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Evaluation of the efficacy, safety, patient comfort, and preference of the fixed combination of brinzolamide 1%/timolol 0.5% in patients with pseudoexfoliation glaucoma

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ABSTRACT

Aims: The efficacy and safety of the fixed combination of brinzolamide 1%/timolol 0.5% (BTFC) have previously been demonstrated in primary open-angle glaucoma (POAG). The aim of this study was to evaluate the efficacy, adverse effect profile, and patient preference of BTFC in patients with pseudoexfoliation glaucoma (PXG), whose treatment approach is similar to POAG but whose clinical management is more challenging for various reasons.

Methods: A total of 37 eyes of 27 patients followed with a diagnosis of PXG were retrospectively analyzed. Intraocular pressure (IOP) values during the previous treatment period, the untreated baseline period, and at 1, 3, and 6 months after initiation of BTFC were evaluated. In addition, the efficacy, adverse effects, and patient preference related to BTFC were assessed.

Results: BTFC achieved a significant reduction of 33.4%-37.2% in IOP compared with baseline in PXG patients ($p<0.001$), and this effect was sustained throughout the 6-month follow-up. The most frequently reported adverse effect associated with BTFC was burning–stinging sensation (77%). While 48.1% of patients rated BTFC as very good and 51.9% as good, 51.9% preferred BTFC, whereas 18.5% preferred their previous treatment.

Conclusion: The findings indicate that BTFC is an effective treatment option preferred by patients with PXG, owing to its comparable efficacy and adverse effect profile relative to other antiglaucomatous therapies.

Keywords: Pseudoexfoliation glaucoma, brinzolamide/timolol, primary open-angle glaucoma

INTRODUCTION

Pseudoexfoliation glaucoma (PXG) is one of the most common causes of secondary open-angle glaucoma, developing as a result of the accumulation of pseudoexfoliative fibrillar material in the anterior segment of the eye, and is generally characterized by higher intraocular pressure (IOP) levels and a more aggressive clinical course.[1] The treatment approach for patients with PXG is similar to that for patients with primary open-angle glaucoma (POAG). However, because PXG patients typically present with higher IOP levels at the time of diagnosis and exhibit greater 24-hour IOP fluctuations, their response to medical therapy is often poorer compared with POAG patients.[2] Therefore, fixed-combination therapies are frequently preferred over monotherapy in this patient group.

Although several treatment options are available, fixed-dose combinations are currently used more frequently in both POAG and PXG patients. Most studies evaluating these combinations in the literature have been conducted in POAG populations. In a study by Mary S. Galose et al.,[3] both the brinzolamide 1%/timolol 0.5% fixed combination (BTFC) and the dorzolamide 2%/timolol 0.5% fixed combination (DTFC) were reported to provide a significant and clinically meaningful reduction in IOP.[3] Another study evaluating BTFC demonstrated that it is a safe and effective treatment option for lowering IOP in patients with POAG.[4]

Studies focusing exclusively on PXG patients are limited in number. In a study including 60 patients diagnosed with PXG, both DTFC and BTFC were shown to be effective in reducing IOP.[5] In another study conducted by Mustafa Eliacık et al.,[6] DTFC was reported to achieve a significant reduction in IOP at the end of the third month in PXG patients. Although the efficacy of both fixed combinations in PXG has been demonstrated, differences in tolerability and effectiveness may influence patient preference. Studies conducted in POAG populations have shown that BTFC is better tolerated than DTFC; additionally, other studies have reported that BTFC is associated with less topical discomfort, improvement in signs of ocular surface disease, and potentially better treatment adherence compared with DTFC.[7,8]

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Based on the available evidence, there is a lack of sufficient and comprehensive data in the literature evaluating the efficacy, tolerability, and patient preference of BTFC exclusively in PXG patients. Given that the IOP-lowering efficacy of both BTFC and DTFC has previously been demonstrated in PXG, and that BTFC has been reported to be better tolerated in POAG populations, it may be anticipated that BTFC would exhibit comparable tolerability and clinical efficacy in PXG patients, which may in turn influence patient preference.

The aim of the present study was to evaluate the IOP-lowering efficacy, adverse-effect profile, and patient preference of BTFC in patients with PXG, in comparison with other antiglaucomatous therapies.

