RELEVANCE OF OCULAR SURFACE DISEASE INDEX (OSDI) QUESTIONNAIRE IN MINIMISING OPTIC NERVE DAMAGE AMONG GLAUCOMA POPULATION IN THE COMMUNITY

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ABSTRACT

BACKGROUND
Glaucoma is one of the leading causes of blindness worldwide. Majority of these patients need lifelong medical therapy in the form of topical medications. Most of these medications contain preservatives, which have deleterious effects on eyes of patients causing Ocular Surface Disorder (OSD). When left undiagnosed, OSD can lead to noncompliance further deteriorating the situation and causing progression of glaucoma. Dry eye symptoms in glaucoma patients under topical medications can be ascertained with a simple 12-query OSDI (ocular surface disorder index) questionnaire. But, it needs to be assessed whether this can be relied on to establish a clinical diagnosis.

The aim of the study is to correlate subjective OSDI scores with objective clinical findings in glaucoma patients using topical medications.

MATERIALS AND METHODS
110 patients of primary open-angle glaucoma on antiglaucoma medications for >3 months underwent OSDI scoring and three clinical tests, Tear Film Break-Up Time (TBUT), Schirmer-1 Test and Lissamine-Green (LG) staining of ocular surface. A clinical diagnosis of dry eye was considered if either eye showed TBUT <10 seconds or on Schirmer-1 test <10 mm or positive LG staining.

Statistical analysis was done to know the correlation between OSDI scores and clinical diagnosis. Setting and Design- Prospective, single visit, comparative study carried in a tertiary care hospital.

RESULTS
44 patients (40%) had OSDI scores ≥13 indicating dry eye disease. 54 patients (49.1%) had TBUT <10 seconds, 41 patients (37.27%) had Schirmer-1 test <10 mm and 18 patients (16.36%) had positive Lissamine-Green staining. So, dry eye was diagnosed in 54 patients (49.1%). We found that OSDI scores have a sensitivity of 81.48% and specificity of 100% in diagnosing dry eye. On Chi-square test, OSDI scores and diagnosis of dry eye have statistically significant correlation (p value <0.0001).

CONCLUSION
In our study, OSDI scores significantly correlates with the prevalence of clinical signs. So, this simple and inexpensive OSDI questionnaire can diagnose dry eye among glaucoma patients and will help in increasing compliance. It can be very helpful in developing countries, particularly in remote communities where objective tests are not available, to preserve vision of glaucoma patients.

KEYWORDS
Dry Eye; OSDI Questionnaire; Glaucoma; Tear Film Break-Up Time; Schirmer-1 Test; Lissamine-Green Staining.

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BACKGROUND
Glaucoma is a major public health concern being the second leading cause of blindness worldwide.1,2 In a cross-sectional study, it was found that one-fifth of Primary Open-Angle Glaucoma (POAG) patients in India had blindness in either eye due to glaucoma.3 Medical treatment being the first line of therapy in POAG may have to be continued for the entire lifetime. Studies show that 75% of patients end up using two or more drugs within 2 years of initial treatment.4 But, long-term administration of these topical drugs cause Ocular Surface Disorders (OSD) with patients suffering from burning or stinging sensations, dry eyes and corneal conjunctival changes. The toxic effects of preservatives like Benzalkonium Chloride (BAK) in topical medications have been well documented.5 These preservatives are toxic to corneal epithelium, conjunctival epithelium and stroma. They make the precorneal tear film unstable, cause

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superficial punctate keratitis and inflammatory scarring of the conjunctiva, thus compromising the success of future filtration surgeries. These changes are both time- and dose-dependent.6,7 Discomfort following instillation of drops may lead to two thirds of the patients discontinuing their treatment8 and consequent progression of glaucoma.4

Ocular Surface Disease Index (OSDI) Score ≥13 was found in more than half of the population with glaucoma and this is more than double the prevalence (15%) of dry eye in elderly patient population.9 Comorbidity of OSD with glaucoma may lead to noncompliance and consequently more drugs are added to control the rising Intraocular Pressure (IOP) creating a vicious cycle.10

As ophthalmologists are more concerned with glaucoma management generally, the issue of OSD remain neglected. A simple subjective test with OSDI questionnaire, which has excellent test-retest reliability can effectively classify clinically normal, mild, moderate and severe OSD to guide the treatment.11 Subjecting all medically-treated glaucoma patients to a simple 12-question OSDI questionnaire may help early identification and management of OSD. Thus, OSDI can help to reduce noncompliance in glaucoma treatment,12 thereby limiting the consequent optic nerve damage. In our densely populated country where objective test facilities are unavailable in remote areas and burden of glaucoma is huge. Introducing this questionnaire can be invaluable in screening of OSD in glaucoma patients under medical management. The test is simple to perform and even nonmedical personnel can easily do it with some training.

