOP for latanoprost group was 9.5 ± 3.56 and dorzolamide group was 7.89 ± 2.29 [Table 4]. The mean IOP reductions in both the drug groups were statistically significant ($P < 0.05$).

Table 3: Number of diabetic patients, hypertensive patients, and smoking risk factors in both drug groups

Risk factor	Number of patients with risk factor
	n=51 (%)
Diabetes mellitus	14/80 (17.5)
Hypertension	25/80 (31.25)
Smoking history	12/80 (15)

Table 4: Baseline mean IOP and third follow-up mean IOP value for latanoprost group and dorzolamide group

Characteristics	Dorzolamide group	Latanoprost group
	Mean±standard deviation	Mean±standard deviation
Baseline IOP	30±4.06	29.78±5.1
Third follow-up IOP	22.11±2.83	20.28±2.45
Difference in IOP	7.89±2.29	9.5±3.56

IOP: Intraocular pressure

The difference in IOP reduction for both drug groups was not following normal distribution (Shapiro–Wilk, $P < 0.05$) and hence the non-parametric Mann–Whitney U-test is used for statistical analysis. The median value for IOP reduction in latanoprost group is 10 and dorzolamide group is 8. Using Mann–Whitney U-test, the difference in IOP reduction among the two groups was calculated and the difference was statistically significant ($P = 0.02$) [Table 5]. Thus, IOP reduction in latanoprost group was better when compared to dorzolamide group.

Adverse Effects of Latanoprost and Dorzolamide Solution

In latanoprost group, nine participants had adverse effects, out of which seven suffered from foreign body sensation and two had conjunctival hyperemia. In dorzolamide group, seven participants suffered from adverse effects, out of which two had foreign body sensation, two had conjunctival hyperemia, and remaining participants suffered from stinging, headache, and dryness of eye [Table 6].

DISCUSSION

The present study was conducted in the out-patient Department of Ophthalmology, McGann Teaching Hospital, Shivamogga Institute of Medical Sciences, Shivamogga, for which 80 POAG participants were included in the study. Glaucoma is the second most common cause for blindness worldwide. Raised IOP, advancing age, family history of glaucoma, decreased corneal thickness, and racial factors are risk factors which can cause development and progression of glaucoma.[2,7,13] The most important risk factor is raised IOP, as it is directly related to glaucoma development and regulation of IOP to normal value halt the progression of glaucoma.[7,8,14] Presently, glaucoma can be treated by medical and surgical therapy.[8] Medical therapy is most preferred treatment for glaucoma.[15] In present study, most patients belong to age group between 61 and 70 years in both the drug groups. Advancing age increases the risk of glaucoma.[16] In present study, male patients in present study were 52% and female patients were 48%. Overall, gender appears to have no major effect on IOP in the 20–40 year age group.[7] In older age groups, the apparent rise in mean IOP is greater among women than men, and coincides with the onset of menopause.[7] Baseline IOP that is IOP recorded during first visit before start on study drugs, i.e., latanoprost and dorzolamide as topical eye drops. The baseline means IOP for latanoprost

Table 5: Difference in IOP reduction between latanoprost and dorzolamide group according to Mann–Whitney U-test

Variable	Group	Median	Interquartile range	*P*-value	Significance
Difference in IOP reduction	Dorzolamide	8	2	0.027	Significant ($P<0.05$)
	Latanoprost	10	4		