METHODS

Ethics

This study was approved by the Clinical Researches Ethics Committee of Ankara Numune Training and Research Hospital (Date: 04.12.2013, Decision No: 56/2013). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Due to the retrospective nature of the study, the ethics committee waived the requirement for individual informed consent.

This study included 37 eyes of 27 patients who were followed in the Glaucoma Unit of our clinic with a diagnosis of PXG and treated with BTFC. Clinical and follow-up data were retrospectively reviewed from patient medical records. The patients included in the study had discontinued their treatments for various reasons and had not attended follow-up visits for at least 28 days; therefore, they could not be monitored during this period. Upon re-presentation, BTFC therapy was initiated in patients in whom elevated IOP was detected.

Patients were evaluated across a total of five distinct periods. The first period was defined as the phase during which antiglaucomatous treatments other than BTFC were used. The second period was defined as the baseline period, during which patients had completely discontinued all IOP-lowering therapies and had not attended follow-up for at least 28 days. Follow-up evaluations after the initiation of BTFC were conducted at 1 month, 3 months, and 6 months.

At all study periods, best-corrected visual acuity measured using the Snellen chart was recorded and converted to the logMAR scale for statistical analysis. Anterior segment examinations were performed using slit-lamp biomicroscopy, and angle assessments were carried out with a Goldmann gonioscopy lens. Fundus examinations were conducted using standard clinical methods. IOP measurements were performed in the morning hours (09:00-12:00) using Goldmann applanation tonometry.

At the sixth-month follow-up visit, patients were questioned regarding potential adverse effects related to BTFC use. Additionally, patients were asked to rate BTFC as "poor," "moderate," "good," or "very good," and to indicate their treatment preference between BTFC and their previous IOP-lowering therapy. In patients who discontinued BTFC, the reasons for treatment discontinuation were recorded.

Patients with a history of ocular trauma or intraocular surgery within the preceding six months, ocular infection or inflammation within the previous three months, uncontrolled diabetes mellitus or hypoglycemia, severe cardiovascular, renal, or hepatic disease, and pregnant patients were excluded from the study.

Statistical Analysis

The data were performed using IBM SPSS Statistics for Windows version 23.0. Continuous variables were expressed as mean±standard deviation and median [minimum-maximum], while categorical variables were presented as numbers and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Changes in IOP over time were analyzed using repeated-measures analysis of variance for normally distributed variables. The assumption of sphericity was evaluated using Mauchly's test; when the sphericity assumption was violated, the Greenhouse-Geisser correction was applied. For variables that did not meet normality assumptions, the Friedman test was used. Post hoc pairwise comparisons between baseline or previous IOP-lowering therapy and BTFC at 1, 3, and 6 months were performed using Bonferroni or Dunn corrections, as appropriate. A p value <0.05 was considered statistically significant. A post hoc power analysis was performed. Assuming a moderate effect size (Cohen's d=0.5), a two-sided alpha level of 0.05, and a paired-samples t-test design, the sample size of 37 eyes yielded a statistical power of 0.84.

RESULTS

The mean age of the patients included in the study was 68.7±9.7 years; 59.3% of the patients were male and 40.7% were female. The demographic characteristics of the patients, as well as visual acuity and biomicroscopic examination findings, are presented in detail in Table 1.

Table 1. Demographic characteristics, visual acuity, and biomicroscopic examination findings of the patients

Demographic characteristics		Treated eye	
Female, n (%)	11 (40.7)	Right, n (%)	6 (22.2)
Male, n (%)	16 (59.3)	Left, n (%)	11 (40.7)
Total patients, n (%)	27 (100)	Bilateral, n (%)	10 (37.03)
Age (years), mean (SD)	68.7±9.7	Visual acuity (LogMAR), mean (SD)	0.64±0.79
Hypertension, n (%)	11 (40.7)	Presence and type of cataract, n (%)	28 (75.6)
Diabetes mellitus, n (%)	7 (25.9)	Nuclear cataract, n (%)	25 (67.6)
Coronary artery disease, n (%)	5 (18.5)	Cortical cataract, n (%)	3 (8.1)
Thyroid disease, n (%)	3 (11.1)	Pseudophakia, n (%)	4 (10.8)
Rheumatoid arthritis, n (%)	1 (3.7)	Total eyes, n (%)	32 (86.5)
Family history of glaucoma, n (%)	10 (37.0)	Cup-to-disc ratio, mean (SD)	0.66±0.24
Smoking, n (%)	3 (11.1)		

SD: Standard deviation

In the pre-BTFC period, the most frequently used IOP-lowering agents were prostaglandin analogues, accounting for 29.7% of treatments. Evaluation of treatment regimens revealed that 37.8% of the patients were receiving monotherapy, 27.0% were treated with DTFC, 40.5% were receiving combination therapy, and 35.1% were on multiple-drug therapy. Subgroups of previous IOP-lowering treatments are summarized in Table 2.

