

# Efficacy and Safety of Bimatoprost for the Treatment of Open-Angle Glaucoma and Ocular Hypertension: A Three-Month, Open-Label Study in Community-Based Practices in Thailand

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The authors evaluated the effectiveness and safety of bimatoprost using an open-label, non-comparative, three-month, community-based surveillance study. Patients ( $n = 458$ ) with open-angle glaucoma or ocular hypertension received bimatoprost 0.03% ophthalmic solution as monotherapy, replacement therapy or adjunctive therapy. Bimatoprost produced a rapid, significant ( $p < 0.0001$ ) reduction in intraocular pressure: monotherapy (34.6% reduction); replacement therapy (16.4% reduction); adjunctive therapy (24.1% reduction). Bimatoprost enabled more patients to achieve their pre-defined target intraocular pressure ( $p < 0.0001$ ), compared to previous treatments, and significantly lowered intraocular pressure, regardless of the patients' baseline pressure level or history of pressure control. Bimatoprost was well-tolerated; the most commonly reported adverse event was conjunctival hyperaemia (19.9%). Most patients and ophthalmologists rated bimatoprost highly, compared to previously used treatments. The authors concluded that bimatoprost is an effective, well-tolerated treatment for lowering intraocular pressure in Thai patients with open-angle glaucoma or ocular hypertension.

**Keywords:** Bimatoprost, Open angle glaucoma, Ocular hypertension, Intraocular pressure, Thailand

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The World Health Organisation has identified glaucoma as one of the three leading causes of blindness<sup>(1)</sup>. In Thailand, glaucoma was identified as the third leading cause of bilateral blindness according to a national survey<sup>(2)</sup>. Effective glaucoma management requires early intervention and access to effective, safe and well-tolerated treatments<sup>(1,3)</sup>.

Bimatoprost, a synthetic prostamide analogue, is a new ocular hypotensive agent<sup>(3,4)</sup>. In Thailand, bimatoprost is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are intolerant of, or unresponsive to, other intraocular pressure lower-

ing medications. Bimatoprost acts as a potent IOP-lowering agent by increasing the outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes<sup>(5-7)</sup>.

Published data on the efficacy and safety of bimatoprost in patients from Asia with open-angle glaucoma or ocular hypertension are extremely limited. Literature searches (MEDLINE) indicate that there have been no published studies on bimatoprost and its effects in patients from Thailand or other Asian countries (e.g. China, Japan, India, Korea, the Philippines). However, bimatoprost has been studied extensively in Caucasian patients with open-angle glaucoma or ocular hypertension under stringent clinical trial conditions<sup>(8-18)</sup>. Comparative studies, conducted primarily in North America and Europe, have demonstrated that bimatoprost treatment provides a greater reduction in

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IOP compared to timolol<sup>(8-12)</sup> and latanoprost<sup>(13-15)</sup>, and a similar or greater reduction in IOP compared to travoprost<sup>(16-18)</sup>. When bimatoprost was used to replace latanoprost, an additional, significant reduction in IOP was achieved<sup>(19)</sup>. Furthermore, bimatoprost treatment has successfully lowered IOP in patients who were unresponsive to latanoprost<sup>(20,21)</sup>.

Bimatoprost treatment has also been compared to dual therapy with other ocular hypotensive agents. A recent three-month clinical trial of bimatoprost demonstrated that bimatoprost monotherapy provided significantly greater IOP lowering, compared to a fixed combination of timolol and dorzolamide<sup>(22)</sup>. These findings are clinically important because, with effective monotherapy, patients need not be exposed to the risk of the potentially additive adverse effects of dual therapy. In addition, monotherapy is associated with increased patient compliance<sup>(23)</sup>.