This study aims to correlate the subjective OSDI scores of glaucoma patients with their objective clinical diagnosis and to establish the relevance of cost-free OSDI questionnaire in diagnosing OSD in glaucoma patients under medical treatment.

MATERIALS AND METHODS

Inclusion Criteria
- Adult patients >40 years of age.
- Diagnosed with bilateral POAG.
- Applying topical antiglaucoma medications in both the eyes for 3 months or more.

Exclusion Criteria
- Previously diagnosed OSD.
- Concurrent conjunctivitis, keratitis, blepharitis or uveitis in either eye.
- Ocular trauma, surgery or laser therapy within last 6 months.
- Use of corticosteroid within last 1 month.
- Contact lens usage.
- Inability to comprehend the OSDI questionnaire.

This was a prospective, randomised, single visit, hospital-based comparative study carried out from November 2016 to June 2017. Ethics committee approval for the study was obtained. Recruitment was done from patients attending glaucoma clinic. 110 patients were selected who met the inclusion and exclusion criteria. After being explained the study protocol, patients signed the informed consent agreement. A detailed history taking with treatment record and clinical examination were done.

The patients were subjected to the OSDI questionnaire. OSDI questionnaire was developed by the Outcomes Research Group at Allergan Inc. (Irvine, California). This questionnaire includes 3 subscales- ocular discomfort (OSDI-symptoms); functioning (OSDI-function); and environmental triggers (OSDI-triggers). Patients responded to the queries on their own based on their personal recent experiences recalled from the past 1 week. The boxes corresponding to the severity of their symptoms were marked. Each answer represented a specific score and finally OSDI score was calculated. The unanswered queries were not factored into the score calculation.

![OSDI Score Formula](image)

OSDI severity was classified on a scale of 0 to 100 with higher scores representing greater disabilities as follows:
- Normal = 0 to 12; Mild = 13 to 22; Moderate = 23 to 32; Severe = 33 to 100.

Then, patients underwent three clinical tests- Tear Film Break-Up Time (TBUT), Schirmer-1 test and Lissamine-Green staining of ocular surface. A normal tear film usually takes >10 seconds to break up. TBUT assesses mucin deficiency of tear film and the average of 3 readings was taken. A TBUT of less than 10 seconds was considered abnormal. To assess aqueous tear deficiency, Schirmer-1 test was done and the amount of wetting of Whatman filter paper No. 41 (5 mm × 35 mm) in 5 minutes was measured. A wetting of less than 10 mm was considered positive. Lissamine-Green (LG) staining identifies devitalised epithelial cells. Otto-Paul van Bijsterveld introduced numerical scoring for the intensity of vital staining of bulbar conjunctiva and of cornea.13 He found the best staining intensity score was 3.5 to differentiate between normal persons and keratoconjunctivitis sicca patients. Cornea and interpalpebral conjunctiva on lateral and medial sides are considered 3 different zones and degree of staining in each zone is measured by van Bijsterveld scoring- 0 = normal/no spots; 1 = few spots; 2 = many spots; 3 = severe/confluent spots. A sum of the degrees of staining of the 3 zones gives the total score and a score ≥4 was considered positive for dry eye. The diagnosis of dry eye was made if any of the three tests was positive in either eye of the patient. Statistical analysis was done to calculate validity and predictive value of the OSDI scores and to find correlation between the OSDI scores and clinical diagnosis of dry eye in glaucoma patients under treatment.

**Figure 1. Ocular Surface Disease Index (OSDI) Questionnaire**

Ask patient the following 12 questions and circle the number in the box. Then, fill in boxes A, B, C, D, and E according to the instructions.
In our study, 110 patients were enrolled and evaluated clinically. Out of 110 patients, 62 were females and 48 were males ranging in age from 44 to 72 years. Patients were under medical treatment and applying topical medication in both the eyes. Time period for treatment in both the eyes was found between 4 months and 18 years.

Out of 110, 44 patients (40%) were diagnosed with dry eye based on their OSDI scores. 11 patients (10%) were graded mild, 15 patients (13.6%) moderate and rest 18 patients (16.4%) had severe dry eye (Table 1). On evaluating TBUT of the patients, we found 54 patients (49.1%) were positive for dry eye (Table 2). Out of these 54 patients, 44 had OSDI scores ≥13. On calculating validity of OSDI score in relation to TBUT, 81.48% sensitivity, 100% specificity was found (Table 3).

### RESULTS

In our study, 110 patients were enrolled and evaluated clinically. Out of 110 patients, 62 were females and 48 were males ranging in age from 44 to 72 years. Patients were under medical treatment and applying topical medication in both the eyes. Time period for treatment in both the eyes was found between 4 months and 18 years.

