RESEARCH PAPER

Impact of Anti-Glaucoma Medications (Polytherapy Versus Monotherapy) On Ocular Surface Changes: A Cross-Sectional Study

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ABSTRACT

Purpose: Anti-glaucoma medications are a well-established cause of ocular surface disease (OSD); however, whether medication burden monotherapy versus polytherapy differentially affects the ocular surface remains underexplored in the Indian population. This study aimed to compare ocular surface parameters between patients on single-drug and multi-drug regimens and to examine the relationship between intraocular pressure (IOP) levels and ocular surface status.

Methods: A cross-sectional, observational study was conducted at a tertiary eye care centre in Gurugram, Haryana (January–December 2025). Seventy-two adults with bilateral primary open-angle glaucoma (POAG) on stable topical therapy for ≥6 months were enrolled: 36 on monotherapy and 36 on polytherapy. Ocular surface evaluation included the Ocular Surface Disease Index (OSDI) questionnaire, Non-Invasive tear break-up time (NIBUT), Schirmer's Test I (without anaesthesia), Oxford corneal staining grade, and Goldmann applanation tonometry. Data were analysed with Jamovi v2.3 using Student's independent t-test, Mann–Whitney U test, chi-square test, and Spearman's rank correlation; significance was set at $p < 0.05$.

Results: Groups were well-matched for age ($p = 0.42$) and sex ($p = 0.61$). Polytherapy patients demonstrated significantly worse performance across all ocular surface metrics: OSDI score (32.6 ± 8.4 vs. 21.3 ± 6.1, $p < 0.001$), NIBUT (6.8 ± 1.9 s vs. 10.9 ± 2.4 s, $p < 0.001$), Schirmer's test (8.2 ± 2.6 mm vs. 12.4 ± 3.1 mm, $p < 0.001$), and Oxford staining grade (median 3 [IQR 2–4] vs. 1 [IQR 1–2], $p < 0.001$). IOP showed moderate positive correlations with OSDI ($r = +0.52$, $p < 0.001$) and Oxford grade ($r = +0.52$, $p < 0.001$), and moderate-to-weak negative correlations with NIBUT ($r = -0.52$, $p < 0.001$) and Schirmer's test ($r_s = -0.41$, $p = 0.002$).

Conclusion: Polytherapy for POAG is associated with substantially greater ocular surface compromise than monotherapy. IOP levels correlate with ocular surface parameters, suggesting a reciprocal relationship between pressure control and surface health. Strategies to reduce medication burden by including fixed-dose combinations, preservative-free formulations, and laser trabeculoplasty merit consideration in patients with concurrent OSD.

Keywords: polytherapy; monotherapy; glaucoma medications; intraocular pressure; ocular surface disease

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1. INTRODUCTION

1.1. Primary Open-Angle Glaucoma and Medical Management

Primary open-angle glaucoma (POAG) is a progressive optic neuropathy characterised by structural damage to the optic nerve head and corresponding loss of visual field; it remains a leading cause of irreversible blindness globally[1,2].The only intervention with robust evidence for slowing disease progression is IOP reduction, and topical pharmacotherapy therefore underpins glaucoma management worldwide[1]. Current drug classes prostaglandin analogues, beta-adrenoceptor blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, and fixed-dose combinations reduce IOP through complementary effects on aqueous humour dynamics[3–5].

1.2. Ocular Surface Disease as a Complication of Anti-Glaucoma Therapy

Despite the efficacy of topical anti-glaucoma agents, their prolonged use is increasingly recognised as a significant cause of OSD. Clinically, this manifests as tear film

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instability, corneal and conjunctival epithelial dysfunction, goblet cell loss, and neurogenic changes, producing symptoms of dryness, foreign body sensation, and blurred vision[2,4]. Epidemiological data suggest that OSD affects 40–60% of glaucoma patients under pharmacological treatment, a prevalence markedly higher than in age-matched controls[6].

