

# A Clinical Study of Subtype-based Prevalence of Dry Eye

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## ABSTRACT

**Introduction:** Dry Eye is a multifactorial disease of the tearfilm and the ocular surface which may be due to reduced tear production or excessive tear evaporation resulting in discomfort, visual disturbance, and tear film instability with a potential damage to the ocular surface. Various population-based studies have been done to find out the prevalence and the magnitude of the problem. Women Health Study reported prevalence of 7.8% after screening 36995 subjects above 49 years by interview. The prevalence reported by Blue Mountain Study was 15.3%. The Beaver Dam Study and Shiphai Eye studies are other studies reporting prevalence of 14.5% and 33.7% respectively. McMonnies questionnaire is a widely used screening instrument for Dry-Eye syndromes with sensitivity reportedly varying between 87% and 98% and specificity between 87% and 97%. Prevalence studies use McMonnie's questionnaire for screening individuals for Dry Eye, whereafter tests like Schirmer's test, Tear Film Break Up Time test, Rose Bengal test, Lissamine Green test and Meibomian Gland Dysfunction test are useful for further evaluation. While these tests help to differentiate the subtypes of Dry Eye such as Lipid Anomaly Dry Eye, Aqueous Tear Deficiency and Mucin Layer Deficiency, however, their sensitivity and specificity has not been widely studied. Additionally, very few studies have reported the prevalence of the various subtypes of Dry Eye.

**Aim and Objectives:** To determine the subtype-based prevalence of Dry Eye, to study the specificity and sensitivity of clinical tests for Dry Eye and to correlate McMonnies questionnaire with Dry

Eye tests results.

**Material and Methods:** A prospective, cross-sectional, observational study, duly approved by the Institutional Ethics Committee, was conducted from October 2010 to April 2012. A total of 4750 subjects above 18 years of age were screened by the McMonnies questionnaire. Respondents having a score greater than 14.5 were subjected to clinical Dry Eye tests. The data obtained was analyzed using chi-square test.  $p$  value  $< 0.005$  was considered statistically significant. The specificity and sensitivity of each clinical test was calculated using Schirmer's test as gold standard.

**Results:** The prevalence of Dry Eye was 15.4%, with a female preponderance ( $p = 0.01$ ) and a significant increase with age above 60 years was noted ( $p < 0.0001$ ). Tear Film Break Up Time was the most reliable test with a good sensitivity (68.85%) and specificity (78.32%). Lipid Anomaly Dry Eye was the most prevalent (14.48%) followed by Aqueous Tear Deficiency (13.36%) and Mucin Layer Deficiency (3.51%). A positive correlation between McMonnies score and severity of Dry Eye was seen.

**Conclusion:** This study suggests that Lipid Layer Anomaly is the most prevalent subtype in Dry Eye. Tear Film Break Up Time test is the most likely test to diagnose mild Dry Eye. McMonnies Questionnaire can be effectively used for screening of a large population. Tear Film Break Up Time was found to have better sensitivity as well as specificity than other tests used for diagnosing Dry Eye.

**Key words:** Dry Eye, McMonnies Questionnaire

## INTRODUCTION

Dry Eye Syndrome (DES), also known as keratoconjunctivitis sicca (KCS), is a multifactorial disease of the tears and the ocular surface that is due to reduced tear production or excessive tear evaporation which results in discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface [1]. It may result from dysfunction of a superficial lipid layer, a middle aqueous layer, an innermost hydrophilic mucin layer, either singly or in combination. Women Health Study reported prevalence of 7.8% after screening 36995 subjects above 49 years by interview [2]. The prevalence reported by Blue Mountain Study [3] was 15.3%. The Beaver Dam Study [4] and Shiphai Eye [5] studies are other studies reporting prevalence of 14.5% and 33.7% respectively. A validated questionnaire like McMonnies Dry Eye Questionnaire has been reported as an effective screening tool in population-based survey [6]. McMonnies questionnaire is a widely used screening instrument for Dry Eye syndromes with sensitivity reportedly varying between 87% and 98% and specificity between 87% and

97% [7,8]. Several diagnostic tests have been used to assess the quantity; quality and functioning of various layers of tear film and diagnose the subtype and severity of Dry Eye although some are suitable only in research laboratory settings, e.g., lysozyme, tear lactoferrin, epidermal growth factor (EGF), as well as tear-film osmolarity. Availability and the cost of these tests may restrict their use in a population-based study. Simple tests like Schirmer's test, Tear Film Break Up Time test, Rose Bengal test, Lissamine Green test and Meibomian Gland Dysfunction test are commonly used in clinical practice. However, the sensitivity and specificity of these tests has not been widely studied. The prevalence of Dry Eye reported in literature varies from 7.8% to 57.59%, 3-5.9 but the subtype based prevalence has only been reported in one study [9].

