

# Retrospective Analysis of Switching Bimatoprost 0.01% to Bimatoprost 0.03% in Patients with Various Types of Glaucoma and Ocular Hypertension

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**Purpose:** Studies comparing the two different formulations of bimatoprost, 0.03% and 0.01%, have shown similar efficacy, but a better adverse effect profile for bimatoprost 0.01% in patients with primary open-angle glaucoma (POAG) and ocular hypertension (OHT). This study assesses the efficacy and tolerability of switching from bimatoprost 0.01% to 0.03% in a patient population with broader spectrum of diagnoses in a real-world clinical setting.

**Design:** Single-centre retrospective observational switch study.

**Methods:** Selected patients were on initial topical therapy with bimatoprost 0.01% prior to switching to bimatoprost 0.03%. Intraocular pressure (IOP) was collected from their pre-switch visit, 6- and 12-week after switch. Paired two-sample *t*-test was performed to compare IOP at different time points versus baseline. Worsening of hyperemia and other adverse events after the switch were identified. Subgroup analysis was performed for POAG and OHT, secondary open-angle glaucoma (SOAG, including pseudoexfoliative and pigmentary glaucoma), normal tension glaucoma (NTG), and angle closure glaucoma (ACG).

**Results:** The study population consisted of 248 eyes (143 patients). There was a significant mean IOP reduction of  $1.0 \pm 3.7$  mmHg ( $p < 0.001$ ,  $n = 248$ ) from baseline to week-6 and  $1.6 \pm 4.0$  mmHg ( $p < 0.001$ ,  $n = 142$ ) from baseline to week-12 after switch. The IOP reduction was statistically significant in patients with POAG and OHT (6-week:  $1.0 \pm 3.8$  mmHg,  $n = 76$ ; 12-week:  $1.5 \pm 4.1$  mmHg,  $n = 49$ ), ACG (6-week:  $1.5 \pm 4.1$  mmHg,  $n = 72$ ; 12-week:  $2.3 \pm 4.5$  mmHg,  $n = 46$ ), and NTG (6-week:  $0.83 \pm 2.5$  mmHg,  $n = 42$ ; 12-week:  $1.12 \pm 2.1$  mmHg,  $n = 25$ ). Patients with SOAG did not show statistically significant reduction in IOP at 6- or 12-week after switch. Forty-two (29%) of 143 patients experienced adverse events, with the most common being hyperemia (16%).

**Conclusion:** Significant reduction in IOP could be seen after switching from bimatoprost 0.01% to bimatoprost 0.03% in various types of glaucoma except SOAG. Intolerance after switch may be experienced, though not in the majority of cases.

**Keywords:** bimatoprost, intraocular pressure, conjunctival hyperemia, glaucoma, ocular hypertension

## Introduction

Glaucoma is a multifactorial, vision-threatening progressive optic neuropathy with characteristic visual field defects and optic disc changes. Intraocular pressure (IOP) has been shown to play a central role in disease progression and has become the main target for medical and surgical management.<sup>1</sup>

Prostaglandin analogues (PGA) and prostamides have become the first-line option for medical treatment of glaucoma and ocular hypertension (OHT) due to their well-established efficacy and tolerability with relatively less systemic side effects compared to other anti-glaucoma medications.<sup>1,2</sup> Bimatoprost, introduced in 2001, is a prostamide that promotes uveoscleral outflow of aqueous humour to lower IOP.<sup>3</sup> Compared to other prostaglandin analogues such as travoprost 0.004% (Travatan Z, Alcon Inc, Fort Worth, TX) and latanoprost 0.005% (Xalatan, Pfizer Inc, New York, NY),

bimatoprost 0.03% (previously Lumigan, Allergan Inc, an AbbVie company, Irvine, CA; currently Vistitan, Aequus Pharmaceuticals Inc, British Columbia, ON) has extensively been shown to have better IOP-reducing effects, but at the expense of increased incidence of adverse events (AE).<sup>4,5</sup>

To improve on the adverse event profile of bimatoprost 0.03% including ocular hyperemia, another formulation containing 0.01% bimatoprost (Lumigan RC, Allergan Inc, an AbbVie company, Irvine CA) was developed with a higher concentration (0.02% rather than 0.005%) of benzalkonium chloride (BAK). BAK is a detergent preservative that disrupts the corneal epithelium by binding to membrane proteins for better drug penetrance.<sup>6–8</sup> In a randomized, double-masked, multi-centre clinical trial, Katz et al showed that a newly formulated bimatoprost 0.01% maintained IOP reduction effects while minimizing AE such as conjunctival hyperemia, skin hyperpigmentation and eye pruritus.<sup>9</sup> Further studies demonstrated improved tolerability of bimatoprost 0.01% and better adherence to treatment compared to bimatoprost 0.03%.<sup>10–12</sup>

