

Assessment of Role of Dietary Intervention in Improvement of Xerophthalmia Patients Using Various Tests at a Tertiary Care Hospital

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ABSTRACT

Background: The symptoms of xerophthalmia are itching, sandy - gritty sensation, tiredness, pain, redness, pressure and photophobia. They are worsened by prolonged reading, computer usage, driving, watching television, hot-dry and low humid climate, air conditioners, fan, heater, hair dryer etc. The present study was conducted to assess the role of dietary intervention in improvement of Xerophthalmia patients using various tests.

Materials and Methods: In this prospective randomised control study, 40 patients of Dry eye disease were recruited from outpatient Department of Ophthalmology, Subharti Medical College, Meerut. Group A: Patients were given tear substitutes (carboxy methyl cellulose 0.5%) q.i.d. as well as omega-3 fatty acids in recommended doses (2 capsules of 300mg Omega-3 fatty acids b.d. for 12 weeks). Group B: Patients were given tear substitutes only q.i.d. (carboxy methyl cellulose 0.5%). Schirmer II test and TBUT were done at every visit. Comparison between randomized groups was done using independent T Test. P value was calculated and p value less than 0.05 was taken as statistically significant.

Results: In the present study we observed that in group A (omega-3 fatty acids + lubricant eye drops) the mean and standard deviation of Schirmer's score showed a rising pattern on the successive follow-ups i.e. from 2.57±1.387mm to 8.99±3.688mm. In group B (lubricant eye drops) the mean and standard deviation showed slight improvement on the first follow up i.e. from 2.54±1.451 mm to 2.77±1.484 mm, then no significant improvement on further follow-ups i.e. 2.59±1.887 on the second follow up and 2.56 ± 1.8836 on the third follow up. On comparing Schirmer's test scores between two groups using independent "t" test the p value was found to be significant on second, third and fourth follow-ups i.e. (p<.05). In the present study we observed that in group A (omega-3 fatty

acids + lubricant eye drops) the mean and standard deviation of TBUT showed a rising pattern on the successive follow-ups i.e. from 2.95±.76 seconds to 8.25±3.51 seconds. In group B (lubricant eye drops) the mean and standard deviation showed slight improvement on the first follow up i.e. from 2.65±.94 seconds to 2.85±1.5 seconds, then no significant improvement on further follow-ups i.e. 2.68±1.66 seconds on the second follow up and 2.66±1.78 seconds on the third follow up. On comparing TBUT test scores between two groups using independent "t" test the p value was found to be significant on second, third and fourth follow-ups i.e. (p<.05).

Conclusion: Our study concluded that in Group A Schirmer's test showed significant improvement from a mean value of 2.57±1.387 mm to 8.99±3.688 mm at 12 weeks. TBUT scores also increased from a 2.95±.76 seconds to 8.25±3.51 seconds at 12 weeks and this improvement was found to be statistically significant (p<0.001). No significant improvement was seen in Group B.


Keywords: TBUT, Schirmer's Test, Xerophthalmia, Dry Eye.

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INTRODUCTION

Dry eye is defined as a disorder of the tear film due to tear deficiency or excessive evaporation that causes damage to interpalpebral ocular surface and is associated with symptoms of discomfort¹. It is now known that dry eye disorder occurs as a

result of underlying immune-mediated inflammatory process that affects the lacrimal gland and the ocular surface not only in Sjogrens but also Non-Sjogrens dry eye. This inflammatory process ultimately disrupts the normal homeostatic functional unit

responsible for normal tear production². Symptom assessment plays a key role in dry eye diagnosis^{3,4} and is more important than many dry eye clinical test results⁵. In addition, the symptoms agree poorly with the clinical tests and signs. McMonnie CW⁶ questionnaire is often used in clinical practice and research, although studies examining its psychometric properties are few. Described by Norn MS⁷ and revised by Lemp MA and Hamill JR⁸ the FTBUT is one of the commonest objective tests, utilized to make diagnosis of dry eye⁹. With this emerging new concept, interesting advances in the treatment of dry eye disorder are being introduced to control the underlying pathogenesis of the disease. Recently, systemic omega-3 fatty acids are thought to be very useful as suggested by the expert panels because research has shown a positive effect on dry eye, subsiding vicious cycle of ocular inflammation. The present study was conducted to assess the role of dietary intervention in improvement of Xerophthalmia patients using various tests.

