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STUDY THE COMPARISON OF NETARSUDIL (0.02%) AND BIMATOPROST (0.01%) IN PATIENTS OF PRIMARY OPEN ANGLE GLAUCOMA PATIENTS

Opthalmology

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ABSTRACT

Background & Objectives: This study compares Netarsudil 0.02% and Bimatoprost 0.01% in reducing intraocular pressure, a major cause of vision loss, to evaluate their efficacy and safety. **Methods:** A prospective double blind randomized control study, analyzed the effect of baseline intraocular pressure (IOP) on the efficacy of two drugs, Netarsudil and Bimatoprost, on patients with primary open angle glaucoma and ocular hypertension. The study included 50 patients, with 46 in group 1 and 23 in group 2. Data analysis included gonioscopy and central corneal thickness assessment at baseline visits. **Results:** The study included 50 patients, with 46 in group 1 and 23 in group 2. Data analysis included gonioscopy and central corneal thickness assessment at baseline visits. Both medications significantly reduced IOP, with Bimatoprost achieving a faster reduction than Netarsudil. Adverse effects were mild, with conjunctival hyperemia being most common in both groups. **Conclusion:** The study compared Netarsudil and Bimatoprost in lowering intraocular pressure (IOP) in patients with glaucoma and ocular hypertension, finding Bimatoprost more effective but causing conjunctival hyperemia and haemorrhage.

KEYWORDS

netarsudil, bimatoprost, primary open angle glaucoma patients

INTRODUCTION

Glaucoma is a chronic optic neuropathy causing changes in the optic nerve head and retinal nerve fibers. It affects approximately 64.3 million people worldwide, with an estimated 11.9 million cases in India. There are two main subtypes: angle-closure glaucoma and open-angle glaucoma. Primary open angle glaucoma (POAG) results in excavation of the optic nerve head and visual field defects, while ocular hypertension (OHT) elevates IOP without visible damage. Early pathologic changes in the visual field can damage up to 50% of optic nerve fibers.[1-3]

Increased IOP is a significant risk factor for glaucomatous optic neuropathy, with 4%-20% of OHT patients developing visual field anomalies within five years. Treatment with IOP-lowering medications is questionable, and the European Glaucoma Society advises against treating OHT when IOP is below 20 mmHg and no other risk factors.[4,5] The distinction between POAG and NTG is arbitrary, as they represent different subsets of patients. Clinical course varies in visual field loss and optic disc injury patterns. There are no established guidelines for POAG treatment based on maintaining the optic nerve head or demonstrating visual fields. Topical anti glaucomatous medications can postpone glaucoma onset, but their use is not limited or described.[6,7]

Open-angle glaucoma is a condition where the eye's aqueous humour is controlled, with the primary way of escape being conventional outflow or uveoscleral outflow. Topical medications are the first line of defense against IOP, but if ineffective, patients may need laser-based therapy or surgical procedures. The beta blocker class of medications is the first line of treatment, with the goal of lowering the patient's IOP by 25%-30%. Patients may require multiple eyedrops from various classes to achieve the required IOP.[8]

In 2017, the FDA approved Netarsudil, the first Rho kinase (ROCK) inhibitor, which can lower episcleral venous pressure and impede norepinephrine transport. In a double-blind, randomized, multicenter ROCKET-1 experiment, patients with an IOP between 20 and 27 mmHg showed a reduction in IOP. In ROCKET-2, patients with an IOP of 25 mmHg showed mean reductions of 3.3-4.6mmHg and 4.1-5.4 mmHg in daily and twice-day Netarsudil, respectively.[9,10]

Bimatoprost, a synthetic prostamide, reduces intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Long-term treatment with a once-daily solution was superior to timolol twice-daily in providing sustained IOP reduction. It demonstrated efficacy comparable to or greater than prostaglandin analogues latanoprost and travoprost in decreasing IOP and achieving goal levels. Common side effects include minor hyperaemia, eyelash growth, and ocular itching.[11]

The study compares the efficacy and adverse effects of Netarsudil 0.02% and Bimatoprost 0.01% in lowering intraocular pressure in patients with POAG and OHT, focusing on mean reduction, global symptoms, and baseline pressure in both groups.