Surveillance Studies of bimatoprost, conducted in real-life clinical practice settings, are needed to complement and extend the findings from randomized, controlled clinical trials<sup>(3)</sup>. Regulatory authorities have reinforced that clinical practice studies are essential for assessing the optimal use of new drugs<sup>(24)</sup>. Surveillance Such studies provide a platform to assess the efficacy and safety of a drug in a heterogeneous population, unrestricted by stringent eligibility criteria. Surveillance studies These studies also provide participating physicians with the opportunity to apply their professional judgment in terms of the appropriateness of treatment and use of concomitant medications. The objective of the present surveillance study, therefore, was to evaluate the efficacy and safety of bimatoprost in Asian patients with open-angle glaucoma or ocular hypertension in clinical practices in Thailand.

## **Material and Method**

### ***Study Design and Setting***

A multi-centre, open-label, non-comparative, three-month surveillance study was conducted in 42 community-based practices in Thailand and involved 58 ophthalmologists. The study was purposefully designed to reflect clinical practice in Thailand.

### ***Patient Description***

All patients were fully informed about the study and provided written informed consent prior to participation. Patients who were diagnosed with open-angle glaucoma or ocular hypertension and who required lowering of IOP were eligible to participate.

Exclusion criteria were: (a) hypersensitivity to the product or any of its components, (b) clinically relevant low or high heart rate or blood pressure for age and (c) women who were pregnant, nursing or considering pregnancy.

### ***Treatment Protocol***

Patients were evaluated according to each ophthalmologist's standard clinical practice. One eye (left or right) or both eyes were assessed per patient. Bimatoprost was prescribed as a 0.03% ophthalmic solution (Lumigan<sup>®</sup>, Allergan, Irvine, USA) and used, at the ophthalmologist's discretion, as monotherapy (for treatment of naïve patients), replacement therapy (previous treatments replaced with bimatoprost) or adjunctive therapy (bimatoprost added to previous treatment regimen). At each visit, the patient was provided with one bottle (3 mL) of bimatoprost, which was sufficient for one month of treatment. One drop of the bimatoprost was applied to each affected eye, once daily, in the evening, for three months. This treatment protocol complied with the current labeling instructions in Thailand for commercially available bimatoprost.

### ***Clinical Evaluation***

Patients were evaluated at baseline and one, two and three months after initiating treatment with bimatoprost. At the baseline visit, patient demographics and clinical history were recorded. Patients were set a pre-defined target IOP level depending on the assessed risk of progressive visual damage. At each visit, IOP was measured according to the ophthalmologist's standard clinical practice. Primary efficacy variables were change in IOP and satisfaction with bimatoprost. Satisfaction was assessed at the end of the study by both the patient and ophthalmologist. Patients were asked to rate the ocular comfort of bimatoprost, compared to previous ocular treatments (5 point scale; very comfortable to very uncomfortable). Patients were also asked if they would use bimatoprost in the future to treat their elevated IOP. Ophthalmologists made an overall assessment of treatment and rated bimatoprost against other IOP-reducing medications (4 point scale; excellent to poor). All adverse events that occurred during the study were recorded.

### ***Statistical Analysis***

Data were entered into a database, with all data checked, queried and resolved. Descriptive statistics were reported. In patients who received bimatoprost treatment in both eyes, a mean IOP from

both eyes was used for the analysis. Mean IOP values at each time point, in each group, were compared to baseline. Probability values were calculated using a paired sample t-test, with  $p < 0.05$  considered significant. The percentage reduction in mean IOP from baseline was calculated as the percentage reduction in IOP from baseline for each patient and then averaged across the group. The percentage of patients who achieved their pre-defined, target IOP was calculated for each group, for each time point. Probability values for the comparison of percentage values were calculated using a chi-square-test, with  $p < 0.05$  considered significant.

## Results

### Patients

The study enrolled 458 patients; with the majority having been diagnosed with open-angle glaucoma and experiencing some level of difficulty in controlling their IOP in the 6 to 12 months prior to study enrolment (Table 1). At the time of study entry, most patients ( $n = 391$ , 85%) had been using at least one other IOP-lowering medication. Based on the judgment of the ophthalmologists, the majority of

patients were prescribed bimatoprost as either adjunctive or replacement therapy. Three-month data were available from 365 (80%) patients. Of the patients who did not complete the study ( $n = 93$ ), 9% ( $n = 39$ ) discontinued due to adverse events, 9% ( $n = 39$ ) were lost to follow up, 2% ( $n = 9$ ) withdrew for 'other' reasons, and 1% ( $n = 6$ ) had no data to explain their withdrawal from the study.