MATERIALS AND METHODS

In this prospective randomised control study, 40 patients of Dry eye disease were recruited from outpatient Department of Ophthalmology, Subharti Medical College, Meerut. The patients

above 40 years of age were included in the study and age matched randomisation of patients was done in two groups of 20 each. **Group A:** Patients were given tear substitutes (carboxy methyl cellulose 0.5%) q.i.d. as well as omega-3 fatty acids in recommended doses (2 capsules of 300mg Omega-3 fatty acids b.d. for 12 weeks). **Group B:** Patients were given tear substitutes only q.i.d. (carboxy methyl cellulose 0.5%). Patient who were diagnosed on the basis of Ocular Surface Disease Index (OSDI), Wetting of Whatman No. 41 filter paper strips < 10 mm after 5 minutes of topical instillation of Xylocaine 4% was considered significant (Schirmer II) and TBUT < 10 seconds was considered significant were included in the study. Patients who had External disease including active ocular infection, contact lens wearers, Previous history of herpetic keratitis, Degenerative corneal disease, Pregnant and lactating females and Patients on systemic drugs like beta-blockers, anti-cholinergics, halothane etc were excluded from the study. Follow up examination was done after two weeks, six weeks and twelve weeks. Schirmer II test and TBUT were done at every visit. Comparison between randomized groups was done using independent T Test. P value was calculated and p value less than 0.05 was taken as statistically significant.

Table 1: Mean & Standard Deviation of Schirmer's Test

S.No.	Groups	Mean ± S.D.			
		First Day	2 Weeks	6 Weeks	12 Weeks
1	Group A	2.57±1.387	4.24±1.749	6.26±2.474	8.99±3.688
2	Group B	2.54±1.451	2.77±1.484	2.59±1.887	2.56±1.8836

Table 2: Comparison Between Two Groups by Independent "t" Test of Schirmer's Test

S.No.	Groups	Probability of Independent "T" Test		
		2 Weeks	6 Weeks	12 Weeks
1	Group A & Group B	.0234* (P<.05) SIG.	.0264* (P<.05) SIG.	.0000* (P<.05) SIG.

*Shows A Significant Difference At .05 Level of Significance. (P<.05)

** Shows No Significant Difference At .05 Level of Significance. (P>.05)

Table 3: Mean & Standard Deviation of TBUT Score

S.No.	Groups	Mean ± S.D.			
		First Day	2 Weeks	6 Weeks	12 Weeks
1	Group A	2.95±.76	4.65±1.73	6.35±2.48	8.25±3.51
2	Group B	2.65±.94	2.85±1.5	2.68±1.66	2.66±1.78

Table 4: Comparison Between Two Groups by Independent "t" Test of TBUT Score

S.No.	Groups	Probability of Independent "t" Test		
		2 Weeks	6 Weeks	12 Weeks
1	Group A & Group B	.0268* (P<.05) SIG.	.0023* (P<.05) SIG.	.0001* (P<.05) SIG.

*Shows A Significant Difference At .05 Level of Significance. (P<.05)

** Shows No Significant Difference At .05 Level of Significance. (P>.05)

RESULTS

In the present study total no. of patients were 40 in which 4 patients drop out. The maximum cases were in the age group 40-50 yrs i.e. 52.77%. Mean age of patients was 49.16 yrs. Disease was bilateral in all patients. Out of 36 patients included in study majority were female i.e 21 (58.33%).

In the present study we observed that in group A (omega-3 fatty acids + lubricant eye drops) the mean and standard deviation of Schirmer's score showed a rising pattern on the successive follow-ups i.e. from 2.57 ± 1.387 mm to 8.99 ± 3.688 mm.

In group B (lubricant eye drops) the mean and standard deviation showed slight improvement on the first follow up i.e. from 2.54 ± 1.451 mm to 2.77 ± 1.484 mm, then no significant improvement on further follow-ups i.e. 2.59 ± 1.887 on the second follow up and 2.56 ± 1.8836 on the third follow up.

On comparing Schirmer's test scores between two groups using independent "t" test the p value was found to be significant on second, third and fourth follow-ups i.e. ($p < .05$).