METHODS

The study was a prospective double blind randomized control study, was conducted Maharshi Vishwamitra Autonomous State Medical College, Ghazipur, Uttar Pradesh, India, over a period of one year. The study included newly diagnosed patients with primary open angle glaucoma and ocular hypertension, aged 40 or older, with IOP between 22-30mmHg, and screened for inclusion and exclusion criteria. Eligible patients were randomly assigned to each group in a 1:1 ratio. Patients with a history of ocular trauma, infection, inflammation, or contraindications for any of the two drugs are excluded from the study. Other exclusion criteria include those unwilling to give written consent, those with systemic conditions that can increase or decrease IOP, those on systemic steroids, those with co-morbidities or psychological unsoundness, variants of POAG, and those with hazy ocular media.

The study to analyze the effect of baseline intraocular pressure (IOP) on the efficacy of two drugs, Netarsudil and Bimatoprost, on patients with varying baseline IOPs. Total 50 patients were included in this study four was lost to follow up and hence data analysis was done only on 46 patients. Out of 46, total 23 (50.0%) patients were included in group 1 and 23 (50.0%) patients were included in group 2. Patients were divided into two groups based on their baseline IOPs, and all were randomly allocated to either group. The study also conducted gonioscopy and central corneal thickness assessment at baseline visits. Symptoms were observed and documented at each follow-up visit, and signs were recorded at baseline and each follow-up visit. The results showed that Netarsudil and Bimatoprost had varying levels of efficacy based on the baseline IOP. The findings could help determine the correlation between the two drugs' efficacy and baseline IOP.

The study used the SPSS program for Windows version 23rd version for statistical analysis, presenting values as mean, median, ±SD, minimum, maximum, number, and percentage. Continuous variables were presented as mean ± SD, while categorical variables were presented as absolute numbers and percentage. ANOVA was used for analysis of multiple groups.

RESULTS:

Total 50 patients were included in this study four was lost to follow up and hence data analysis was done only on 46 patients. Out of 46, total 23 (50.0%) patients were included in group 1 and 23 (50.0%) patients were included in group 2. The percentage of male and female gender was 43.5%, 56.5% in group 1 and 47.8%, and 52.2% in group 2,

respectively. The percentage of male and female gender was not significantly different in between groups. The mean age was 56.30±6.98 in group 1 and 56.29±7.8 in group 2. The mean age was not significantly different in between groups. (Table 1)

Table 1: The Distribution Of Patients According To Gender In Group 1 And Group 2.

Gender	Group 1 Base line IOP 22-25 mmHg (n=23)		Group 2 Base line IOP 26-30 mmHg (n=23)		Chi Sq.	p-Value
	n	%	n	%		
Male	10	43.5%	11	47.8%	0.01	0.914
Female	13	56.5	12	52.2%		
Mean ±SD	56.30±6.98		56.29±7.8		t=1.00	0.422

The study compared mean intraocular pressure (IOP) between group 1 and group 2 at baseline and 3 months. The mean IOP varied between groups, with higher values in group 2 compared to group 1 in both eyes. The mean IOP was significantly higher in group 2 compared to group 1 at baseline and 3 months. (Table 2)

Table 2: Comparisons Of Mean IOP In Between Group 1 And Group 2 At Baseline To 3 Months Follow Up [Day Diurnal Variation Test (day DVT)].

Mean IOP (mmHg)		Group 1 (n=23) Mean ± SD	Group 2 (n=23) Mean ± SD	t	p-Value
Baseline	RE	23.65 ± 1.43	27.09 ± 2.26	-5.41	<0.001*
	LE	23.30 ± 1.66	28.18 ± 1.66	-8.00	<0.001*
at 2 weeks	RE	16.84 ± 1.95	19.88 ± 3.02	-3.54	0.001*
	LE	16.96 ± 2.2	20.48 ± 3.29	-3.71	0.001*
6 weeks	RE	14.32 ± 2.54	16.91 ± 3.39	-2.49	0.018*
	LE	14.41 ± 2.48	16.91 ± 3.2	-2.51	0.017*
3 months	RE	12.23 ± 2.26	14.55 ± 3.7	-2.26	0.031*
	LE	12.23 ± 2.23	14.36 ± 3.32	-2.22	0.034*