IOP: Intraocular pressure

group was 29.78 ± 5.1 and for dorzolamide group was 30 ± 4.06, respectively. Hence, there is no major difference in baseline mean IOP between two groups ($P > 0.05$). Then, the patients were administered latanoprost and dorzolamide as a monotherapy topical eye drops. Then, follow-up IOP was recorded at 2 weeks, 4 weeks, and 8 weeks visit. Third follow-up IOP at 8 weeks from commencement of the study was taken for comparison between two drug groups. The third follow-up mean IOP for latanoprost group was 20.28 ± 2.45 and for dorzolamide group was 22.11 ± 2.83. IOP reduction was calculated as the difference between baseline mean IOP and third follow-up mean IOP. IOP reduction for latanoprost group was 9.5 ± 3.56 and in dorzolamide group was 7.89 ± 2.29. This finding indicates that topical latanoprost eye drop was more effective in reducing IOP than topical dorzolamide eye drop. IOP reduction in both the groups was statistically significant ($P < 0.05$). In present study, both latanoprost and dorzolamide drugs were well tolerated during the study period. The most common side effects by both the drug groups were foreign body sensation and conjunctival hyperemia, the latanoprost group had highest number of patients with foreign body sensation ($n = 7$). Other less common side effects which were seen were headache, stinging, and dryness of eye in dorzolamide group. More side effects were seen in latanoprost group compared to dorzolamide group, but statistically not significant ($P > 0.05$).

In a population-based Japanese study, IOP did not differ between women and men.[7] In the Barbados eye study, which had a mixed population of participants, IOP was higher among women than men.[7] Many studies have shown a higher prevalence of POAG in males.[17,18] However, Alieja *et al*. and Possner and Schlossman studies have found equal prevalence of POAG in both males and females.[19,20] In present study, 14 POAG patients were associated with diabetes mellitus, 25 POAG patients were associated with hypertension, and 12 patients had smoking history. Tobacco smoking causes a transient rise in the IOP immediately after smoking, possibly through a mechanism of vasoconstriction and elevated episcleral venous pressure.[7] However, the direct risk of tobacco on POAG is not evident from epidemiologic and case–control studies.[7] Shephard *et al*. study showed smoking is not risk factor for glaucoma.[21] Baltimore eye survey showed no relationship between POAG and diabetes mellitus.[22] Mitchell *et al*. study showed association between POAG and diabetes mellitus.[23] The present study mean IOP reduction of latanoprost group value is comparable with other studies within range of 0.4–0.6 mmHg such as Khizar and Raja study,[24] Indian latanoprost study group,[25] Ravi *et al*. study.[26] Mean IOP reduction of latanoprost group in the present study value is more compared to O'Donoghue study[27] and Imtiyaz *et al*. study[9] [Table 7]. The present study means IOP reduction of dorzolamide group (7.89 ± 2.29) is more when compared to O'Donoghue study[27] (5.6 ± 2.6), Khizar and Raja study[24] (6.6 ± 2.1), and Imtiyaz *et al*. study[9] (4.7 ± 2.4). The difference in IOP reduction between latanoprost and dorzolamide group was statistically significant ($P < 0.05$). The same result is seen in Imtiyaz *et al*.,[9] Khizar and Raja study,[24] and O'Donoghue study.[27] Latanoprost is a prodrug, during absorption it undergoes hydrolysis and gives "active acid Latanoprost," which act on prostanoid FP receptor cause release of matrix metalloproteinase, and this will cause degradation or remodeling of the collagen in between the muscle bundles in the ciliary muscle and intern this will increase uveoscleral outflow.[6,9] In many types of glaucoma raised that IOP is due to impaired outflow but not due to excessive formation of aqueous humor.[9] Hence, latanoprost is more effective in controlling IOP compared to dorzolamide. Effect of latanoprost, i.e., IOP reduction starts about 3–4 h after administration of topical drug and maximum effect is reached after 8–12 h. The pressure reduction is maintained for the entire 24 h.[27] Dorzolamide acts by decreasing aqueous humor formation. Aqueous humor is important media to supply nutrition to avascular

Table 6: Adverse effects of latanoprost solution and dorzolamide solution

Adverse effects	Latanoprost group	Dorzolamide group
Foreign body sensation	7	2
Conjunctival hyperemia	2	2
Stinging sensation	0	1
Headache	0	1
Dryness of eye	0	1