### Effect on IOP

Daily treatment with bimatoprost 0.03% ophthalmic solution as monotherapy, replacement therapy or adjunctive therapy significantly reduced IOP over the three-month study period (Fig. 1). At the three-month visit, the mean reduction in IOP from baseline was 9.0 mmHg (34.6%,  $p < 0.0001$ ) with bimatoprost monotherapy, 3.9 mmHg (16.4%,  $p < 0.0001$ ) with bimatoprost replacement therapy and 6.6 mmHg (24.1%,  $p < 0.0001$ ) with bimatoprost adjunctive therapy. Significant reductions in mean IOP, relative to baseline levels ( $p < 0.0001$ ), were achieved across all treatment groups within one month of starting bimatoprost treatment and were sustained over the three-month study period (Fig. 1).

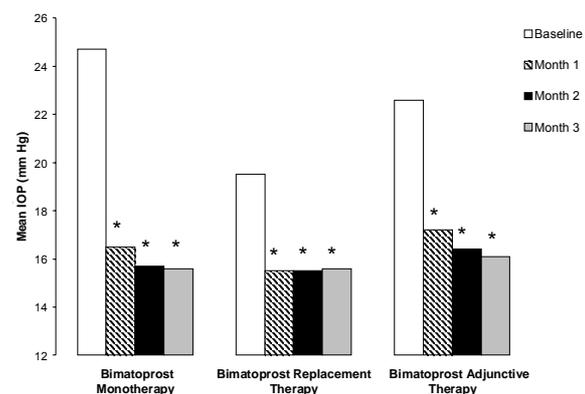
**Table 1.** Patient demographics and baseline characteristics ( $n = 458$ )

Characteristics	Number	(%)
Age		
$\geq 50$ years	374	81.6
Gender		
Female	237	51.8
Race		
Asian	457	99.8
Other	1	0.2
Diagnosis		
Open-angle glaucoma	400	87.3
Ocular hypertension	58	12.7
IOP at baseline (Ophthalmologist classification)		
Very difficult to control	19	4.1
Difficult to control	118	25.7
Somewhat difficult to control	151	33.0
Not difficult to control	98	21.4
No previous data	72	15.8
Treatment prescribed*		
Bimatoprost monotherapy	48	10.5
Bimatoprost replacement therapy	147	32.1
Bimatoprost adjunctive therapy	256	55.9

\* The prescribed treatment regimen was not provided for seven patients

### Effect on achieving low target IOP

The proportion of patients who achieved their target IOP level was significantly higher with bimatoprost treatment (all three therapy groups combined), compared to baseline (Fig. 2). At baseline, only 23% of the patients achieved target IOPs of  $\leq 17$  mmHg. After one month of bimatoprost treatment, 62% of patients achieved target IOPs of  $\leq 17$  mmHg. This improvement



**Fig. 1** Effect of treatment with bimatoprost as monotherapy, replacement therapy or adjunctive therapy on IOP. \*  $p < 0.0001$  compared to baseline (Paired t-test)