The study compared the signs of Conjunctival Hyperemia, conjunctival haemorrhage, cornea verticillata, and erythema of eyelid between Bimatoprost and Netarsudil drugs. Both drugs showed similar signs, with Netarsudil showing more cornea verticillata and conjunctival hyperemia. Symptoms of Pruritus and burning and stinging pain were higher in Netarsudil, with 11.76% and 17.65% of Bimatoprost and 17.65% and 29.41% of Netarsudil, respectively. However, the incidence of Pruritus and burning and stinging pain was higher in Netarsudil. (Table 3)

Table 3: Comparison Of Signs & Symptoms In Between Bimatoprost And Netarsudil Drug

Eye disorders	Bimatoprost (n=17)		Netarsudil (n=17)		Chi	p-Value
Sign	n	%	n	%		
Conjunctival Hyperemia	6	35.29	8	47.06	0.12	0.728
Conjunctival haemorrhage	1	5.88	2	11.76	0.65	0.545
Cornea verticillata	1	5.88	2	11.76	0.65	0.545
Erythema of eyelid	1	5.88	1	5.88	0.00	1.00
Symptoms						
Pruritus	2	11.76	3	17.65	0.23	0.628
burning and stinging pain	3	17.65	5	29.41	0.16	0.686

The study compared drug use in two groups: group 1 and group 2, with patients using Bimatoprost and Netarsudil at 52.17% and 47.83% respectively, and 43.5% and 56.5% respectively, with no significant differences between groups. (Table 4)

Table 4: Comparisons Of Drug Use In Group 1 And Group 2.

	Group 1 (n=23)	Group 2 (n=23)	OR (95% CI)	p-value
Bimatoprost	12 (52.17%)	10 (43.5%)	1.31 (0.31-5.14)	0.714
Netarsudil	11 (47.83%)	13 (56.5%)		

The study compared the change in intraocular pressure (IOP) from baseline to 3 months in Bimatoprost and Netarsudil drug uses in two groups. Both drugs significantly reduced IOP in both eyes. However, Bimatoprost showed a more significant decrease in IOP than Netarsudil in both groups. (Table 5)

Table 5: Comparison Of Change In IOP From Baseline To 3 Months In Bimatoprost And Netarsudil Drug Uses In Group 1 And Group 2 Patients.

	IOP in group 1									IOP in Group 2								
Group 1	Base line		2 weeks		6 weeks		3 months		p-Value	Baseline		2 weeks		6 weeks		3 months		p-value
	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD		Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	
Bimatoprost																		
RE	23.83	1.37	15.50	1.76	12.33	1.44	10.10	1.08	<0.001*	26.53	2.76	18.33	2.75	14.33	1.51	11.20	1.10	<0.001*
LE	23.56	1.67	15.50	1.93	12.50	1.45	10.20	1.24	<0.001	28.27	1.61	19.17	2.63	14.44	1.50	11.20	1.10	<0.001*
Netarsudil																		
RE	23.17	1.08	18.30	0.69	16.48	1.43	14.40	1.40	<0.001*	27.56	1.56	21.56	2.33	19.33	2.42	17.33	2.42	<0.001*
LE	22.18	2.15	18.55	1.11	16.48	1.43	14.50	1.33	<0.001	27.44	1.29	22.11	2.99	19.22	2.17	17.00	1.67	<0.001*

The study analyzed gonioscopy details in two groups, with the percentages of Open till CBB and Open till SS being 65.22% and 34.78% in group 1, and 73.9% and 26.08% in group 2. (Table 6)

Table 6: Gonioscopy In Group 1 And Group 2

Gonioscopy	Group 1 (n=23)		Group 2 (n=23)		OR (95% CI)	p-Value
	n	%	n	%		
Open till CBB	15	65.22	17	73.9	0.70 (0.14-3.42)	0.963
Open till SS	8	34.78	3	26.08		

DISCUSSION

Intraocular pressure (IOP) is a major risk factor for glaucoma in POAG and PAG patients. Lowering IOP can slow or prevent glaucoma progression. Treatments include uveoscleral drainage and aqueous humour production. However, no IOP-lowering treatment is effective for all patients. New therapies, like Rho kinase inhibitors, are needed to address degenerative alterations in outflow pathways. Netarsudil, approved in 2017, treats elevated IOP in POAG and OHT patients.[11]