## Aim & Objectives

This study was conducted with the aim to determine the subtype-based prevalence of Dry Eye, to correlate McMonnies questionnaire

with Dry Eye tests results and to study the specificity and sensitivity of clinical tests for dry eye.

## MATERIAL AND METHODS

A prospective, non-randomized, cross-sectional study was carried out in a tertiary health centre from October 2010 to April 2012. Institutional Ethics Committee approval was obtained prior to commencing the study. Study included all subjects of both the sexes above 18 years of age attending Ophthalmology OPD. Patients having active ocular infection, those on topical medications, and those who had undergone intra-ocular or extra-ocular surgery in the previous six months were excluded.

Individuals were enrolled in the study after taking a due informed consent for both participation in the study as well as for any subsequent publication of data from the study.

All subjects were asked to fill McMonnies questionnaire. The scores ranged from 0 to 45. Individuals having McMonnies score greater than 14.5 were evaluated further for Dry Eye diagnosis.

After noting history and complete ocular examination, all subjects underwent following Dry Eye tests.

**I. Meibomian Gland Dysfunction:** Lid margins and meibomian orifices were evaluated on a slit lamp. Subjects having moderately altered expressibility with inspissated OR severely altered expressibility (toothpaste-like) were considered to have meibomian gland dysfunction.

**II. Tear Film Break Up Time:** A 2% fluorescein strip was moistened and placed in the lateral one-third of lower lid in a non-anaesthetised eye and patient was asked to blink only once or twice to avoid pooling of fluorescein, following which the strip was removed. Using the cobalt blue light of the slit lamp, the time lapse between the last blink and the appearance of the first randomly distributed dark discontinuity in the fluorescein-stained tear film is the tear break up time. Values of less than 10 seconds were considered abnormal.

**III. Rose Bengal Test:** Rose Bengal strips were used by applying tear substitutes to the impregnated strips and touching the wet strip to the inferior palpebral conjunctiva. After 15 seconds, stained areas in the conjunctiva were examined with red-free filter on slit lamp. Results were evaluated using a grading system developed by Van Bijsterveld, in which the ocular surface is separated into three sections (cornea, medial and lateral bulbar conjunctiva), each of which is graded 1-3 according to severity. Each eye was scored separately. Staining was graded on a four-tier scale for each area separately.

0-No staining. 1-Mild staining.  
2-Moderate staining. 3-Extensive staining.

Total score more than 3.5 was considered positive for Dry Eye.

**IV. Lissamine Green:** Test was performed and results were evaluated in the same way as Rose Bengal test.

**V. Schirmer's Test:** A standard Schirmer's strip was placed over the lateral one-third of lower lid after instilling a drop of Proparacaine 0.5%. After five minutes, the level of strip wetting (in millimetres) was noted. Reading less than ten millimetres wetting was considered as positive Schirmer's test.

An interval of 5 minutes was kept between two tests. Schirmer's test positive was considered as Aqueous Tear Deficiency. Positive Rose Bengal and Lissamine Green staining test was considered as Mucin Layer Deficiency. Meibomian Gland Dysfunction was considered Lipid Layer Anomaly.

Severity of Dry Eye was classified using the following criteria:- McMonnies score more than 14.5 in any one of the tests positive was considered as mild Dry Eye And McMonnies score more than 14.5 in two or more tests positive was considered as moderate Dry Eye. Diagnosis of severe Dry Eye was done when all five tests were positive along with McMonnies score more than 14.5. Data

was captured on a standardized proforma. Results were tabulated and statistically analyzed using Chi-square test. A p-value of <0.005 was considered statistically significant. Considering Schirmer's test as standard, specificity and sensitivity of each test was calculated.

## RESULTS

This hospital-based study was conducted on 4750 subjects (2165 males, 2585 females) who were administered the McMonnies Questionnaire. Scores greater than 14.5 were obtained in 782 subjects (15.6%) of which 305 (14.60%) were males and 477 (18.45%) were females. ( $p < 0.0001$ ) in 6.36% males and 10.09% females who were positive on screening were below 40 years of age [Table/Fig-1]. A definitive increase in prevalence with age was noted in both the sexes above 60 years including 26.28% of the males and 31.72% of the females. ( $p = 0.01$ ) Out of these, 743 subjects were diagnosed to have Dry Eye on the basis of clinical tests, whereas no test was positive in 39 (4.98%) subjects.