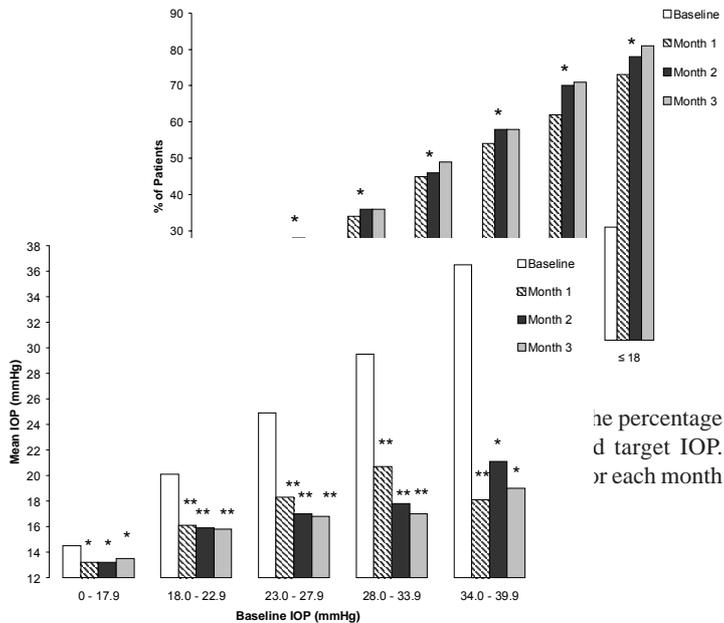
in achieving target IOP was sustained during the three-month study period. At three months, 71% of patients had IOPs  $\leq 17$  mmHg.

### Effect of baseline level of IOP

Bimatoprost treatment significantly reduced IOP, regardless of the patient's baseline IOP (Fig. 3). The reduction in IOP occurred within one month of initiating bimatoprost treatment and was sustained over the study period. Even in patients with a low baseline IOP (0.0 to 17.9 mm Hg), bimatoprost treatment was associated with a further lowering of IOP.

### Effect of baseline control of IOP

Bimatoprost treatment significantly reduced IOP, regardless of how difficult it was to control IOP in the 6 to 12 months prior to the present study (Fig. 4).

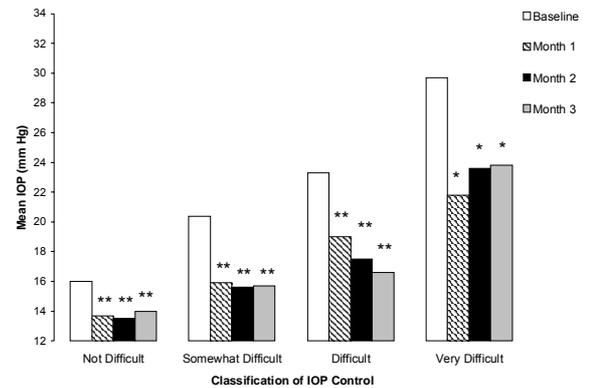


**Fig. 3** Effect of bimatoprost treatment on IOP in patients with variable baseline IOP levels. \*  $p < 0.05$  compared to baseline; \*\*  $p < 0.0001$  compared to baseline (Paired t-test)

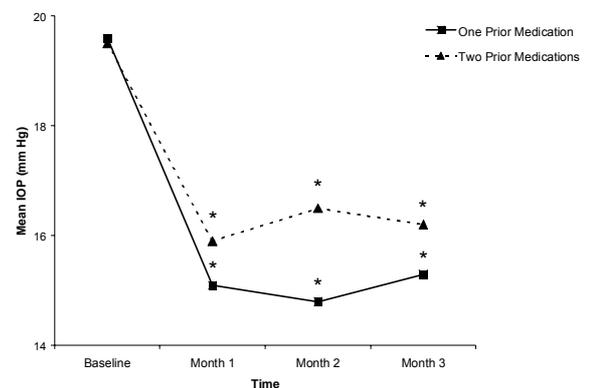
The reduction in IOP occurred within one month of initiating bimatoprost treatment and was sustained over the study period. Even in patients who were classified as 'very difficult to control', bimatoprost treatment provided clinically relevant lowering of IOP.

