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Original Article

Ophthalmology Section

Prevalence of Dry Eye Disease among Patients with Glaucoma using Topical Antiglaucoma Medications: A Cross-sectional Study from a Tertiary Care Hospital of Eastern India

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ABSTRACT

Introduction: Dry Eye Disease (DED) is a common, chronic, multifactorial disorder of the tear film and ocular surface that significantly affects quality of life and treatment adherence in patients with glaucoma. Long-term use of the topical antiglaucoma medications, especially those containing preservatives, has been implicated in ocular surface damage.

Aim: To determine the prevalence and severity of DED among patients with glaucoma using topical antiglaucoma medications.

Materials and Methods: This hospital-based, cross-sectional study was conducted in the Department of Ophthalmology of a tertiary care teaching Institute in Kolkata, West Bengal, India, over 18 months (June 2023-December 2024). Glaucoma patients, aged more than 40 years, on topical antiglaucoma therapy for ≥6 months, were included. DED was evaluated using the Ocular Surface Disease Index (OSDI), Schirmer's I test, Tear Film Break-up Time (TBUT) and corneal fluorescein staining. Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 23.0. Association of glaucoma with various background-related study parameters of patients were analysed by using the Chi-square test and binary logistic regression analysis. A p-value <0.05 was considered statistically significant.

Results: A total of 206 patients with glaucoma were included in the study among them 78 (37.9%) were male and 128 (62.1%) were female with the mean age of 64.38±10.288 years. The prevalence of DED was 68.9%. Increasing age (p-value=0.04), longer duration of topical antiglaucoma therapy (p-value <0.001), and higher number of topical medications (p-value=0.027) were significantly associated with DED. A Receiver Operating Characteristics (ROC) curve analysis demonstrated that duration of topical therapy was a strong predictor of DED {Area Under Curve (AUC=0.965)}, with a cut-off value of 10.5 months showing 97.2% sensitivity and 81.2% specificity.

Conclusions: DED is highly prevalent among patients with glaucoma using topical antiglaucoma medications. Duration of therapy is a strong predictor of DED development. Early screening and appropriate management of ocular surface disease are essential to improve quality of life and treatment adherence.

Keywords: Benzalkonium compounds, Medication adherence, Ocular surface diseases, Tear film instability

INTRODUCTION

Dry Eye Disease (DED) is a common, chronic, and multifactorial disorder of the tear film and ocular surface, characterised by symptoms of discomfort, visual disturbance, and tear film instability, often accompanied by increased osmolarity and inflammation of the ocular surface. It has significant impacts on patients' quality of life and can interfere with adherence to topical ocular therapies [1]. Glaucoma, the second leading cause of irreversible blindness worldwide, is typically managed with long-term use of topical intraocular pressure-lowering medications [2]. While these medications are essential for preserving visual function, their chronic use, particularly those containing preservatives such as Benzalkonium Chloride (BKC), has been strongly implicated in contributing to ocular surface disease. BKC, due to its detergent properties, may disrupt the lipid layer of the tear film, damage epithelial cells, and exacerbate inflammation, leading to or worsening DED [3]. Furthermore, the cumulative effect of multiple medications and frequency of doses further increases the risk of developing dry eye symptoms. Previous research has reported a higher prevalence of DED in patients undergoing antiglaucoma therapy compared to the general population [4]. The prevalence of subjective Ocular Surface Disease (OSD) was significantly higher among users of topical antiglaucoma medications than non users. Hence, preserved topical medication use is a serious concern for increased ocular surface morbidity among glaucoma patients. This calls for more attention to be paid to the consequences of OSD among glaucoma patients on topical medications [5]. OSD could influence treatment adherence and prognosis, thus greatly influencing the quality of life of glaucoma patients [6]. Despite these observations, several gaps remain in the existing literature. Most studies have been limited by small sample sizes and heterogeneous diagnostic criteria [7,8]. Data from Eastern India are scarce, particularly studies [6,9,10] that comprehensively evaluate both prevalence and severity of DED using a combination of subjective symptom assessment and objective tear function tests. Furthermore, while duration and number of medications have been identified as risk factors, the predictive value of treatment duration and clinically relevant cut-off thresholds for early identification of DED has not been adequately explored. With this background, the present study was conducted to determine the prevalence and severity of DED in patients using antiglaucoma medications.

