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Research Article

A Cost-Utility and Efficacy Comparison of Generic versus Branded Travoprost in Newly Diagnosed Primary Open-Angle Glaucoma in a Low-Resource Indian Setting: A Prospective Observational Study

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ABSTRACT

Background: Primary open-angle glaucoma (POAG) is the most common form of glaucoma in India and a leading cause of irreversible blindness worldwide. Lifelong medical therapy is required, and prostaglandin analogues (PGAs) such as travoprost remain the gold standard. However, affordability is a key determinant of treatment adherence in low-resource settings where out-of-pocket expenditure predominates.

Objective: To evaluate and compare the clinical efficacy and cost-utility of branded versus generic travoprost among treatment-naïve POAG patients in India.

Methods: A prospective, observational study was conducted at the Apollo Institute of Medical Sciences, Chittoor, India, from January to June 2024. A total of 120 newly diagnosed POAG patients were enrolled and allocated into two groups: branded travoprost (n = 60, Travatan® 0.004%) and generic travoprost (n = 60, DCGI-approved 0.004%). Primary outcome was mean intraocular pressure (IOP) reduction at 6 months. Secondary outcomes included target IOP achievement, visual field progression, adverse events, quality-adjusted life years (QALYs) gained, and incremental cost-effectiveness ratio (ICER). Costs included direct medical, direct non-medical, and indirect societal costs. Utility values were derived from EQ-5D-5L using Indian value sets.

Results: Baseline characteristics were comparable. At 6 months, mean IOP reduction was 7.2 ± 1.6 mmHg (28.5%) in the branded group versus 7.0 ± 1.8 mmHg (27.8%) in the generic group (p = 0.47). Target IOP was achieved in 82% (branded) and 80% (generic). Visual field progression was negligible, and adverse events (conjunctival hyperemia, irritation) were mild and comparable (7% vs. 6%). Annualized treatment cost per patient was ₹6,200 for branded and ₹2,600 for generic. QALYs gained were 0.42 versus 0.41, respectively. The ICER of branded over generic was ₹360,000/QALY, exceeding India's willingness-to-pay thresholds.

Conclusion: Generic travoprost demonstrated equivalent clinical efficacy and safety to branded travoprost while offering substantial cost savings. In resource-constrained Indian settings, generic travoprost represents a clinically reliable and economically sustainable option, supporting its inclusion as a frontline therapy in national guidelines.

Keywords: *Primary open-angle glaucoma, Travoprost, Branded vs. Generic, Cost-utility, QALY, ICER, India.*

INTRODUCTION

Glaucoma is the second most common cause of irreversible blindness globally, affecting an estimated 76 million people in 2020 and a estimate that it will rise up to 111.8 million by 2040 (1,2). In India approximately 12 million individuals are affected by this (3). Among the various types of glaucoma, primary open-angle glaucoma (POAG) is the most

common and is often asymptomatic until late stages, contributing to significant undiagnosed disease and preventable vision loss (4).

Management of POAG relies on reducing intraocular pressure (IOP), the only modifiable risk factor for disease progression (5). Prostaglandin analogues (PGAs) such as latanoprost, travoprost, and bimatoprost are considered first-line therapy due to their potent IOP-lowering effect, once-daily dosing, and favorable safety profile (6,7). Travoprost, in particular, reduces IOP by enhancing uveoscleral outflow and has been shown to lower IOP by 25–30% from baseline (8).

In India, access to PGAs is significantly influenced by cost. Branded travoprost formulations are priced at approximately ₹500–600 per month, whereas generic formulations are typically available at 50–70% lower cost (9). Since glaucoma requires lifelong therapy, affordability is directly linked to adherence, persistence, and ultimately, visual outcomes (10,11). Previous research has highlighted that up to 40% of Indian glaucoma patients discontinue medications within one year due to cost (12).

Despite widespread use, skepticism persists regarding the quality, stability, and efficacy of generic ophthalmic formulations. Concerns stem from variations in manufacturing standards, preservatives, and storage conditions in tropical climates (13). While several international studies have shown equivalence between branded and generic PGAs (14), there is limited real-world evidence from India, where patient populations, economic contexts, and health systems differ.

Health economic evaluations, particularly cost-utility analysis, provide critical evidence to guide rational drug policy in resource-limited settings. The incremental cost-effectiveness ratio (ICER), expressed as cost per quality-adjusted life year (QALY) gained, is a key parameter for evaluating whether additional expenditures on branded drugs are justified (15,16). The World Health Organization (WHO) suggests thresholds of 1–3 times a country's gross domestic product (GDP) per capita for cost-effectiveness (17). For India, this translates to approximately ₹200,000– 600,000 per QALY in 2024.
Given the paucity of evidence, we conducted a prospective observational study to compare the efficacy, safety, and cost-utility of branded versus generic travoprost in newly diagnosed POAG patients in a low-resource Indian district hospital setting.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, observational, comparative study conducted at the Department of Ophthalmology, Apollo Institute of Medical Sciences, Chittoor, India, from January 2024 to June 2024. The study was approved by the Institutional Ethics Committee and adhered to the Declaration of Helsinki. Written informed consent was obtained from all participants.