Table 7: Baseline mean IOP, mean IOP reduction in different studies

Parameters	Present study		O'Donoghue *et al*. study[27]		Khizar and Raja study[24]		Imtiyaz and Lonestudy[9]		Indian latanoprost study group[25]	Ravi *et al*. study[26]
No of cases	80		224		60		44		126	150
Duration of study	8 weeks		3 months		3 months		3 months		3 months	3 months
Drugs used	Lat, od	Dor, tid	Lat, od	Dor, bd	Lat, od	Dor, bd	Lat, od	Dor, bd	Lat, od	Lat, od
Baseline mean IOP mmHg	29.78±5.1	30±4.06	27.7±3.2	27.8±4.0	27.9±2.6	27.9±3.1	29.3	28.7	27.1±6.0	24.9±3.16
Mean IOP reduction mmHg	9.5±3.56	7.89±2.29	8.5±3.3	5.6±2.6	8.9±2.4	6.6±2.1	6.8±3.1	4.7±2.4	9.1±3.9	8.9±7.1

Lat-latanoprost (0.005%), Dor-Dorzolamide (2%), od-once a day, tid-3 times a day, bid-twice a day. IOP: Intraocular pressure

structures such as cornea and lens. Hence, suppression of aqueous humor formation may lead deleterious effects.[9] Dorzolamide effect starts immediately after administration and maximum effect is reaches after 2 h.[27] In addition to reduction in IOP, dorzolamide also has got an advantage of increase in blood flow to retinal nerve fibers, protecting neuronal damage from raised IOP.[28] In concern with reduction in IOP, timolol is superior to dorzolamide.[27] Dorzolamide is less efficacious in IOP reduction compared to timolol due to weaker aqueous humor suppressive effect.[27] Considering these above two facts fixed drug combination of timolol and dorzolamide showed greater IOP reduction compared to latanoprost monotherapy.[29] Hence, this combination is more efficacious compared to timolol monotherapy.[29,30] In Imtiyaz *et al*. study conjunctival hyperemia, conjunctivitis, superficial punctate keratitis, and uncontrolled IOP were side effects seen in latanoprost group, and in dorzolamide group conjunctival hyperemia, conjunctivitis, superficial punctate keratitis, and uncontrolled IOP were the side effects seen.[9] In O'Donoghue study more side effects were seen in dorzolamide group compared to latanoprost group; conjunctival hyperemia was most common side effects seen in both the groups.[27] Conventionally, timolol is considered standard drug for IOP reduction, but meta-analysis study showed that latanoprost is superior to timolol for reducing IOP.[31] Because latanoprost is more efficacious for IOP reduction compared to timolol, IOP reduction for latanoprost is 6.7 ± 3.4 mmHg and for timolol is 4.9 ± 2.9 mmHg.[31] Large diurnal variations are an independent risk factor for glaucomatous damage. Therefore, stabilized IOP for 24 h can prevent progression of glaucoma. Latanoprost drug significantly reduces diurnal variation. Single-dose of 0.005% latanoprost controls 24 h IOP, as it has long duration of action. Zhang *et al*. study showed that latanoprost once-daily administration produces consistent reduction in IOP and stabilizes the IOP diurnal curve as well.[31] In contrast, timolol has no additional benefit of stabilization of IOP compared to latanoprost.[24,26] Thus, latanoprost can be considered as first-line therapy for POAG.[7,9,24]

The study was conducted prospective type, which helped to assess the efficacy of the drug and able to record adverse drug reactions. The limitation of study was less sample size, single center, and short duration.

CONCLUSION

This study was conducted to compare the efficacy between 0.005% latanoprost and 2% dorzolamide as a topical application in POAG. Both latanoprost and dorzolamide significantly reduce the IOP and both drugs can be used in glaucoma. Latanoprost (0.005%) is more efficacious compared to dorzolamide (2%) as a monotherapy. Both latanoprost and dorzolamide are well tolerated and no serious adverse effects seen during the study period. Advancing age is a risk factor for the development of glaucoma.

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