Table 2. Subgroups and classification of previous intraocular pressure-lowering treatments

Treatment subgroup	Number of eyes, n (%)
None	2 (5.4)
PGA	11 (29.7)
Betaxolol 2.5%	3 (8.1)
DTFC	3 (8.1)
PGA/timolol 0.5%	5 (13.5)
DTFC+brimonidine 0.15%	2 (5.4)
PGA+brimonidine 0.15%	5 (13.5)
PGA+DTFC	3 (8.1)
PGA+dorzolamide 2%+brimonidine 0.15%	1 (2.7)
PGA+DTFC+brimonidine 0.15%	2 (5.4)
Total	37 (100)
Treatment category	**Number of eyes, n (%)**
Monotherapy	14 (37.8)
Combination therapy	15 (40.5)
DTFC-containing regimens	10 (27.0)
Multiple-drug therapy	13 (35.1)

DTFC: Dorzolamide 2%/timolol 0.5% fixed combination, PGA: Prostaglandin analogues (bimatoprost 0.03%, latanoprost 0.005%, travoprost 0.004%)

Compared with baseline IOP values, BTFC therapy resulted in statistically significant reductions in IOP at 1, 3, and 6 months, with decreases of 33.4%, 37.2%, and 36.4%, respectively ($p<0.001$ for all). In contrast, when compared with previous IOP-lowering therapies, reductions in IOP at 1, 3, and 6 months were 0.77%, 8.85%, and 7.19%, respectively, and these differences did not reach statistical significance ($p=0.482$, $p=0.051$, and $p=0.174$, respectively). All IOP values, as well as absolute and percentage changes, are presented in Table 3.

Adverse effects related to BTFC use were observed in approximately 33.3% of the patients, with the most frequently reported adverse effect being a burning-stinging sensation, accounting for 77.7% of reported events. All adverse effects associated with BTFC are listed in Table 4.

When patients evaluated BTFC in terms of comfort, all participants (100%) reported satisfaction with the treatment, rating it as good or very good. Accordingly, 51.9% of the patients indicated a preference for BTFC therapy. Findings related to comfort assessment and treatment preference are presented in Tables 5, 6 and Figure.

Table 4. Adverse effects observed after BTFC use

		n	%
Patients with adverse effects		9	33.3
Adverse effects	Blurred vision	2	22.2
	Metallic taste	1	11.1
	Burning-stinging sensation	7	77.7
	Ocular redness	2	22.2
	Dizziness	1	11.1

BTFC: Brinzolamide 1% / timolol 0.5% fixed combination

Table 5. Evaluation of BTFC in terms of comfort

Comparison with previous therapy	n	%
Very good	13	48.1
Good	14	51.9
Moderate	0	0
Poor	0	0

BTFC: Brinzolamide 1% / timolol 0.5% fixed combination

Table 6. Treatment preference of the patients

Treatment preference	n	%
BTFC	14	51.9
Previous IOP-lowering therapy	5	18.5
No preference	8	29.6

BTFC: Brinzolamide 1%/timolol 0.5% fixed combination, IOP: Intraocular pressure

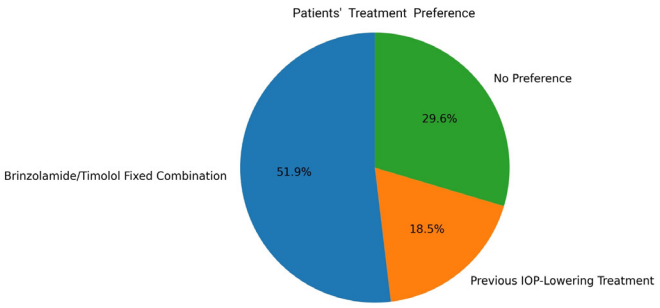

Figure. Treatment preference of the patients
IOP: Intraocular pressure

Table 3. Comparison of intraocular pressure values at 1, 3, and 6 months after initiation of BTFC according to baseline and previous therapy