The pathogenesis is multifactorial. Long-term topical medication disrupts tight junctions of the corneal epithelium, reduces goblet cell density, and destabilises the lipid and mucin layers of the tear film[4–6].Benzalkonium chloride (BAK), the most widely used ophthalmic preservative, has been identified as a principal contributor through induction of epithelial apoptosis, oxidative stress, and upregulation of pro-inflammatory cytokines[7–9]. Jaenen et al., demonstrated that preserved formulations were associated with a higher frequency of OSD symptoms and signs than their preservative-free counterparts[7]. A study in Indian patients by Kumar et al. likewise found that BAK-preserved travoprost produced greater symptom burden and poorer quality of life than preservative-free formulations[9].

However, preservative toxicity alone does not fully explain ocular surface compromise. Preservative-free formulations have also been associated with surface changes, implying independent roles for the active drug molecule, instillation frequency, and cumulative dose[10,11]. Li et al., highlighted the importance of evaluating both local and systemic adverse effects when assessing long-term glaucoma pharmacotherapy[8].

1.3. Medication Burden, Treatment Adherence, and Alternatives

When a single agent fails to achieve target IOP, escalation to polytherapy is routine clinical practice. Several studies have established that patients on multiple topical agents have inferior tear film stability, greater epithelial staining, and higher symptom scores compared with those on monotherapy[12]. A five-year follow-up within the Glaucoma Intensive Treatment Study (GITS) further demonstrated that sustained polytherapy was associated with progressive deterioration of ocular surface health[13]. A systematic review by Kemer et al. confirmed medication burden as an important modifiable contributor to OSD in this population[14].

Adherence to multi-drop regimens is also compromised by the discomfort and instillation frequency associated with polytherapy. Evidence supports that fixed-dose combinations improve adherence and patient-reported outcomes by consolidating treatment into fewer daily drops[15,16]. Selective laser trabeculoplasty(SLT) has demonstrated non-inferior IOP reduction compared with topical medication in systematic reviews and meta-analyses, and may reduce or eliminate dependence on eye drops in eligible patients[17].

Despite global evidence, comparisons between monotherapy and polytherapy specifically within Indian patient populations remain limited, and the relationship between IOP levels and ocular surface compromise has not been clearly characterised. The present study therefore aimed to: (i) compare ocular surface parameters between POAG patients on monotherapy and polytherapy in a North Indian cohort; and (ii) examine the association between IOP levels and ocular surface health.

2. METHODS

2.1. Study Design and Participants

The study was a cross-sectional, observational, hospital-based study conducted at Shivom Eye Care, a private tertiary eye care centre in Gurugram, Haryana. Patient enrolment took place between January and December 2025. The study was conducted in accordance with the tenets of the Declaration of Helsinki[18]. Written informed consent was obtained from all participants after the purpose and procedures of the study had been explained in detail.

Seventy-two adults with bilateral POAG were recruited from routine outpatient follow-up visits. Inclusion required: characteristic glaucomatous optic disc changes with reproducible visual field loss, open anterior chamber angles, age ≥40 years, and continuous use of stable topical anti-glaucoma therapy for at least six months (to allow adequate time for surface changes to manifest)[1,2].An additional criterion requiring medication stability for at least three months immediately preceding enrolment was applied to minimise the confounding effect of acute medication changes on baseline surface parameters.

Patients were excluded if they had undergone ocular surgery within the preceding six months, had active ocular infection or inflammation, used contact lenses, used topical corticosteroids, had systemic autoimmune disease affecting lacrimal function, or had meibomian gland dysfunction requiring active treatment, as these conditions independently alter tear film parameters[3,4].

Participants were allocated to one of two groups based solely on the number of anti-glaucoma agents used: a monotherapy group (single topical agent, n = 36) and a polytherapy group (two or more agents, whether administered as individual drops or as a fixed-dose combination, n = 36). Drug class was not used as a criterion for group allocation. To prevent reflex tearing, all ocular surface assessments were performed before tonometry.

2.2. Ocular Surface Assessments

Symptom severity was quantified using the Ocular Surface Disease Index (OSDI), a validated 12-item questionnaire scored from 0 (no symptoms) to 100 (maximum severity) that assesses both symptom frequency and vision-related functional impact[18].