In our study the mean age was not significantly associated with increased risk of Intraocular pressure in Primary open angle glaucoma and Ocular hypertension patients. Similarly, The relationship between intraocular pressure (IOP) and glaucoma varies with age, with hypertension having a protective effect in younger patients and potentially increasing IOP. However, older patients are at a higher risk of developing glaucoma due to blood vessel changes caused by arterial hypertension. Age and greater IOP levels are positively correlated, but a strong inverse relationship exists in POAG patients. This may be due to decreased aqueous humor production, which is related to aging. Aging-related structural changes in the trabecular meshwork can also make it harder for aqueous humor to exit the body and raise IOP. Factors such as age, race, gender, higher IOP, larger vertical cup-disc ratio, pattern standard deviation, heart disease, and thinner central corneal measurement are significant predictors of POAG development.[12-17]

In this study the intraocular pressure did not changes by male and female in Primary open angle glaucoma and Ocular hypertension patients. Dielemans et al. found no gender-specific variation in intraocular pressure, while Chuang et al found a significant correlation between male gender and increased intraocular pressure in POAG patients.[12,13]

In this study the retinal nerve fiber layer (RNFL) was more in base line IOP 26-30mmhg group as compared to base line IOP 22-25mmhg but not significantly different in primary open angle glaucoma and Ocular hypertension. Tu et al. reported that the faster rates of progressive RNFL loss were related to higher IOP. IOP level and baseline/residual RNFL thickness were both critical variables for RNFL damage rate and future damage, respectively.[18]

Moreover, in group–1(IOP 22-25mmHg), 52.17% patients used Bimatoprost and 47.83% used Netarsudil. In group–2 (IOP 26-30mmHg) 43.5% patients used Bimatoprost and 56.5%used Netarsudil.

In our study total 50% patients used Bimatoprost and 50% patients

used Netarsudil drug. Moreover, the percentage of number of patients used Bimatoprost and Netarsudil drug were 52.17% and 47.83% in base line IOP 22-25mmhg group and 43.5% and 56.5% in base line IOP 26-30mmhg group, respectively.

In this study, both Bimatoprost 0.01% and Netarsudil 0.02% demonstrated significant intraocular pressure (IOP) reduction from baseline to 3 months ($p < 0.001$). However, the magnitude of reduction was greater in the Bimatoprost group compared to the Netarsudil group. In Group 1 (Bimatoprost), mean IOP in the right eye decreased from 23.83 ± 1.37 mmHg at baseline to 10.10 ± 1.08 mmHg at 3 months, and in the left eye from 23.56 ± 1.67 mmHg to 10.20 ± 1.24 mmHg. In Group 2 (Bimatoprost), baseline IOP of 26.53 ± 2.76 mmHg reduced to 11.20 ± 1.10 mmHg (RE) and from 28.27 ± 1.61 mmHg to 11.20 ± 1.10 mmHg (LE).

In contrast, Netarsudil showed a slower and lesser IOP decline. Group 1 eyes reduced from 23.17 ± 1.08 mmHg to 14.40 ± 1.40 mmHg (RE) and 22.18 ± 2.15 mmHg to 14.50 ± 1.33 mmHg (LE). Group 2 eyes reduced from 27.56 ± 1.56 mmHg to 17.33 ± 2.42 mmHg (RE) and 27.44 ± 1.29 mmHg to 17.00 ± 1.67 mmHg (LE). These findings indicate that while both drugs significantly lower IOP, Bimatoprost achieves a greater and faster reduction compared to Netarsudil.

In this study the bimatoprost and netarsudil drugs were significantly reduced the IOP from baseline to 3 months follow-up in both the groups. Numerous prior observational studies have shown that Bimatoprost 0.01% is well tolerated and effective at lowering IOP.[19] Patients with POAG or OHT who had never received treatment benefited from an IOP reduction of 30% over the course of 12 weeks in a clinical practise setting, with 93% of patients suffering mild, trace, or no hyperaemia.[10] In patients who switched from prior medication, Bimatoprost 0.01% was well tolerated and related with an additional 10%–15% reduction in IOP. In a comprehensive observational trial with more than 10,000 patients, Bimatoprost 0.01% significantly reduced mean IOP from a baseline of 20.1–4.5 mmHg in all study participants and from 20.1–6.5 mmHg in patients who had not previously received treatment.[20] Patients who had previously only received beta blockers (4.6 mmHg), latanoprost (2.8 mmHg), travoprost (3.1 mmHg), tafluprost (2.8 mmHg), bimatoprost 0.03% (1.0 mmHg), brinzolamide (4.4 mmHg), and dorzolamide experienced additional IOP reduction (4.2 mmHg). In comparison to bimatoprost 0.03%, Bimatoprost 0.01% has shown equal IOP-lowering efficacy and enhanced tolerability, including less frequent and severe conjunctival hyperaemia.[21] Bimatoprost 0.01% is equal to bimatoprost 0.03% in terms of effectiveness for decreasing IOP throughout a 12-month treatment period, according to research by Katz et al. [22] Bimatoprost 0.01% demonstrated better patient adherence than bimatoprost 0.03% in prior observational research.[20] Adherence in the current study was better than or equal to that of the previous therapy in more than 97% of patients who switched from a previous therapy to bimatoprost 0.01%.