Baseline	BTFC			p (baseline vs 1st month)	p (baseline vs 3rd month)	p (baseline vs 6th month)
	1st month	3rd month	6th month			
Mean IOP (mmHg Hg) 27.3±6.9	17.5±3.5	16.4±3.2	16.7±3.8			
Mean change in IOP (mmHg)	-9.84	-10.48	-10.21	p<0.001	p<0.001	p<0.001
Mean percentage change in IOP (%)	-%33.4	-%37.2	-%36.4			
Previous IOP-lowering treatment	BTFC			p (previous IOP-lowering therapy vs 1st month)	p (previous IOP-lowering therapy vs 3rd month) 1st month	p (previous IOP-lowering therapy vs 6th month) 3rd month
	1st month	3rd month	6th month			
Mean IOP (mmHg) 18.6±5.2	17.5±3.5	16.4±3.2	16.7±3.8			
Mean change in IOP (mmHg)	-1.14	-2.55	-2.27	p= 0.482	p=0.051	p=0.174
Mean percentage change in IOP (%)	-%0.77	-%8.85	-%7.19			

BTFC: Brinzolamide 1% / timolol 0.5% fixed combination, IOP: Intraocular pressure

DISCUSSION

The main finding of the present study is that BTFC may be considered a preferred treatment option among patients with PXG, given its comparable efficacy and adverse-effect profile when compared with other antiglaucomatous therapies.

PXG is a more severe and progressive form of glaucoma, characterized by higher IOP levels and marked fluctuations in the diurnal IOP curve; consequently, it exhibits a more resistant clinical course to medical therapy.[2] Although treatment is generally initiated with monotherapy, dual or multiple combination therapies are frequently required at an early stage, particularly in the management of PXG, to achieve lower and more stable IOP levels. DTFC and BTFC are commonly used in many glaucoma patients, either as direct fixed combinations or as components of multiple combination regimens added to other therapies. Consistent with the literature, our study demonstrated that most PXG patients were receiving combination or multiple therapies, with DTFC being the most frequently used agent among combination treatments. Previous studies including patients with PXG and POAG have shown that both DTFC and BTFC, which are widely used in combination therapy, provide effective IOP reduction.[5,9] Another study reported that BTFC is an effective treatment option and provides additional IOP reduction regardless of prior therapy.[10] In our study, BTFC therapy in patients with PXG was associated with a statistically significant reduction in IOP compared with baseline values. However, when BTFC was compared with previous IOP-lowering therapies, no statistically significant additional reduction in IOP was observed at any follow-up visit, indicating that the efficacy of BTFC was comparable rather than superior to that of prior treatments. Given the heterogeneity of prior treatment regimens and the absence of direct head-to-head drug comparisons, we believe that the efficacy outcomes observed after switching to BTFC should be interpreted with caution.