The stability of the tear film was determined by Non-Invasive Non-invasive tear break-up time (NIBUT). Without instilling any fluorescein dye, we positioned the patient at the slit lamp. The patient was asked to blink several times naturally, and then the patient was asked to keep the eyes open. The interval from the last blink to the appearance of the first dry spot was recorded. The Non-invasive tear break-up time is the interval from the last blink to the appearance of the first dry spot on the ocular surface[19]. Three consecutive readings were obtained and averaged; a value below 10 seconds was considered indicative of tear film instability.

Aqueous tear secretion was measured using Schirmer's Test I without topical anaesthesia. Standardised Whatman No. 41 filter paper strips were placed at the junction of the outer and middle thirds of the lower eyelid margin. Patients were asked to close their eyes gently; wetting length was measured after five minutes. A result below 10 mm was classified as reduced tear secretion[20].

Corneal and conjunctival epithelial integrity was evaluated using fluorescein staining graded according to the Oxford grading scheme (grades 0–5, higher grades indicating greater epithelial compromise)[21].

IOP was measured by Goldmann applanation tonometry, the recognised gold standard for clinical IOP assessment[22]. The mean of two measurements was used for analysis.

2.3. Statistical Analysis

Statistical analyses were performed with Jamovi software (version 2.3; The Jamovi Project, Sydney, Australia). Continuous data are reported as mean ± standard deviation (SD); ordinal data are reported as median and interquartile range (IQR). Distributional normality was assessed using the Shapiro–Wilk test. Between-group comparisons of normally distributed continuous variables used Student's independent t-test; the Mann–Whitney U test was applied for non-normally distributed data. Categorical variables were compared with the chi-square test. Associations between IOP and ocular surface parameters were examined using Spearman's rank correlation coefficient (r_s). All tests were two-tailed; statistical significance was defined as $p < 0.05$.

3. RESULTS

3.1. Baseline Demographic and Clinical Characteristics

Seventy-two patients were included (36 per group). Baseline characteristics were comparable between groups: mean age was 58.4 ± 9.2 years in the monotherapy group and 60.1 ± 8.7 years in the polytherapy group (p = 0.42, independent t-test); sex distribution did not differ significantly between groups (p = 0.61, chi-square test).

3.2. Comparison of Ocular Surface Parameters

Patients on polytherapy exhibited significantly worse outcomes across all four ocular surface parameters compared with those on monotherapy (Table 1, Figure 1).

OSDI scores were substantially higher in the polytherapy group (32.6 ± 8.4) than in the monotherapy group (21.3 ± 6.1), with a mean difference of 11.3 (95% CI: 7.6–15.0; p < 0.001). NIBUT was markedly shorter in polytherapy patients (6.8 ± 1.9 s vs. 10.9 ± 2.4 s; mean difference: −4.1 s, 95% CI: −5.1 to −3.1; p < 0.001). Aqueous tear secretion measured by Schirmer's Test I was also reduced in the polytherapy group (8.2 ± 2.6 mm vs. 12.4 ± 3.1 mm; mean difference: −4.2 mm, 95% CI: −5.6 to −2.8; p < 0.001). Corneal epithelial staining was more severe in polytherapy patients, with a median Oxford grade of 3 (IQR 2–4) compared with grade 1 (IQR 1–2) in the monotherapy group (Mann–Whitney U test, p < 0.001).

Analysis of severity grade distribution revealed a clear shift toward more severe categories in the polytherapy group across all parameters (Figure 2). No polytherapy patient achieved a normal NIBUT or Schirmer's value, whereas 3% and 22% of monotherapy patients did, respectively.