MATERIALS AND METHODS

This hospital-based, cross-sectional study was conducted at the Ophthalmology Outpatient Department (OPD) of a tertiary care teaching

Institute in Kolkata, West Bengal, India, over the period of 18 months from June 2023 to December 2024, on patients diagnosed with any type of glaucoma, who were on topical antiglaucoma medication(s) for at least 6 months and above. All procedures performed in the current study were approved by the Institutional Ethics Committee in accordance with the 1964 Helsinki declaration and later amendments (IEC Memo No. R G Kar MCH/RKC/900, Date: 5.06.2023). Informed written consent was obtained from each patient.

Inclusion criteria: The patients above 40 years of age diagnosed with any type of glaucoma, on topical antiglaucoma medication(s) for 6 months or longer, were included in this study.

Exclusion criteria: Patients having pre-existing DED, prior history of ocular trauma, chemical injury, active or recent ocular infection, prior corneal surgery, pre-existing eyelid abnormality, lacrimal or meibomian gland abnormality and unwilling persons were excluded.

Sample size calculation : As per a similar study in India done by Sujatha G et al., the proportion of dry eye cases among glaucoma patients was 84%[6]. The sample size in the study was calculated as

$(n) = z^2p(1-p)/d^2$

where (z) = 1.96, absolute precision (d) = 5%, (p) = 16%, Confidence Interval (CI) = 95%]

= 206.

From each patient, the eye that fulfilled the inclusion criteria and didn't meet any of the exclusion criteria was selected. When both eyes met the inclusion and exclusion criteria, the eye with the more severe dry eye was selected for the study.

Study Procedure

Demographic characteristics, including age, gender, co-morbidities, duration of therapy, no of topical antiglaucoma medications and study parameters data were noted on a predesigned proforma. Following detailed clinical examination, ocular examination, aided Snellen's visual acuity, intraocular pressure (Goldman applanation tonometry), ocular surface evaluation tests, TBUT, Schirmer's I test, corneal and conjunctival fluorescein staining and OSDI were performed.

The OSDI responses were elicited in a 5-point Likert scale. Scores were assigned against each answer. The higher the score, the greater the severity of the DED [11]. The OSDI questionnaire, originally developed by Schiffman RM et al., in 2000 was used to assess dry eye symptoms and their impact on vision-related functioning [12].

Total OSDI score was calculated using the formula:

$$\frac{\text{sum of scores for all questions asked X 25}}{\text{total number of questions answered.}}$$

Based on the OSDI score, the severity of DED was as follows:

- Normal (score within 0-12),
- Mild (score within 13-22),
- Moderate (score within 23-32),
- Severe (score within 33-100).

Schirmer's test I without anaesthesia to assess tear production was done. Wetting of less than 10 mm in 5 minutes would indicate a diminished lacrimal secretion.

Values were classified as follows:

- Normal tear production (>10 mm),
- Mild to moderate tear deficiency (6-10 mm),
- Severe deficiency of tears (<6mm) [13].

The TBUT to assess tear film stability was done and the values were classified as normal tear film stability (10 seconds), mild to moderate loss in tear film stability (5-9 seconds), severe loss in tear film stability (<5 seconds) [14].

Corneal and conjunctival fluorescein staining was done to assess tissue integrity under a slit-lamp microscope with 10x magnification. The extent of staining of the conjunctiva and cornea was assessed and grading was done as per the standard Oxford chart [15]. No staining (grade 0), mild staining (grades I and II), moderate staining (grade III) and severe staining (grade IV and V) grades were given.