The results of the Tear Film Break Up Time Test, Schirmer's Test and Meibomian gland dysfunction are given in [Table/Fig-2]. Tear Film Break Up Time was positive in maximum number of subjects (82.50%) followed by MGD (31.89%) and Rose Bengal staining test (22.47%) whereas Schirmer's was positive only in 16.41% subjects of Dry Eye. All the subjects showing a positive Lissamine Green test showed a positive Rose Bengal test.

Mild Dry Eye was diagnosed in 58.95% subjects having any one Dry Eye test positive. Moderate to severe Dry Eye showing two or more tests positive was diagnosed in 34.78% subjects. All four tests were positive in 3% subjects. Lipid layer anomaly was most prevalent (92.59%) amongst Dry Eye subjects in which Tear Film Break Up Time and/or Meibomian Gland Dysfunction test was positive. Mucin Layer Deficiency was diagnosed in 22.47% subjects who showed Rose Bengal Test and/or Lissamine Green stain was positive [Table/Fig-3].

Tear Film Break Up Time was the most frequently positive test in all McMonnies score ranges, but there was increase in the number of subjects having positive Meibomian Gland Dysfunction test and Rose Bengal staining in scores above 23 [Table/Fig-4].

Age (years)	Male		Female		Total	
	screened	Score >14.5	screened	Score >14.5	screened	Score >14.5
18-40	707	45 (6.36%)	901	91 (10.09%)	1608	136 (8.45%)
41-60	914	117 (12.69%)	981	163 (16.71%)	1895	280 (14.77%)
>60	544	143 (26.28%)	703	223 (31.72%)	1247	366 (28.86%)
Total	2165	305 (14.60%)	2585	477 (18.45%)	4750	782 (16.40%)

[Table/Fig-1]: Age And Sex wise Distribution of Population Studied

Dry Eye Tests	Positive Subjects	Out of 743	Out of 4750
Schirmer's Test	122	16.41%	2.56%
TFBUT	613	82.50%	12.90%
MGD	237	31.89%	4.98%
Rose Bengal Test	167	22.47%	3.51%
Lissamine Green Test	77	10.36%	1.62%

[Table/Fig-2]: Dry eye test results

Subtype of dry eye	Total	(%) of dry eye (n=743)	(%) out of population studied (n=4750)
Aqueous Tear Deficiency	635	85.46%	13.36%
Lipid Layer Anomaly	688	92.59%	14.48%
Mucin layer Deficiency	167	22.47%	3.51%

[Table/Fig-3]: Subtype Based Diagnosis of Dry Eye

Sensitivity and specificity of each test compared to Schirmer's test was as follows: - The sensitivity of Tear Film Break Up Time was 68.85% and specificity was 78.32%. The Rose Bengal test had sensitivity of 75.8% and specificity of 10.14%. Lissamine Green dye test showed sensitivity of 60.01% and specificity of 7.24%. The Meibomian gland dysfunction test showed sensitivity of 32.71 % and specificity of 30.60% [Table/Fig-5].

McMonnies Score	Total	Schirmer's Test	TFBUT	MGD	Rose Bengal	Lissamine Green
15-16	118	11.86%	66.94%	25.42%	25.42%	12.71%
17-18	257	12.06%	72.73%	28.01%	15.83%	5.83%
19-20	240	13.33%	84.10%	30.00%	19.45%	11.28%
21-22	148	23.64%	87.16%	39.18%	25.00%	10.81%
23-24	19	52.63%	89.47%	63.15%	63.15%	15.78%

**[Table/Fig-4]:** Correlation of Mc Monnies Score And Dry Eye Test Results

Tests	Sensitivity	Specificity
Tfbut	68.85%	78.32%
Mgd	32.71%	30.60%
Rose Bengal Test	75.8%	10.14%
Lissamine Green Test	60.01%	7.24%

**[Table/Fig-5]:** Sensitivity and Specificity of each dry eye test

## DISCUSSION

The McMonnies score indicated a 16.4% prevalence of dry eye symptoms in the total population studied as compared to 15.64% when correlated with Dry Eye tests. In our study, McMonnies score proved to be a good screening tool with a sensitivity of 97.7%.