Crichton et al conducted an observational study of bimatoprost 0.01% in the Canadian Lumigan RC Early Analysis Review (CLEAR) trial to discern the IOP-lowering efficacy and safety of patients with primary open-angle glaucoma (POAG) and ocular hypertension (OHT) in a real-world clinical setting.<sup>13</sup> The study demonstrated statistically significant improvement to ocular hyperemia following switch to bimatoprost 0.01% from 0.03% but did not show statistically significant changes to IOP.<sup>13</sup>

To date, studies on bimatoprost 0.01% versus 0.03% have mainly included patients with POAG and OHT. Comparison of their performances in patients with other types of glaucoma such as normal tension glaucoma (NTG), secondary open-angle glaucoma (SOAG) such as pseudoexfoliative glaucoma (PXG) and pigment dispersion glaucoma (PDG), and angle closure glaucoma (ACG) remain to be further explored. The aim of this study was to evaluate the efficacy in IOP reduction and tolerability of switching bimatoprost 0.01% (Lumigan RC, Allergan Inc, an AbbVie company, Irvine, CA) to bimatoprost 0.03% (Vistitan, Aequus Pharmaceuticals Inc, British Columbia, ON) in patients with different types of glaucoma in a real-world practice setting, to evaluate if bimatoprost 0.03% can be considered an alternative to bimatoprost 0.01% when further IOP reduction is indicated.

## Subjects and Methods

### Design

This is a retrospective, single-centre study comparing the IOP-reducing efficacy and adverse events of two different concentrations (0.01% and 0.03%) of bimatoprost in patients with glaucoma. Clinical indication for switch is that the IOP did not meet the target based on patient's glaucoma staging, as per Canadian Ophthalmological Society glaucoma guidelines.<sup>1</sup> Washout period was not performed before switching for three reasons: 1) the IOP was checked at week-6 after switch to allow sufficient washout of the effect of previous prostaglandin analogue; 2) the switch was to a higher concentration of bimatoprost; 3) our study aims to show the outcome from real-life practice where washout period is often not performed when switching medications for glaucoma treatment.

This study was approved by an independent ethics committee (Hamilton Integrated Research Ethics Board) and followed the tenets of the Declaration of Helsinki and the Good Clinical Practice guidelines. The need for patient informed consent was waived by the ethics board as this is a retrospective chart review that only required anonymized data to ensure patient confidentiality.

### Subjects

Subjects were selected retrospectively from electronic medical records if they had initial topical monotherapy with bimatoprost 0.01% before switching directly to bimatoprost 0.03%, with at least 6-weeks follow-up after switch. Patients identified were aged 18 years old or over and were diagnosed with glaucoma in either eye. Patients were excluded if they had any procedures to the eye that would affect the intraocular pressure after their medication switch.

## Parameters Analyzed

IOP at pre-switch baseline visit and at 6- and 12-week post-switch were included in the analysis. Magnitude of IOP reduction from baseline to follow-up visits was included. Adverse events after switch were noted by ophthalmic history and examination. Patients were also analyzed by subgroups, including POAG and OHT, ACG, NTG, and SOAG (PDG, PXG).

## Statistical Analyses

All statistical analyses were completed using Microsoft Excel Professional Plus 2013 Software (Microsoft Corp., Redmond, WA, USA) with statistical significance defined as *p* value of <0.05. Nominal variables such as sex and incidence of adverse outcomes are presented as count and percentage. Continuous variables such as age and IOP are given as mean, standard deviation and ranges. Mean IOP from baseline was compared to follow-up visits using a paired two-sample *t*-test. The study population was analyzed as subgroups based on types of glaucoma.

## Results

### Demographics

The study population consisted of 143 individuals who had at least one eye switched from bimatoprost 0.01% to bimatoprost 0.03%. Age was  $75.2 \pm 12.0$  years (mean  $\pm$  standard deviation, range: 36–97). Eighty-two (57.3%) patients were male and 61 (42.7%) were female. There were 248 glaucomatous eyes enrolled in this study, 124 (50%) being right and 124 (50%) being left eyes (Table 1).