Table 1. Comparison of Ocular Surface Parameters Between Monotherapy and Polytherapy Groups

Parameter	Monotherapy (n = 36)	Polytherapy (n = 36)	p-value
OSDI score, mean ± SD	21.3 ± 6.1	32.6 ± 8.4	<0.001*
NIBUT (s), mean ± SD	10.9 ± 2.4	6.8 ± 1.9	<0.001*
Schirmer's Test I (mm), mean ± SD	12.4 ± 3.1	8.2 ± 2.6	<0.001*
Oxford staining grade, median (IQR)	1 (1–2)	3 (2–4)	<0.001*

**Statistically significant (p < 0.05). OSDI = Ocular Surface Disease Index; NIBUT = Non invasive tear break-up time; SD = standard deviation; IQR = interquartile range.*

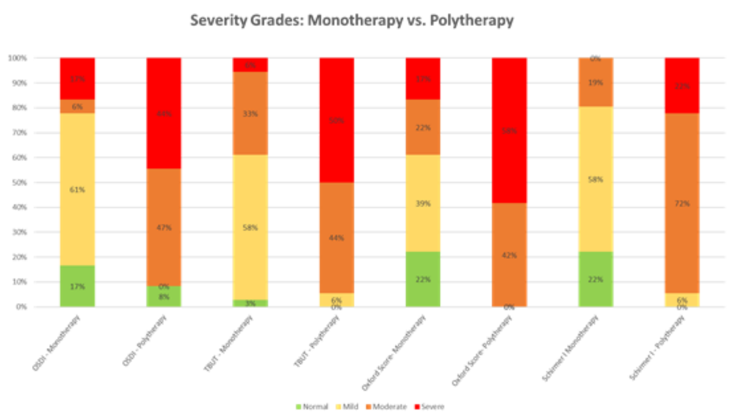

Figure 1: Comparison of Severity Grades: Monotherapy vs. Polytherapy

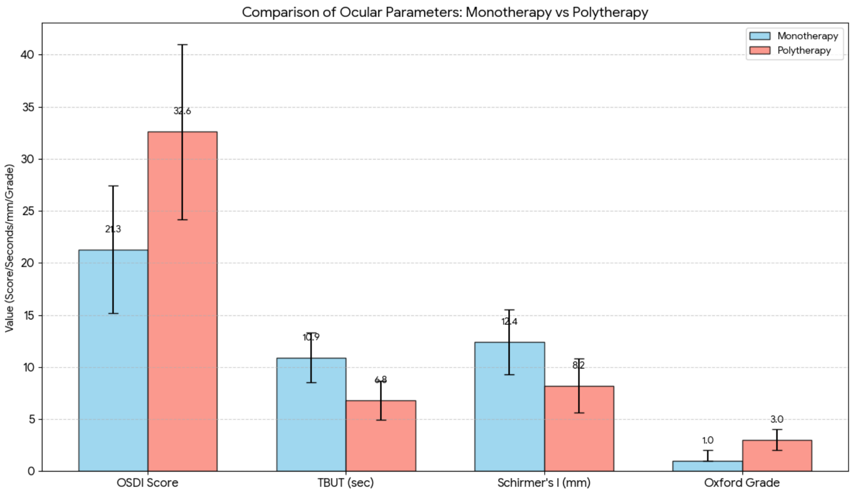

Figure 2: Comparison of Ocular Surface Parameters between Monotherapy and Polytherapy Groups

3.3. Correlation Between IOP and Ocular Surface Parameters

Spearman's rank correlations between IOP and ocular surface parameters as summarised in Table 2 and illustrated in Figure 3, IOP showed moderate positive associations with symptom severity as measured by OSDI ($r = +0.52$, $p < 0.001$) and with corneal staining severity ($r = +0.52$, $p < 0.001$). Conversely, IOP was moderately negatively correlated with NIBUT ($r = -0.52$, $p < 0.001$) and weakly negatively correlated with Schirmer's Test I values ($r = -0.41$, $p = 0.002$). These findings collectively indicate that higher IOP levels were associated with more severe ocular surface disease across both symptom and objective parameters.