STATISTICAL ANALYSIS

The principles of descriptive statistics were applied to organise and present the data in tables and diagrams. Data analysis was done by using the Statistical Package for Social Sciences (SPSS) version 23.0. Association of glaucoma with various background-related study parameters of patients were analysed by using the Chi-square test and binary logistic regression analysis. Sensitivity and specificity assessment and ROC curve analysis were used to predict the development of DED. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 206 patients with glaucoma were included in the study, among them, 78 (37.9%) were male and 128 (62.1%) were female. Mean age of presentation of DED was 64.38±10.288 years [Table/Fig-1]. Sixty-two participants out of a total 122 (50.81%) urban population and 43 out of a total 84 (51.1%) rural population presented with DED.

Age range (in years)	Frequency (%)
40-50	26 (12.6)
51-60	34 (16.5)
61-70	86 (41.7)
71-80	51 (24.8)
>81	9 (4.4)
Total	206
Age (Mean±SD)	64.38±10.288 years

[Table/Fig-1]: Distribution of study participants as per their age (N=206).

The mean duration of topical antiglaucoma therapy was 14.981±6.770 months. Most participants, 125 patients (60.7%) had been on that therapy for 13-24 months [Table/Fig-2].

Duration of topical medication (in months)	n (%)
<12	65 (31.6)
13-24	125 (60.7)
25-36	16 (7.8)
Total	206 (100)

[Table/Fig-2]: Distribution of study participants as per duration of topical antiglaucoma medications (N=206).

The majority 97 patients (47.1%) were prescribed two topical medications, while 94 (45.6%) were on three medications [Table/Fig-3].

No. of topical antiglaucoma drugs prescribed	n (%)
1	15 (7.30)
2	97 (47.1)
3	94 (45.6)
Total	206 (100)
No. of topical drugs per study subject (Mean±SD)	2.38±0.620

[Table/Fig-3]: Distribution of study participants as per number of topical antiglaucoma medications prescribed (N=206).

A total of 142 study participants (68.9%) were found to have DED as per the OSDI score, whereas 64 (31.1%) were not found to have DED [Table/Fig-4]. Seventy-one patients (34.5%) had mild to moderate loss in tear film stability and 72 (35%) had severe loss in tear film

stability [Table/Fig-4]. Sixty-five patients (31.6%) had normal tear production, 54 (26.2%) had mild to moderate tear deficiency and 87 (42.2%) had severe tear deficiency. Among them, 62 (30.1%) patients had normal conjunctival and corneal tissue integrity, 64 (31.1%) had mild, 35 (17%) had moderate and 45 (21.8%) had a severe degree of damage in conjunctival and corneal tissue integrity [Table/Fig-4].

Severity of DED (based on OSDI score)		TBUT		Tear production (Schirmer's test I)		Damage in corneal integrity (CF staining)	
Study variable	n (%)	Study variable	n (%)	Study variable	n (%)	Study variable	n (%)
None	64 (31.1)	Normal	63 (30.5)	Normal	65 (31.6)	None	62 (30.1)
Mild	41 (19.9)	Mild to moderate loss	71 (34.5)	Mild to moderate loss	54 (26.2)	Mild	64 (31.1)
Moderate	59 (28.6)	Severe loss	72 (35)	Severe loss	87 (42.2)	Moderate	35 (17)
Severe	42 (20.4)					Severe	45 (21.8)

[Table/Fig-4]: Distribution of study subjects as per severity of DED based on OSDI score, tear film stability based on Tear Film Break-up Time (TBUT), tear film stability based on tear production (Schirmer's test) and damage in corneal tissue integrity based on conjunctival and Corneal Fluorescein staining (CF staining) (N=206).

Patient's age (p-value 0.04), duration of topical antiglaucoma medication (p-value <0.001), and number of topical antiglaucoma agents prescribed (p-value=0.027) were statistically significant with the development of DED among the study participants [Table/Fig-5].