### Intraocular Pressure (Table 2)

Mean IOP was compared between pre-switch and post-switch at 6- and 12-week visits for all patients and subgroups based on diagnoses. For all patients included, there was a significant reduction in mean IOP from baseline to week-6 of  $1.0 \pm 3.7$  mmHg ( $p < 0.001$ ,  $n = 248$ ), and from baseline to week-12 of  $1.6 \pm 4.0$  mmHg ( $p < 0.001$ ,  $n = 142$ ). There was a statistically significant reduction in IOP in patients diagnosed with POAG and OHT at 6-weeks ( $1.0 \pm 3.8$  mmHg,  $p < 0.05$  compared to baseline pre-switch,  $n = 76$ ) and 12-weeks ( $1.5 \pm 4.1$  mmHg,  $p < 0.05$ ,  $n = 49$ ), and similarly for ACG (6-weeks:  $1.5 \pm 4.1$  mmHg,  $p < 0.05$ ,  $n = 72$ ; 12-weeks:  $2.3 \pm 4.5$  mmHg,  $p < 0.05$ ,  $n = 46$ ), and NTG (6-weeks:  $0.83 \pm 2.5$  mmHg,

**Table 1** Demographics and Characteristics of Study Population

Number of Subjects	143
Age in years	
Mean $\pm$ SD (Range)	75.2 $\pm$ 12.0 (36–97)
Gender (n, % of subjects)	
Male	82 (57.3)
Female	61 (42.7)
Laterality	Total = 248 (100)
Right	124 (50)
Left	124 (50)
Diagnosis (n, % total eyes)	
POAG	72 (29)
NTG	42 (17)
SOAG	58 (23)
ACG	72 (29)
OHT	4 (2)

**Abbreviations:** POAG, primary open-angle glaucoma; NTG, normal tension glaucoma; SOAG, secondary open-angle glaucoma; ACG, angle closure glaucoma; OHT, ocular hypertension.

**Table 2** Comparison of Intraocular Pressures (mmHg) Before and After Switch from 0.01% to 0.03% Bimatoprost in Different Patient Subgroups. Paired two sample t-test was performed comparing IOP at follow-up to baseline.

	Baseline	Week 6	Mean IOP Change	P-value	Week 12	Mean IOP Change	P-value
All patients	18.0±5.0 (n=248)	17.0±4.7 (n=248)	1.0±3.7 (n=248)	<0.001	16.8±4.0 (n=142)	1.6±4.0 (n=142)	<0.001
POAG and OHT	17.8±4.4 (n=76)	16.8±4.2 (n=76)	1.0±3.8 (n=76)	0.0188	16.5±3.8 (n=49)	1.5±4.1 (n=49)	0.0122
ACG	18.6±4.3 (n=72)	17.0±3.6 (n=72)	1.5±4.1 (n=72)	<0.001	17.4±3.8 (n=46)	2.3±4.5 (n=46)	0.001
NTG	13.6±2.6 (n=42)	12.8±2.5 (n=42)	0.83±2.5 (n=42)	0.0372	13.3±2.3 (n=25)	1.12±2.1 (n=25)	0.0146
SOAG	19.7±4.9 (n=58)	19.3±5.3 (n=58)	0.40±3.5 (n=58)	0.391	19.1±3.9 (n=25)	0.28±3.1 (n=25)	0.660

**Table 3** Overall Rates of Adverse Events After Switch from 0.01% to 0.03% Bimatoprost

	Total Population n=143
Total patients with any adverse events, n (%)	42 (29)
Hyperemia	23 (16)
Ocular surface disease	13 (9)
Eyelid erythema	5 (3)
Pigmentary cells	4 (3)
Eye pruritus	4 (3)
Cystoid macular edema	2 (1)
Other	4 (3)

p<0.05, n=42; 12-weeks: 1.12±2.1 mmHg, p<0.05, n=25). Patients who were diagnosed with SOAG did not show a statistically significant reduction in IOP at 6- or 12-weeks.

## Adverse Events (Table 3)

After switching to bimatoprost 0.03%, 42 (29%) out of 143 patients experienced new or worsening adverse events. The most common was hyperemia, which was graded as 0 (none), +0.5 (trace), +1 (mild), +2 (moderate), +3 (severe). We found 23 (16%) of patients either developed new (change from 0 to higher grading) or had worsening of their hyperemia (increase in hyperemia grading). Ocular surface disease was the second most common with 13 (9%) patients. This included subjective reports by patients of dry sensation, foreign body sensation, burning sensation, and/or tear breakup time <10 seconds, and/or corneal fluorescein staining >grade 1 (Oxford grading). Patients in the “Other” category complained of adverse events such as skin rashes, coughs at night, or glare and flashes in vision.