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Chi-square test value 72.692, p-value <0.0001.
Sensitivity = 44/(44+10) = 81.48%.
Specificity = 56/(56+0) = 100%.

Schirmer-1 test diagnosed dry eye in 41 patients (37.27%), out of which, 39 patients had abnormal OSDI scores and 2 patients had normal OSDI scores (Table 4). Hence, OSDI scores were found to have 95.12% sensitivity and 90.14% specificity in diagnosing dry eye if compared with Schirmer-1 test (Table 5).

<table>
<thead>
<tr>
<th>Schirmer-1 Test Reading (in either Eye)</th>
<th>No. of Patients</th>
<th>% of Patients</th>
<th>No. of Patients with Abnormal OSD Score (≥13)</th>
<th>No. of Patients with Normal OSD Score (&lt;13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 mm</td>
<td>41</td>
<td>37.27%</td>
<td>39</td>
<td>2</td>
</tr>
<tr>
<td>≥10 mm</td>
<td>69</td>
<td>62.73%</td>
<td>5</td>
<td>64</td>
</tr>
<tr>
<td>Total</td>
<td>110</td>
<td>100%</td>
<td>44</td>
<td>66</td>
</tr>
</tbody>
</table>

**Table 4. Results of Schirmer-1 Test**

Chi-square test value = 79.129, p value <0.0001.
Sensitivity = 39/(39+2) = 95.12%.
Specificity = 64/(64+5) = 90.14%.

LG staining of ocular surface in our patients showed 18 patients (16.36%) to be positive for dry eye (Table 6). All these patients had an abnormal OSDI score; 16 of them had severe OSD, while 2 patients had mild-to-moderate dry eye according to their OSDI scores (Table 8). High sensitivity of 100% and specificity of 71.73% was found in diagnosing dry eye with OSDI scores in relation to LG staining (Table 7).

<table>
<thead>
<tr>
<th>OSDI Scores</th>
<th>Schirmer-1 Test Reading &lt;10 mm</th>
<th>Schirmer-1 Test Reading ≥10 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal OSDI score (≥13)</td>
<td>39</td>
<td>5</td>
</tr>
<tr>
<td>Normal OSDI score (&lt;13)</td>
<td>2</td>
<td>64</td>
</tr>
</tbody>
</table>

**Table 5. Validity of OSDI Scores and Correlation with Schirmer-1 Test**

Chi-square test value = 29.363, p value <0.0001.
Sensitivity = 18/(18 + 0) = 100%.
Specificity = 66/(66 + 26) = 71.73%.

Chi-square tests show statistically significant correlation between OSDI scores and all the three clinical tests (calculated individually for each test) in diagnosing dry eye in glaucoma patients under medical treatment (Table 3, 5, 7). P value was significant (<0.0001) in each case (Table 3, 5, 7).

Results of clinical tests also revealed that all the 18 patients who had severe dry eye as per OSDI scores were clinically positive based on their TBUT and Schirmer-1 test. The 26 patients with mild-to-moderate OSDI score were all positive for dry eye according to their TBUT, but only 21 were positive on Schirmer-1 test. Out of the remaining 66 patients who had normal OSDI scores, 10 patients (15.15%) had positive TBUT, and among these, 10 patients, 2 patients (3%) were also Schirmer-1 test positive. Hence, a total of 54 patients were diagnosed clinically with dry eye (Table 8).

<table>
<thead>
<tr>
<th>OSDI Score, No. of Patients</th>
<th>TBUT (&lt;10 secs) No. of Patients (%)</th>
<th>LG Staining (≥13) No. of Patients (%)</th>
<th>Schirmer-1 (≥10 mm) No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe (≥33) (18 patients)</td>
<td>18 (100%)</td>
<td>16 (88.9%)</td>
<td>18 (100%)</td>
</tr>
<tr>
<td>Mild-to-moderate (13-32) (26 patients)</td>
<td>26 (100%)</td>
<td>2 (7.7%)</td>
<td>21 (80.7%)</td>
</tr>
<tr>
<td>Normal (&lt;13) (66 patients)</td>
<td>10 (15.15%)</td>
<td>0 (0%)</td>
<td>2 (3%)</td>
</tr>
</tbody>
</table>

**Table 8. Corroboration of TBUT, LG Staining and Schirmer-1 Test with OSDI Scores**

On further analysis, it was found that OSDI scores have 81.48% sensitivity, 100% specificity, 100% positive predictive value, 84.85% negative predictive value and 90.91% diagnostic accuracy. Statistically significant (p<0.0001) correlation between OSDI scores and clinical diagnosis of dry eye in glaucoma patients on topical medications was found with Chi-square test (Table 9).