Table 2. Spearman's Rank Correlations Between IOP and Ocular Surface Parameters

Parameter	Spearman's r	p-value
OSDI	+0.52	<0.001*
NIBUT	−0.52	<0.001*
Schirmer's Test I	−0.41	0.002*

**Statistically significant (p < 0.05). IOP = intraocular pressure; OSDI = Ocular Surface Disease Index; NIBUT = Non-invasive tear film break-up time.*

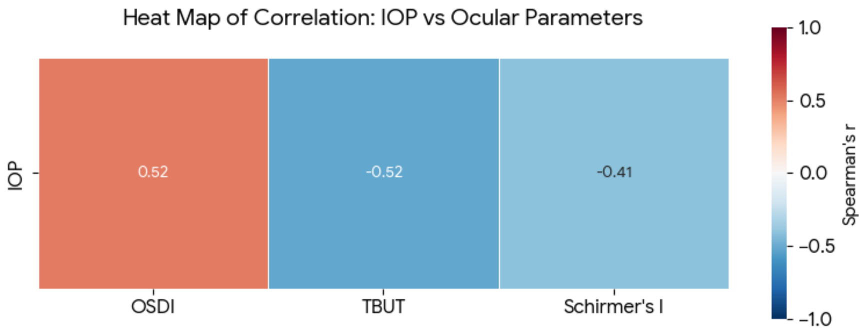

Figure 3: Heat map demonstrating correlations between intra-ocular pressure and ocular surface parameters.

3.4. Preservative Exposure Burden

In recognition of the known toxicity of BAK on the ocular surface, a post-hoc descriptive analysis compared daily preservative exposure between groups. As illustrated in Figure 4, there were marked differences in both the type and quantity of preservative exposure.

All patients in the polytherapy group were exposed to BAK, with 27.8% receiving high-frequency BAK exposure (two to three applications per day) due to the use of multiple preserved formulations. In contrast, 8.3% of monotherapy patients used preservative-free formulations and 11.1% used alternative preservative systems; none experienced high-frequency BAK loading. These differences in cumulative preservative burden may contribute to the pronounced surface changes observed in the polytherapy group, although causal inference is not possible from a cross-sectional design.

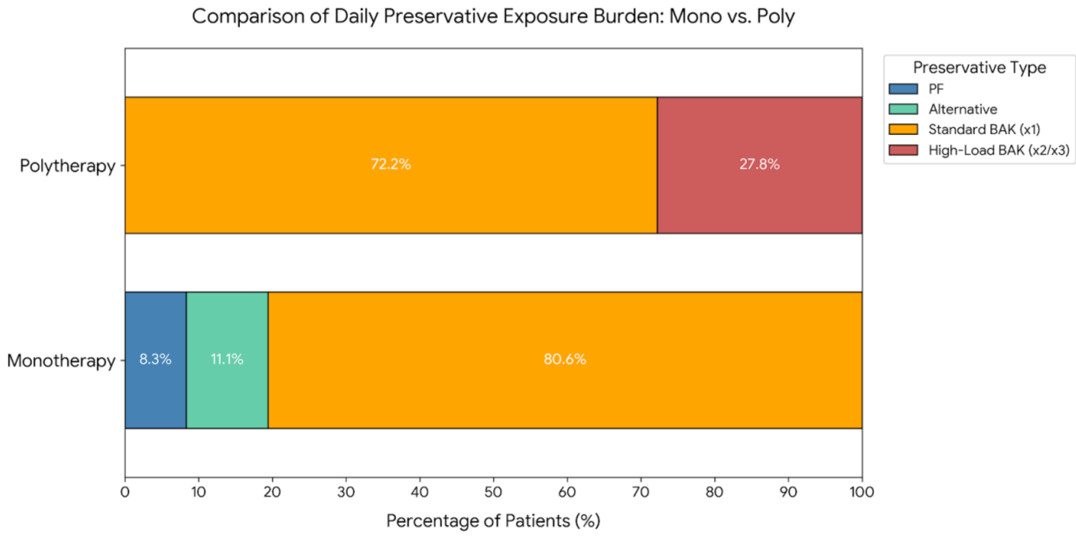

Figure 4: Comparison of Daily Preservative Exposure Burden: Monotherapy vs. Polytherapy

4. DISCUSSION

The principal finding of this study is that POAG patients receiving polytherapy had significantly worse ocular surface health as assessed by subjective symptoms and three objective clinical tests — compared with patients on monotherapy. This gradient of surface compromise with increasing medication burden aligns with prior literature[4,5,12] and extends this evidence base to a North Indian clinical population, where dedicated comparative data have been limited.