### Effect of replacing baseline monotherapy or dual therapy

When bimatoprost treatment replaced the monotherapy or dual therapy treatment regimen used prior to study entry, an additional, significant reduction in IOP was achieved (Fig. 5). Three months of bimatoprost treatment provided an additional mean reduction in IOP of 4.5 mmHg (19.4%,  $p < 0.0001$ ) for patients ( $n = 93$ ) on one prior medication and an additional mean reduction of 3.0 mmHg (12.9%,  $p < 0.0001$ ) for patients ( $n = 45$ ) on two prior medications. The



**Fig. 4** Effect of bimatoprost treatment on IOP in patients with varying difficulty of IOP control prior to study entry. \*  $p < 0.05$  compared to baseline; \*\*  $p < 0.0001$  compared to baseline (Paired t-test)



**Fig. 5** Effect of bimatoprost treatment on IOP in patients who were using one or two ocular hypotensive agents prior to study entry. \*  $p < 0.0001$  compared to baseline (Paired t-test)

monotherapy medications that were most often replaced by bimatoprost were non-selective beta-blockers (used by 69% of patients) and latanoprost (used by 20% of patients). The medications used in a dual therapy regimen that were most frequently replaced by bimatoprost included non-selective beta-blockers (used by 98% of patients), miotics (used by 36% of patients) and carbonic anhydrase inhibitors (used by 24% of patients).

#### **Patient and ophthalmologist satisfaction**

Satisfaction with bimatoprost treatment was rated highly by both patients and ophthalmologists in Thailand. The majority (83.7%) of patients stated that bimatoprost was at least as comfortable as previously used medications and most (84.4%) patients indicated that they would be willing to use bimatoprost again. The ophthalmologists who provided an overall evaluation (n = 23) rated bimatoprost as 'good' (69.6%) or 'excellent' (30.4%) compared to other IOP-lowering agents.

#### **Adverse events**

Bimatoprost treatment had a favourable safety profile and was well-tolerated. The most commonly reported adverse events were: conjunctival hyperaemia (19.9%), ocular irritation/burning (5.9%), pruritis (5.2%) and lid findings (3.9%). Most adverse events were mild or moderate in severity. Only 9% (n = 39) of patients discontinued due to adverse events, with most discontinuations due to conjunctival hyperaemia (6% of patients; n = 28).

#### **Discussion**

To the best of the authors' knowledge, this is the first clinical practice study in Thailand to demonstrate that bimatoprost treatment, as monotherapy, replacement therapy or adjunctive therapy, results in significant lowering of IOP in Asian patients with open-angle glaucoma or ocular hypertension. Bimatoprost treatment was associated with a rapid reduction in IOP, which was evident within one month and sustained over the three-month study period. The benefits of bimatoprost treatment were evident in patients regardless of their baseline level of IOP or the degree of difficulty in IOP control prior to study entry. In the Thai patients studied, bimatoprost treatment had a favourable safety profile and was well-tolerated. Both patients and ophthalmologists in Thailand were highly satisfied with bimatoprost treatment.

In terms of clinical importance, researchers have advocated that IOP-lowering agents should

reduce IOP by 15 to 20%, relative to baseline IOP<sup>(16)</sup>. In the present study, bimatoprost treatment provided clinically important reductions in IOP, whether prescribed as monotherapy, replacement therapy or adjunctive therapy. The effectiveness of bimatoprost treatment, as shown in our clinical practice study, supports and extends the efficacy findings from randomized, controlled, clinical trials with bimatoprost<sup>(8-22)</sup>. Of particular clinical interest was the effectiveness of bimatoprost monotherapy, when replacing baseline dual therapy. Even though the sample subset for this group was relatively small (n = 45), this clinically relevant finding warrants further study given the advantages of monotherapy over dual therapy in terms of convenience, cost and patient compliance<sup>(23)</sup>.

Achieving and maintaining low IOP is an important part of the management strategy to halt the progression of visual field loss in glaucoma patients<sup>(25-28)</sup>. In previous studies, IOPs > 17 mmHg have been associated with progression<sup>(26)</sup> or more substantial visual field damage<sup>(25)</sup>, compared to patients with IOPs ≤ 17 mmHg. In the present study, bimatoprost treatment enabled three times as many patients to achieve a target IOP ≤ 17 mmHg by three months, compared to their previous management strategies. This result extends the findings from bimatoprost clinical trials<sup>(8,10,11,13,14)</sup> and is clinically relevant. In contrast to results from stringent clinical trials, the present results may be more readily generalized to the wider population of Thai patients with glaucoma or ocular hypertension because of the present study's broad eligibility criteria and clinical practice-based study design.