Chi-square test value = 72.692, p-value <0.0001.
Sensitivity = 44/(44 + 10) = 81.48%.
Specificity = 56/(56 + 0) = 100%.
Positive predictive value = 44/(44 + 0) = 100%.
Negative predictive value = 56/(10 + 56) = 84.85%.
Diagnostic accuracy = (44 + 56)/(44 + 56 + 10 + 0) = 90.91%.

<table>
<thead>
<tr>
<th>OSDI Score</th>
<th>No. of Patients Diagnosed with Dry Eye</th>
<th>No. of Patients Without Dry Eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal OSDI score ≥13</td>
<td>44 (a)</td>
<td>0 (b)</td>
</tr>
<tr>
<td>Normal OSDI score &lt;13</td>
<td>10 (c)</td>
<td>56 (d)</td>
</tr>
</tbody>
</table>

**Table 9. Correlation of OSDI Scores with Dry Eye Disease Diagnosed Clinically by TBUT/Schirmer-1 Test/LG Staining**
DISCUSSION
The purpose of this study was to find the correlation between subjective scores of OSDI questionnaire and objective findings of different clinical tests used to assess OSD in the glaucoma-treated patients attending a tertiary hospital of eastern India. The OSDI was reported by Schiffman et al as a valid and reliable means to quantify the severity of dry eye.12 Our study used OSDI as the primary tool to assess the symptoms of dry eyes in the enrolled patients. It is a 12-item questionnaire designed for rapid assessment of symptoms of ocular irritation consistent with dry eye disease and their impact on vision-related functioning.

In our study, 44 of the 110 glaucoma-treated patients (40%) had OSDI scores of ≥13 (mild = 10%, moderate = 13.6%, severe = 16.4%) indicating dry eye disease in at least one of their eyes (Table 1). Using OSDI, Fechtner et al10 reported OSD symptoms in glaucoma-treated patients to be 48.4% (mild = 21.3%, moderate = 13.3%, severe = 13.8%). Leung et al found dry eye in 59% (severe = 27%) and reported that the severity of OSD symptoms increases with the number of glaucoma medications used.14 But, symptoms of dry eyes were reported in approximately 15% of the elderly in an American population-based study conducted by Schein et al.9 There is no single, practical, reproducible test that can help diagnose and stage OSD. The International Dry Eyes Workshop in 2007 published its guidelines for diagnosing and treating OSD.15 These are-measure tear film break-up-time with fluorescein, perform vital staining with Rose Bengal or Lissamine-Green, evaluate production of tears with Schirmer-1 test and assess morphology of eyelids and meibomian glands and test their function.

TBUT is a sensitive and practical method for assessing the stability of precorneal tear film. In our study, 49.1% patients were found to have a TBUT of <10 seconds (Table 2), but Leung et al14 had higher result with 78%. Vital staining with Lissamine-Green was done, because it is better than Rose-Bengal and does not stain healthy epithelium or affect their viability.16 In our study, a van Bijsterveld score of ≥4 was found in 18 patients (16.36%) (Table 6), whereas Leung et al14 found in 22% patients. LG staining test appeared to correlate excellently with severe OSD as 16 out of 18 patients with OSDI scores ≥33 were LG stain positive. The statistical analysis demonstrates clearly the validity of OSDI scores in diagnosing dry eye in glaucoma patients.

It is estimated that almost 12 million Indians are affected by glaucoma and it is the cause of 12.8% of total blindness.17 These patients are at a high risk of developing OSD due to prolonged use of antiglaucoma medications containing preservatives. Many emerging technologies like functional wave front imaging, ocular coherence tomography, confocal microscopy and osmolarity tests show promise to simplify the diagnosis of OSD, but until these new tests become standard, clinicians have to rely on the objective clinical tests for OSD. In India, there is a large population of glaucoma patients; so clinical diagnosis of OSD with objective tests will cause extra pressure on already overburdened healthcare system. The subjective OSDI scores of the glaucoma patients correlate well with their objective clinical test findings. Moreover, this test is very easy to perform and can even be used as a self-survey by the glaucoma patients themselves to diagnose dry eye. Early detection and treatment of OSD will increase the compliance of the glaucoma patients and thereby decrease progressive damage to optic nerve.

CONCLUSION
The 12-query OSDI questionnaire is a simple, inexpensive and effective tool to diagnose and stage the OSD symptoms in a fast and reliable manner anywhere in clinical practice. This score can help to minimise OSD in glaucomatous eyes, increase compliance and tolerability, reduce the total number of antiglaucoma drugs and thereby the cost ultimately decreasing progression of optic nerve damage. It is a cost-effective tool with high reliability and validity for any glaucoma clinic particularly in the developing countries.

REFERENCES