In all the population-based studies the diagnosis was based on symptoms and history alone and no confirmation by diagnostic clinical tests was done. Albiets, Julie M. established Dry Eye by McMonnies Questionnaire followed by diagnostic clinical tests. and have reported prevalence of 10.1% which was lesser than the Dry Eye prevalence in our study [9]. An Indian hospital-based population study conducted in the year 2005 has shown 18.4% prevalence of Dry Eye on the basis of clinical tests alone. In our study, the prevalence of Dry Eye was significantly higher in females (18.45%) than in males (14.60%) ( $p=0.01$ ). The prevalence of Dry Eye was 6.36% in males and 10.09% in females below 40 yrs of age. A significant increase in prevalence with age was noted in both the sexes above 60 yrs including 26.28% of the males and 31.72% of the females. The difference was statistically significant. ( $p<0.0001$ ). The hospital-based population study done in India reported a 36.1% prevalence of Dry Eye in the age group above 70 years and 20% in the age group 31-40 years [10]. The population-based study in Indonesia reported increased prevalence of 37.6% in older population.5 Other studies also have shown similar results, where Dry Eye prevalence progressively increases with age [11].

Tear Film Break Up Time was most frequently reported positive test (82.50%). A rapid tear film break up time is seen in both aqueous tear deficiency as well as Meibomian gland dysfunction. The lid abnormalities and Meibomian gland dysfunction were recorded in 237 (31.89%) subjects. Rose Bengal staining was positive in 167 (22.47%) subjects. Lissamine green was seen in 77 (10.36%) subjects. Rose Bengal dye and Lissamine green dye are used to study the epithelial cells that are not coated with mucin indicating mucin layer deficiency. Positive Schirmer's test was noted only in 122 (16.41%) subjects indicating Aqueous Tear Deficiency. Schirmer's test is known to give variable results [12].

In our study, Tear Film Breakup Time showed better chances of diagnosing Dry Eye than any other tests, which was contradictory to the study by Rehman A and Yahya K, who showed the Schirmer's test to be more reliable [2].

The Lipid Layer Anomaly was most commonly seen in 92.59% of Dry Eye subjects followed by Aqueous Tear Deficiency, diagnosed in 85.46% subjects. Mucin tear deficiency was recorded in only 22.47% subjects. There was overlapping of the test results showing simultaneous involvement of multiple layers. The overall prevalence of Lipid Layer Anomaly in the population screened was 14.48% followed by Aqueous Tear Deficiency (13.36%) and Mucin Layer Deficiency (3.51%) of the total study population.

Subtype-based prevalence reported by Albiets, Julie M was Lipid Anomaly Dry Eye (4.0%), Aqueous Tear Deficiency (1.7%) and there was no diagnosed case of primary mucin anomaly caused by cicatricial disease. The overall prevalence (10.8%) reported by them was also less than that observed in our study. Further, they included the allergic or toxic Dry Eye and primary epitheliopathies and lid surfacing or blinking anomalies as two separate subtypes with prevalence of 3.1% and 1.8% respectively [9].

Tear Film Break Up Time test was the most frequently positive test in all McMonnies score ranges, but there was increase in the number of subjects having positive Meibomian Gland Dysfunction test and Rose Bengal staining in subjects having scores above 23. A positive correlation between McMonnies score and the Dry Eye tests result was noted.

Taking Schirmer's test as gold standard, screening test analysis was done. The sensitivity of Tear Film Break Up Time was 68.85% and specificity was 78.32%. The Rose Bengal test had sensitivity of 75.8% and specificity of 10.14%. Lissamine Green dye test showed sensitivity of 60.01% and specificity of 7.24%. The Meibomian gland dysfunction test showed sensitivity of 32.71 % and specificity of 30.60%.

Studies by Bjisterveld and Vitali both have shown a high sensitivity (85% and 83% respectively) of Schirmer's test. In the same study, Vitali has shown TFBUT sensitivity and specificity to be 72% and 68% respectively. Menegehar LS et al., [13] has shown TFBUT to have a sensitivity (83%) and high specificity (85%). Meibomian gland function test showed a low sensitivity (27.41%) and low specificity (42.12%) when compared with Schirmer's test).

## LIMITATIONS

In our study, the cases having severe ocular surface inflammations, those having intraocular/extrocular surgery in past six months and those having topical medications were excluded from the study. Further subjects who had score lesser than 14.5 but still could have Dry Eye were missed. All these factors could have affected prevalence of Dry Eye.

## CONCLUSION

Overall prevalence of Dry Eye was 15.54% among the total population screened. Lipid Layer Anomaly Dry Eye was most prevalent (14.48%) followed by Aqueous Tear Deficiency (13.36%) and Mucin Layer Deficiency (3.51%). McMonnies Questionnaire was found to be effective in screening Dry Eye when correlated with Dry Eye clinical tests. Tear Film Break Up Time was found to have better sensitivity as well as specificity than other tests used for diagnosing Dry Eye.

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