## Discussion

Under current guidelines in Canada, PGAs and prostamides have become the first-line medical therapy for glaucoma due to the medication's superior IOP-lowering ability and low risk of systemic side-effects.<sup>1,2</sup> Bimatoprost has shown to have superior IOP-reducing capabilities compared to other common antiglaucoma medications,<sup>4,5</sup> including in subgroups such as pseudoexfoliation glaucoma,<sup>14</sup> normal tension glaucoma,<sup>15</sup> and POAG.<sup>16</sup>

There has not been any study so far evaluating efficacy and tolerability on switching from bimatoprost 0.01% to bimatoprost 0.03%, and those that compared these two formulations included only patients with POAG and OHT.<sup>9,12,13</sup> Our study included subjects diagnosed of different types of glaucoma from a subspecialty glaucoma practice. In our study, there was a significant change in mean IOP from baseline to week-6 of 1.0±3.7 mmHg (n=248) and to week-12 of 1.6±4.0 mmHg (n=142) for all patients. The subgroups of POAG and OHT, ACG and NTG subgroups showed statistically significant changes in mean IOP from baseline to week-6 and week-12. The mean IOP changes were not statistically significant for patients with SOAG, which included patients with pseudoexfoliation and pigmentary glaucoma. The lack of difference in efficacy between 0.01% and 0.03% bimatoprost specifically in SOAG patients in our

study is intriguing, and may be due to the more volatile IOP fluctuations seen in these types of glaucoma. Longer duration studies including diurnal IOP data are warranted to further validate any efficacy difference between 0.01% and 0.03% bimatoprost.

There may have been a transient improvement in compliance after switching to a new medication resulting in a significant decrease in IOP with bimatoprost 0.03%. Campbell et al showed that while persistence with bimatoprost 0.01% and bimatoprost 0.03% declined over a 12-month period, bimatoprost 0.01% maintained a higher survival rate after 2 months of starting treatment.<sup>11</sup> In addition, Newman-Casey et al demonstrated that 90% of the patients on glaucoma medications maintained the adherence pattern they established after the first year of medication use in three subsequent annual follow-ups.<sup>17</sup>

The ocular adverse effect profile of PGAs and prostamides has been extensively discussed with conjunctival hyperemia being most prominent.<sup>9,10,12,13,18,19</sup> Studies have shown that bimatoprost, compared to travoprost and latanoprost, reduced IOP more effectively, but had higher incidence of ocular hyperemia.<sup>4,20</sup> Randomized prospective trials comparing two formulations of bimatoprost, 0.01% and 0.03%, and observational studies switching from 0.03% to 0.01% have been conducted to evaluate their efficacy and tolerability.<sup>9,10,12,13</sup>

Close to one-third of patients reported adverse events after switching from 0.01% to 0.03% bimatoprost, with conjunctival hyperemia (23 [16%]) being the most common followed by ocular surface disease (13 [9%]). Our results reflect similar adverse event profile to what has been found in past studies for bimatoprost 0.03%. Katz et al reported the incidence of conjunctival hyperemia after 12 months of treatment being 37.4% in the bimatoprost 0.03% group and 28.6% in the bimatoprost 0.01% group, representing a relative increase of 30.8%.<sup>9</sup> In the CLEAR trial, Crichton et al demonstrated that 20.8% of the study population had an improvement of their conjunctival hyperemia after switching from bimatoprost 0.03% to bimatoprost 0.01%.<sup>13</sup> There has yet to be a prospective study following changes in conjunctival hyperemia from bimatoprost 0.01% to bimatoprost 0.03%.

Though there may only be a small magnitude of further IOP reduction as suggested by our results, when clinicians are considering switching from 0.01% to 0.03% bimatoprost, patients should be counselled on the potential side effects and intolerance that can be experienced. Our study reflects clinical practice in a real-world setting but is limited by the retrospective nature and limited time frame after medication switch, and that not all patients had data beyond 6 weeks post-switch due to an ocular procedure, adverse event, or missed follow-up.

## Conclusion

In our study, there was a significant decrease in IOP up to 12 weeks after switching from 0.01% to 0.03% bimatoprost. Subgroup analysis showed this to be the case for patients with POAG and OHT, NTG and ACG, but not SOAG including PXG and PDG. There was adverse effect after switch in almost one-third of the subjects. Nonetheless, the findings from our retrospective study provide insights for a future prospective study that can be done via crossover design to compare 0.01% and 0.03% bimatoprost in multiple types of glaucoma.

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## Disclosure

Dr Kai Man Xu reports grants from Aequus, during the conduct of the study. Dr Toby Yiu Bong Chan reports grants from Aequus Pharmaceuticals, during the conduct of the study; personal fees for consultant and/or advisory board, and speaker honorarium from Johnson & Johnson, Bausch & Lomb, Allergan (AbbVie), Iridex, Aequus, Ivantis, Latician Thea; research grants and personal fees for consultant and/or advisory board from Alcon and Novartis, outside the submitted work. The authors report no other conflicts of interest in this work.

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