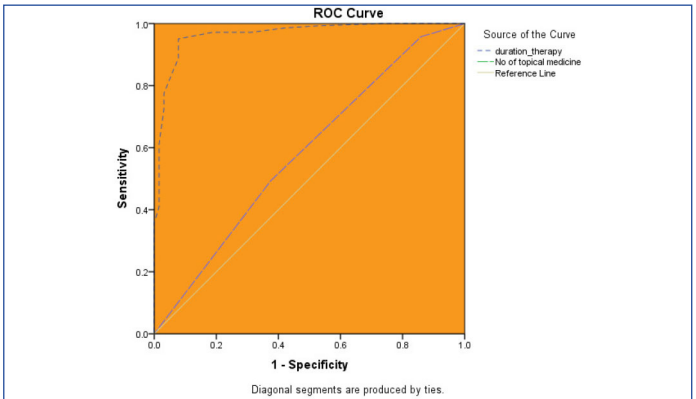
Study variables	Total sample (N=206)	Study subjects as per DED (frequency)		Chi- square test
		Present (n=)	Absent (n=)	p-value
Age range (in years)				
40-50	26	16	10	0.04*
51-60	34	18	16	
61-70	86	62	24	
71-80	51	37	14	
>81	9	9	0	
Residence				
Urban	122	62	60	0.138
Rural	84	43	41	
Gender				
Male	78	55	23	0.702
Female	128	87	41	
Duration of topical antiglaucoma therapy (in months)				
<12	65	6	59	<0.001**
13-24	125	120	5	
25-36	16	16	0	
No. of topical antiglaucoma agents prescribed				
1	15	6	9	0.027*
2	97	66	31	
3	94	70	24	

[Table/Fig-5]: Bivariate analysis between DED with background characteristics of study subjects (N=206).

Duration of topical antiglaucoma medication in months was a significant predictor for the development of DED (AUC value=0.965). Duration of disease had a higher discriminative value than the number of topical medicines prescribed [Table/Fig-6,7]. Duration of topical antiglaucoma medications for more than 10.5 months can be an effective tool to predict DED development with a sensitivity of 97.2% and specificity 81.2%.

Parameters	AUC	Standard error	Significance	95% CI	
				Lower bound	Upper bound
Duration of therapy	0.965	0.013	<0.001**	0.939	0.991
Number of topical medicines prescribed	0.581	0.044	0.062	0.495	0.667

[Table/Fig-6]: Area Under the Curves (AUC) value for ROC curves.



[Table/Fig-7]: ROC curve analysis to assess duration of topical antiglaucoma medication vs number of topical antiglaucoma medicines prescribed for prediction of development of DED (N=162).

DISCUSSION

In the present study, the mean age of the study population was 64.38±10.29 years, with the majority of patients belonging to the 60-70 year age group and a female predominance (128 or 62.1%). This age distribution is comparable to the findings of Shah S and Jani H [16] who reported a mean age of 58.6 years among glaucoma patients with ocular surface disease. Advancing age is a well-recognised risk factor for DED due to age-related changes in tear film composition, reduced lacrimal gland function, and increased ocular surface inflammation. The overall prevalence of DED in this study was 68.9% (142/206), indicating a high burden of ocular surface disease among glaucoma patients receiving topical antiglaucoma medications. This prevalence is comparable with previous reports by Zemba M et al., (prevalence 63%) [17] and Sahlu M and Giorgis AT (prevalence 76%) [18], reinforcing the strong association between chronic topical antiglaucoma therapy and DED. In the present study, moderate to severe DED constituted nearly half of the affected cases, highlighting the clinical significance of ocular surface involvement in this population.

A cross-sectional study conducted by Thirunavukkarasu A and Karunakaran R found mild to severe abnormality in 106 (66%) corneal staining, 79 (49%) TBUT, and 91 (57%) Schirmer's test in the glaucoma patients [19].

In the present study, the prevalence of OSD in patients on topical antiglaucoma medications was found to be 68.9%, 68.4%, 69.5% based on OSDI questionnaire, Schirmer's test and TBUT test, respectively which can be corroborated with a study done by Chanekar SN et al., [9] They observed the prevalence of OSD as 74%, 69% and 83% based on OSDI questionnaire, Schirmer's test, and TBUT test, respectively.