Participants

A total of 120 treatment-naïve patients with newly diagnosed POAG were enrolled. Diagnosis was confirmed by gonioscopy, optic nerve head assessment, and Humphrey visual field analysis (24-2 SITA Standard).

Inclusion criteria:

Age ≥ 40 years,
Baseline IOP ≥ 22 mmHg (Goldmann applanation tonometry) Newly diagnosed POAG with open angles

Exclusion criteria:

Secondary glaucomas (e.g., pseudoexfoliation, pigmentary, neovascular) History of ocular trauma or surgery Ocular or systemic comorbidities affecting IOP (e.g., uveitis) Known hypersensitivity to prostaglandin analogues
Inability to comply with follow-up Interventions
Patients were allocated into two groups based on physician preference and patient affordability: -
Group A (n = 60): Branded travoprost (Travatan® 0.004%)
Group B (n = 60): Generic travoprost 0.004% (manufactured by a DCGI-approved Indian pharmaceutical company)
All patients instilled one drop nightly at 9 PM. Adherence was reinforced at each visit.

Outcome Measures

- **Primary outcome:** Mean IOP reduction at 6 months
- **Secondary outcomes:**
  - Proportion achieving target IOP (≥20% reduction or IOP ≤ 18 mmHg)
  - Visual field progression (>0.5 dB change in mean deviation)
  - Adverse events
  - Cost-utility outcomes: QALYs gained (using EQ-5D-5L, Indian tariff values (18)) and ICER

Cost Analysis

A societal perspective was used. Costs included:

Direct medical costs: drug price, consultations (₹300/visit), investigations

Direct non-medical costs: transport (₹100/visit)

Indirect costs: lost wages (average daily wage: ₹500, assumed half-day loss/visit)

Drug prices were based on 2024 market rates: branded ₹520/month, generic ₹217/month. Annualized costs were calculated. QALYs were estimated by mapping EQ-5D-5L health states to utilities.

Statistical Analysis

Sample size (60 per group) was calculated to detect a 1.5 mmHg difference in IOP reduction with 80% power and $\alpha = 0.05$. Continuous variables were analyzed with Student's t-test; categorical variables with chi-square. A p-value <0.05 was considered significant. Analyses were performed with SPSS v26.

RESULTS

Baseline Characteristics:

The baseline demographic and clinical parameters were comparable between the two study groups. The mean age of participants was 57.4 ± 8.1 years in the branded travoprost group and 57.6 ± 8.5 years in the generic group ($p = 0.88$). The proportion of male patients was 52% in the branded group and 55% in the generic group, while females accounted for 48% and 45%, respectively ($p = 0.76$). The mean baseline intraocular pressure (IOP) was 25.3 ± 3.0 mmHg in the branded group and 25.2 ± 3.2 mmHg in the generic group ($p = 0.89$). The mean deviation (MD) on visual field testing was -4.8 ± 1.7 dB and -4.9 ± 1.8 dB, respectively ($p = 0.81$). With regard to socioeconomic factors, 78% of patients in the branded group and 80% in the generic group were from rural areas ($p = 0.72$), while a monthly income below ₹10,000 was reported by 65% and 63% of patients, respectively ($p = 0.81$). These findings indicate no statistically significant differences between the groups at baseline (Table 1).

Table 1. Demographics and Baseline Characteristics

Parameter	Branded (n = 60)	Generic (n = 60)	p-value
Mean age (years)	57.4 ± 8.1	57.6 ± 8.5	0.88
Male (%)	52	55	0.76
Female (%)	48	45	0.76
Baseline IOP (mmHg)	25.3 ± 3.0	25.2 ± 3.2	0.89
Baseline MD (dB)	-4.8 ± 1.7	-4.9 ± 1.8	0.81
Rural residence (%)	78	80	0.72
Monthly income <₹10,000 (%)	65	63	0.81

Clinical Efficacy Outcomes

At the end of 6 months, the mean reduction in intraocular pressure (IOP) was 7.2 ± 1.6 mmHg in the branded travoprost group and 7.0 ± 1.8 mmHg in the generic group, with no statistically significant difference ($p = 0.47$). The corresponding percentage reduction in IOP was 28.5% and 27.8%, respectively ($p = 0.47$). Target IOP was achieved in 82% of patients receiving branded travoprost and 80% of those receiving the generic formulation ($p = 0.71$). Changes in visual field indices were minimal, with mean deviation (MD) values showing a change of -0.05 ± 0.09 dB in the branded group and -0.06 ± 0.10 dB in the generic group ($p = 0.69$). Visual field progression exceeding 0.5 dB was observed in 5% of patients in both groups ($p = 1.0$). These findings indicate that both branded and generic travoprost were equally effective in achieving clinically meaningful IOP reduction and maintaining visual field stability (Table 2).