A study by Park et al.[23] found that patients with an IOP of 21 mmHg experienced a 15.9% decrease in IOP after 12 weeks of treatment with Bimatoprost 0.03%. A Japanese study showed a 19.9% reduction in IOP after 12 weeks of treatment, and similar decreases were observed in patients with an IOP of 13 mmHg.[24] These findings are the first to demonstrate the effects of Bimatoprost administration in this group.

Sit et al.[25] found that once-daily doses of Netarsudil ophthalmic solution reduced intraocular pressure (IOP) in individuals with POAG or OHT by 35% and 25% compared to vehicle-treated controls. The mean IOP change was around 20%, with a larger increase in monkeys. Animal studies also showed an increase in outflow facility, but with higher concentrations and two drops per eye. Even modest decreases in IOP can have clinical significance.

Netarsudil, a potent IOP-lowering agent, demonstrated significant reductions in mean IOP in patients who received it alone or in combination with other drugs. It was found to be effective in reducing IOP regardless of the number of antiglaucoma medications used, overcoming the principle of diminishing returns. Netarsudil's mechanism of action involves enhancing trabecular outflow, which is significantly influenced by episcleral venous pressure. Regardless of the drug used, Netarsudil can deliver consistent IOP-lowering efficacy.[11,24]

The study found that a significant portion of patients taking Netarsudil as solo or concurrent therapy had IOP below thresholds of 14-18 mmHg. The benefits of adding Netarsudil to treatment regimens for glaucoma patients with insufficient IOP control have been investigated in retrospective evaluations. Both bimatoprost and netarsudil showed significant decrease in IOP, with bimatoprost being more effective in decreasing IOP in all patients, especially in the higher base line group.[26]

In this study comparing the intraocular pressure (IOP) lowering efficacy and adverse effects of Netarsudil 0.02% and Bimatoprost 0.01%, gonioscopic evaluation revealed a predominance of open angles in both groups. In Group 1 (Netarsudil), 65.22% of eyes were open till the ciliary body band (CBB) and 34.78% till the scleral spur (SS), while in Group 2 (Bimatoprost), 73.9% were open till CBB and 26.08% till SS. These findings suggest a comparable distribution of angle configuration between groups, minimizing the influence of angle anatomy on IOP outcomes. The slightly higher proportion of wider angles (open till CBB) in the Bimatoprost group might contribute marginally to its IOP-lowering response. However, the overall similarity supports that differences in efficacy are more likely drug-related rather than anatomical. Gonioscopy findings thus strengthen the validity of the comparative analysis between Netarsudil and Bimatoprost regarding their pressure-lowering efficacy and tolerability profiles.

The study compares the efficacy and safety of Netarsudil 0.02% and Bimatoprost 0.01% in patients with primary open-angle glaucoma and ocular hypertension. It has strengths like a well-defined patient population, regular follow-up, and consistent measurement techniques. Limitations include a small sample size, short follow-up, lack of diurnal IOP variation assessment, subjective reporting of side effects, and lack of long-term safety data. Future research should include larger, multicentric populations, and evaluate combination therapy potential and quality-of-life outcomes.

CONCLUSION:

The study compared the efficacy and adverse effects of Netarsudil 0.02% and Bimatoprost 0.01% in lowering IOP in patients with primary open angle glaucoma and ocular hypertension. Results showed that both drugs significantly reduced IOP from baseline to 3 months, with Bimatoprost being more effective. However, both drugs caused conjunctival hyperemia, haemorrhage, cornea verticillata, and erythema, with Bimatoprost causing pruritus and burning and stinging pain.

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