In the majority of patients in the present study, management strategies prior to study entry involved non-selective beta-blockers. Throughout Asia and other regions, non-selective beta-blockers are commonly prescribed for the management of glaucoma, due to their efficacy and low cost. However, non-selective beta-blockers are known to have a number of systemic side effects<sup>(29)</sup> and concurrent use of systemic beta-blockers can affect the efficacy and safety of topical non-selective beta-blockers<sup>(30)</sup>. The latter finding is clinically relevant given that the risks of glaucoma<sup>(31)</sup> and cardiovascular disease increase with age<sup>(32)</sup>.

In the present study, bimatoprost treatment had a favourable safety profile and was well-tolerated. In agreement with previous studies<sup>(3,13,20)</sup>, the most frequent adverse event associated with bimatoprost was mild to moderate conjunctival hyperaemia. Based on the transient and mild nature of the hyperaemia associated with bimatoprost treatment, other researchers

have concluded that conjunctival hyperaemia should not be regarded as a significant safety concern<sup>(33)</sup>. The fact that the majority of patients in the present study indicated that they would be willing to use bimatoprost again provides additional, indirect support for the tolerability of bimatoprost treatment.

In conclusion, the present Thai surveillance study shows that bimatoprost is an effective and well-tolerated treatment for Thai patients with open-angle glaucoma or ocular hypertension. in Thailand. Bimatoprost treatment was associated with a rapid, significant reduction in IOP when used as monotherapy, replacement therapy or adjunctive therapy, in a broad range of Asian patients. Both patients and ophthalmologists were highly satisfied with bimatoprost treatment.

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**ประสิทธิภาพและความปลอดภัยของยา ไบมาโทโพรส ในการรักษาโรคต้อหินแบบมุมเปิดและโรคความดันลูกตาสูง: เป็นการศึกษาระยะ 3 เดือน โดยจักษุแพทย์หลายสถาบัน**

บุญส่ง วณิชเวชารุ่งเรือง, วัลลภ เอี่ยมสมบูรณ์

เป็นการศึกษาประสิทธิภาพและความปลอดภัยของยา Bimatoprost ในการใช้รักษาผู้ป่วยต้อหินในระยะ 3 เดือน โดยที่การจ่ายยานี้เป็นแบบ open-label และไม่มีกลุ่มศึกษาที่เป็น control มีผู้ป่วยต้อหินแบบมุมเปิดและผู้ที่เป็นความดันลูกตาสูง ที่เข้าร่วมการศึกษา 458 ราย โดยได้รับยา 0.03% Bimatoprost ชนิดที่เป็นยาตัวเดียว หรือให้ทดแทนยาอื่น หรือ ให้ร่วมกับยาอื่น ยานี้สามารถลดความดันลูกตาได้ในผู้ที่ใช้ทั้งสามกลุ่ม ( $p < 0.0001$ ) โดยลดความดันลูกตาได้ 34.6% ในกรณีที่ใช้ยาตัวเดียว, 16.4% ในกรณีที่ให้ทดแทนยาอื่น, และ 24.1% ในกรณีให้ร่วมกับยาอื่น ยานี้สามารถลดความดันลูกตาให้อยู่ที่ target pressure ที่ต้องการได้ดี ( $p < 0.0001$ ) ผู้ป่วย สามารถทนต่อผลข้างเคียงของยานี้ได้ดี โดยที่มีผลข้างเคียงที่สำคัญคือ conjunctival hyperemia (19.9%) พบว่าผู้ป่วยและจักษุแพทย์มีความรู้สึกพอใจต่อการใช้นี้เมื่อเทียบกับการรักษาด้วยยาอื่นที่ผ่านมา โดยสรุปพบว่ายานี้ ใช้อย่างมีประสิทธิภาพโรคต้อหินแบบมุมเปิดและความดันลูกตาสูงในคนไทย