Although the efficacy of combination therapies has been well established, differences exist in their adverse-effect profiles. The majority of the available literature involves POAG and ocular hypertension (OHT) populations, in which PXG patients have often been evaluated only as a subgroup. In patients with POAG or OHT, DTFC and BTFC have been shown to provide comparable IOP-lowering efficacy; however, BTFC has been associated with less ocular irritation. Moreover, switching from DTFC to BTFC has been reported to be well tolerated, without negatively affecting IOP control or treatment adherence, and may represent an appropriate therapeutic alternative, particularly for glaucoma patients experiencing burning or stinging sensations.[11-14] Similarly, a common finding across other studies in comparable populations is that DTFC is more frequently associated with ocular irritation, whereas BTFC is more commonly linked to blurred vision.[15,16] Although the majority of the patients included in the study did not report any adverse effects, the most frequently reported adverse effect was a burning-stinging sensation, followed by blurred vision and ocular redness, both observed at similar frequencies. On the other hand, several studies have also evaluated the tolerability of these therapies and patient preference. In the study by Lanzl et al.,[10] the existing IOP-lowering treatments of patients diagnosed with POAG, OHT, and PXG were replaced with BTFC, and both IOP levels and treatment tolerability were assessed. At the end of the study, 87.2% of patients reported a positive treatment response (good/very good). When treatment preference was evaluated, 75.9% of patients indicated a preference for BTFC, 8.6% preferred to continue their previous therapy, and 15.5% reported no noticeable difference between treatments. In studies including POAG and OHT populations, the reported preference for BTFC has ranged from 60% to 79.2%,[16-18] and BTFC use has been associated with lower levels of patient-reported ocular discomfort.[18] In our study, all patients evaluated the transition to BTFC favorably, rating it as good or very good, and overall, nearly half of the PXG patients demonstrated a preference for BTFC over their prior therapies. The apparent discrepancy between the relatively high frequency of reported burning-stinging sensations and the universally favorable comfort ratings may be explained by the transient and mild nature of these symptoms. In addition, comfort was assessed as a global patient-reported outcome rather than a symptom-specific measure, which may have contributed to this observation. Furthermore, patients may have perceived these effects as less bothersome than those experienced with their previous treatments, particularly regimens involving DTFC or multiple topical agents. DTFC has a pH of 5.6, whereas BTFC has a pH of 7.2, which is more compatible with physiological ocular pH. This difference in pH may represent a potential explanation for the improved short-term ocular comfort and higher patient preference observed with BTFC in our study. Indeed, previous reports have suggested that the more pronounced ocular burning and stinging associated with DTFC use may be related to differences in pH.[19] Another possible contributing factor may be differences in the concentrations of the preservative benzalkonium chloride contained in combination formulations. Benzalkonium chloride has been shown to induce subclinical conjunctival inflammation and exacerbate ocular surface disease.[20] In our study, approximately one-third of patients had been using more than one topical preparation in their prior treatment regimens, which may have resulted in higher cumulative exposure to benzalkonium chloride. This increased exposure may have contributed to greater ocular irritation and, consequently, to a preference for BTFC therapy. In addition, switching from regimens involving two or more topical agents to a single fixed combination such as BTFC reduces the number of instilled drops, potentially improving ease of use and treatment adherence, which may further influence patient preference in favor of BTFC.

Limitations

This study has several limitations. First, its single-center, retrospective design and relatively small sample size may limit the generalizability of the findings. Second, the use of a non-randomized within-subject design, in which each patient served as their own control, together with the absence of a parallel control group, restricts the ability to perform direct head-to-head comparisons and to draw causal inferences regarding the superiority of BTFC over other antiglaucomatous therapies. In addition, the assessment of patient comfort and preference using subjective scales, rather than objective measures of ocular surface disease such as tear break-up time or ocular surface staining scores, necessitates cautious interpretation of conclusions suggesting greater acceptability of BTFC compared with other treatments.

Moreover, IOP measurements were obtained between 09:00 and 12:00. Given the well-documented diurnal fluctuations in IOP in PXG, peak IOP values may have been missed, which represents an additional limitation of the study. Furthermore, the frequent underrepresentation of PXG patients in the literature has resulted in limited availability of comparable data, making comprehensive comparisons with previous studies more challenging.

When these limitations are taken into account, the findings suggest that BTFC may represent a well-tolerated and patient-accepted therapeutic option in PXG; however, larger prospective controlled studies with greater sample sizes are required to confirm these observations.

CONCLUSION

In this study, the finding that BTFC demonstrates an efficacy and adverse-effect profile comparable to other antiglaucomatous therapies suggests that it may represent a suitable and potentially preferred treatment option for patients with PXG. In the existing literature, PXG patients have generally been evaluated within the broader context of POAG rather than as a distinct group. Accordingly, the present study is among the first to directly assess the efficacy, tolerability, and patient preference associated with BTFC specifically in patients with PXG.

ETHICAL DECLARATIONS

Ethics Committee Approval

This study was approved by the Clinical Researches Ethics Committee of Ankara Numune Training and Research Hospital (Date: 04.12.2013, Decision No: 56/2013).

Informed Consent

As this was a retrospective study, formal written informed consent was not required and was therefore not obtained.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

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Author Contributions

Author Contributions Concept: HE, ÖE; Design: HE, ÖE; Control: HE, ÖE; Data Collection and/or Processing: HE, ÖE; Analysis and/or Interpretation: HE, ÖE; Literature Review: HE, ÖE; Article Writing: HE, ÖE; Critical Review: HE, ÖE.

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