In the present study, advanced age (p-value=0.04*), duration of topical therapy (p-value <0.001**) and number of topical antiglaucoma agents prescribed (p-value=0.027**) were significantly associated with the development of DED. Frequency of DED was directly related to the duration of topical antiglaucoma therapy. Total of 120 out of 125 patients (96%) using antiglaucoma medications for 12-24 months developed DED in the current study. This observation corroborates the findings of Sujatha G and Palle S [6], the authors observed a serious impact on the tear function tests and low-grade metaplasia in 84% of the patients at the end of 12 months of treatment and the impact was directly related to the number of medications used. They also found that ocular surface disease

could influence treatment adherence and prognosis, thus greatly influencing the quality of life.

Duration of topical antiglaucoma medication was found to have better predictive value in ROC curve analysis than number of topical drugs prescribed to study subjects in the present study. A hospital based descriptive cross-sectional study conducted by Abu EK et al., [20] had shown that DED was prevalent among glaucoma patients in Ghana and was associated with age, duration of glaucoma medication, type of preservatives, and number of topical antiglaucoma medications used. Another study done by Leung EW et al., found that 60 (59%) patients reported symptoms of OSD in at least 1 eye. Multivariate logistic regression models were used in that study to investigate the association between the number of BKC-containing eyedrops and the results on the clinical tests of OSD. They concluded that each additional BKC-containing eyedrop was associated with an approximately 2 times higher odds of showing abnormal results on the lissamine green staining test (odds ratio=2.03; p-value=0.034)*. [7] There was an increase in the severity of OSD with increased duration of treatment and a higher number of topical antiglaucoma medications. Severity of OSD was directly proportional to duration of treatment and number of drugs used as observed by Chanekar SN et al., [9]. Patients on longer duration (greater than 15 months) of topical antiglaucoma medications and on multiple topical antiglaucoma drugs had higher OSDI score, lesser TBUT, and lesser Schirmer test values. OSDI score had strong positive correlation with TBUT (p-value=0.0001;r-value=0.82) and Schirmer's test (p-value=0.0001;r-value=0.89) as observed by Thirunavukkarasu A and Karunakaran R [19]. A prospective randomised trial conducted by Ingle SY and Biswas S at Susrut Eye Foundation and Research Centre, Kolkata, investigated that 50 eyes of 25 patients using two or more antiglaucoma medications for six months had a greater prevalence of ocular surface disease and dry eye. The causative factors were medications with preservatives and longer treatment duration. [10] Since antiglaucoma drugs had to be used for a long period of time, chronic side effects were the major concern. The most common side-effects were ocular surface changes and reduced tear secretion, resulting in dry eyes apart from causing irritation, stinging, redness and blepharoconjunctivitis. These ocular side effects were caused either by the drug itself or its preservatives [21].

There is a lack of widely accepted criteria for the diagnosis of dry eye. The OSDI questionnaire was used as a screening survey for assessing symptoms and their impact on visual functions. It could also discriminate between normal, mild, moderate and severe ocular surface disease [22]. The current study assessed the prevalence and severity of DED among glaucoma patients using topical antiglaucoma medications, which is still underdiagnosed in Eastern India.

Limitation(s)

The present study was unicentric, hospital-based and might not reflect the burden of DED in the community. Future researchers can conduct larger studies in this domain, particularly for studies of longitudinal design with a greater sample size in a multicentre manner.

CONCLUSION(S)

A high prevalence of DED (68.9%) was observed among glaucoma patients treated with topical antiglaucoma medications. Ocular surface changes, alteration in corneal tissue integrity and reduction in tear production were prominent in those patients. Age, duration of topical antiglaucoma medication and multiple antiglaucoma drugs might be a significant predictive tool for the occurrence of DED. Duration of topical antiglaucoma medications for ≥ 10.5 months could be an effective tool to predict DED. Adequate management of dry eye could prevent morbidity effectively.

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