The mechanisms underlying medication-related OSD are well established. Prolonged topical anti-glaucoma therapy compromises the structural integrity of the corneal epithelium, reduces goblet cell density, impairs mucin and lipid secretion, and promotes chronic subclinical inflammation, as demonstrated in histological and confocal microscopy studies by Fineide et al.[4], and in cumulative tear film analyses by Zhou et al[5]. The role of BAK is particularly prominent in polytherapy patients: our descriptive analysis confirmed that more than a quarter of patients in this group were exposed to BAK multiple times daily, a pattern not observed in any monotherapy patient. This differential preservative burden almost certainly contributes to the severity gradient observed. However, it must be acknowledged that, even in the absence of preservatives, some degree of surface compromise has been reported, attributable to the pharmacological action of the active compounds and the mechanics of repeated drop instillation[11].

Findings from Kumar et al. and Bakirtzis et al., have demonstrated that switching to preservative-free formulations attenuates OSD severity, yet full recovery of surface parameters is not reliably achieved[9,10]. This observation underscores the importance of minimising medication load as a primary strategy, rather than relying solely on preservative elimination. A systematic review by Kemer et al. reinforced this principle, concluding that reducing medication burden should be considered an integral component of OSD management in glaucoma patients[14].

The correlation between IOP and ocular surface parameters observed in this study adds a further dimension to this discussion. Higher IOP was associated with greater symptom burden and more severe corneal staining, as well as shorter NIBUT and reduced Schirmer's values. Although a cross-sectional design precludes causal attribution, two plausible interpretations exist: first, patients with higher IOP are more likely to be on polytherapy, thereby incurring greater surface toxicity; second, OSD itself may adversely affect drug delivery and absorption, potentially reducing therapeutic efficacy and leading to suboptimal IOP control. These mechanisms are not mutually exclusive and may operate in a reinforcing cycle. The term "bidirectional" has been used in this context in prior literature, though longitudinal data would be required to formally test directionality.

Fixed-dose combinations offer a practical means to reduce both instillation frequency and total preservative exposure while maintaining IOP reduction, with adherence benefits documented in comparative studies[15,16]. Selective laser trabeculoplasty represents a non-pharmacological alternative that may reduce or eliminate dependence on topical therapy, with IOP-lowering efficacy equivalent to medication in eligible patients[17].

Several limitations should be considered. The cross-sectional design does not permit inference of causality or temporality. Recruitment from a single tertiary centre may limit generalisability. The duration of therapy, which is a relevant confounder, was not systematically recorded or analysed. Drug class-specific effects could not be isolated because grouping was based solely on drug number. Meibomian gland function was not assessed. Inflammatory biomarkers and medication adherence were not quantified.

Future longitudinal studies incorporating drug class stratification, preservative exposure quantification, and biomarker measurement would strengthen the evidence base.

5. CONCLUSION

Polytherapy for POAG is associated with significantly greater ocular surface compromise than monotherapy across symptom, tear film, secretory, and epithelial parameters. IOP levels were positively associated with OSD severity and negatively associated with tear film stability and secretion, consistent with an interaction between pressure burden and surface health. These findings reinforce the clinical rationale for minimising medication load through fixed-dose combinations, preservative-free agents, or laser-based therapy in patients with concurrent or at-risk OSD. Prospective multicentre studies with drug class stratification and longer follow-up are warranted to determine causality and optimal management pathways.

DECLARATIONS

Consent to Participate: This study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

Author Contributions: YA: conceptualisation, data collection, formal analysis, writing — original draft. RS: supervision, writing — review & editing. KM: clinical expertise, patient recruitment, writing — review & editing.

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