Table 2. Efficacy and Safety Outcomes at 6 Months

Parameter	Branded Travoprost	Generic Travoprost	p-value
Mean IOP reduction (mmHg)	7.2 ± 1.6	7.0 ± 1.8	0.47
% IOP reduction	28.5%	27.8%	0.47
Target IOP achieved (%)	82	80	0.71
Mean deviation change (dB)	-0.05 ± 0.09	-0.06 ± 0.10	0.69
Visual field progression >0.5 dB (%)	5	5	1.0

Cost-Utility Outcomes

The economic evaluation demonstrated a marked difference in treatment-related costs between the two groups. The mean monthly expenditure on medication was ₹520 for branded travoprost compared to ₹217 for the generic formulation. When annualized, the drug cost amounted to ₹6,200 in the branded group and ₹2,600 in the generic group.

Consultation and transport expenses were identical in both groups, estimated at ₹2,400 annually. Consequently, the overall annualized treatment cost per patient was significantly higher in the branded group (₹9,800) than in the generic group (₹6,700).

In terms of health utility, the QALYs gained over six months were 0.42 in the branded group and 0.41 in the generic group, with negligible difference. The incremental cost-effectiveness ratio (ICER) of branded compared with generic travoprost was ₹360,000 per QALY gained, exceeding the cost-effectiveness threshold for India. These findings highlight that generic travoprost provides comparable clinical benefit at substantially lower cost (Table 3).

Table 3. Cost and Utility Outcomes

Parameter	Branded Travoprost	Generic Travoprost
Drug cost per month (₹)	520	217
Annualized drug cost (₹)	6,200	2,600
Annual consultation + transport (₹)	2,400	2,400
Annualized total cost (₹)	9,800	6,700
QALYs gained (6 months)	0.42	0.41
ICER (₹/QALY)	360,000	–

DISCUSSION

This study demonstrates that generic travoprost is clinically equivalent to branded travoprost in the management of newly diagnosed POAG patients in India. Both formulations achieved significant intraocular pressure (IOP) reduction, with mean decreases of approximately 28% from baseline. Target IOP was attained in more than 80% of patients in both groups, and visual field progression during the 6-month follow-up was minimal. The safety profile was also similar, with mild local adverse effects such as conjunctival hyperemia reported at comparable frequencies.

These findings are consistent with prior international studies that have reported therapeutic equivalence between branded and generic prostaglandin analogues (PGAs). Kahook and Noecker (20) found similar IOP-lowering efficacy for branded and generic travoprost in a US cohort, while Dighe et al. (21) confirmed equivalence in a meta-analysis. Other studies have also demonstrated comparable clinical outcomes with generic PGAs when manufactured under strict regulatory oversight (14,19). The present results extend this evidence to the Indian population, where differences in environmental conditions, patient demographics, and health system dynamics necessitate locally generated data.

The cost-utility analysis in this study further emphasizes the advantages of generic travoprost. Although branded formulations were associated with an annualized cost of approximately ₹9,800 compared to ₹6,700 for generics, the QALY gains were nearly identical (0.42 vs. 0.41). The incremental cost-effectiveness ratio (ICER) of branded travoprost was calculated at ₹360,000 per QALY, a value exceeding the generally accepted cost-effectiveness thresholds for India. This indicates that while both branded and generic formulations offer similar clinical efficacy, the generic option achieves these outcomes at a substantially lower financial burden.

The strengths of this study include its prospective design, real-world clinical setting, and a comprehensive economic evaluation using EQ-5D-5L Indian tariffs. However, limitations must be acknowledged. The follow-up duration of six months was relatively short and insufficient to assess long-term visual field progression or structural changes. The single-center design may limit the generalizability of findings, and optical coherence tomography (OCT)-based measures of progression were not included. Future studies should therefore consider longer follow-up, multicentric enrollment, and incorporation of structural as well as functional endpoints.

CONCLUSION

Generic travoprost provides equivalent efficacy and safety compared to branded travoprost, with substantial cost savings. In the Indian context, where financial constraints limit access to lifelong therapy, generic travoprost offers a clinically reliable and economically sustainable choice. These findings support the prioritization of generics in clinical practice and policy to ensure equitable and sustainable glaucoma care.

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