In the present study we observed that in group A (omega-3 fatty acids + lubricant eye drops) the mean and standard deviation of TBUT showed a rising pattern on the successive follow-ups i.e. from $2.95 \pm .76$ seconds to 8.25 ± 3.51 seconds.

In group B (lubricant eye drops) the mean and standard deviation showed slight improvement on the first follow up i.e. from $2.65 \pm .94$ seconds to 2.85 ± 1.5 seconds, then no significant improvement on further follow-ups i.e. 2.68 ± 1.66 seconds on the second follow up and 2.66 ± 1.78 seconds on the third follow up.

On comparing TBUT test scores between two groups using independent "t" test the p value was found to be significant on second, third and fourth follow-ups i.e. ($p < .05$).

DISCUSSION

The present study has been undertaken to study the role of dietary intervention in improvement of Xerophthalmia patients using various tests. In this prospective randomised control study, 40 patients of Dry eye disease were recruited from outpatient Department of Ophthalmology, Subharti Medical College, Meerut. The patients above 40 years of age were included in the study and age matched randomisation of patients was done in two groups of 20 each. There were 4 drop outs due to lack of follow up. Thus, the findings of present study are based on observation made on 36 patients. Group A: Patients were given tear substitutes (carboxy methyl cellulose 0.5%) q.i.d. as well as omega-3 fatty acids in recommended doses (2 capsules of 300mg Omega-3 fatty acids b.d. for 12 weeks). Group B: Patients were given tear substitutes only q.i.d. (carboxy methyl cellulose 0.5%). In the present study the maximum number of patients 52.77% were in the age groups of 40-50 years followed by 47.22% in the age group of 50-60 years. The mean age of patient was 49.16 years in our study. In the present study 41.66% of the cases were males and 58.33% were females.

A Schirmer's score of < 10 mm was taken as abnormal in the present study. Mean Schirmer's score in the present study in Group A was 2.57 mm (S.D. = 1.38) which increased to 8.9 mm (S.D.=3.68) at the end of therapy. The changes in Schirmer's score became statistically significant after 2 weeks of therapy i.e. 4.24mm (S.D.=1.749) and remained significant after 12 weeks of the therapy i.e. 8.99mm (S.D.=3.68), while in Group B their was no improvement in Schirmer's test score.

Our results were consistent with a study done by Kangari H et al¹⁰ in 2013 who assessed the effect of short-term oral omega-3 fatty acids on TBUT, Schirmer's test score, OSDI score. 2 capsules of omega-3 fatty acids were given daily for 30 days. 64 patients with dry eye between 45 to 90 years were randomized into 2 groups, 33 patients in treatment group and 31 patients in placebo group. Initially the Schirmer's test score mean was 5.8mm (S.D.=2.5) and finally it was 6.8 mm (S.D.=2.8). Changes in the treatment and placebo groups were 22.3% and 5.1% respectively for Schirmer's score ($p=0.033$). They demonstrated consumption of omega-3 fatty acids twice daily is associated with decrease in rate of tear evaporation, improvement in dry eye symptoms and increase tear secretion. In their study also no significant improvement was there in placebo group.

Our result also matched the study done by Wojtowicz JC et al¹¹ in 2011 who studied the effect of dietary supplementation with omega-3 fatty acids on Schirmer's type 1, TBUT and OSDI score in 36 patients for 3 months. They found that at the end of study 70% of patients became asymptomatic. They also found that average tear production and tear volume increased as indicated by Schirmer's testing and fluorophotometry. Initially the Schirmer's score mean was 8.13mm (S.D.=5.07) and finally it was 12.33mm (S.D.=9.86).

Our result was also consistent with a study done by Pinheiro MN et al¹² in 2007 who evaluated the role of oral flaxseed space oil in treatment for dry eye Sjogren syndrome. 38 female patients with Sjogren syndrome were included in this study for 180 days (6 months). He concluded that at the end of study statistically significant changes ($P < 0.005$) were seen in Schirmer's test score. A cut off limit of less than 10 seconds was taken as abnormal for TBUT in the present study. A significant improvement in TBUT ($p < 0.001$) was noted in group A in which mean TBUT increased from 2.95seconds (S.D=0.76) to 4.65 seconds (S.D=1.73) at the end of 2 weeks. This improvement was also seen after 12 weeks of treatment with mean of 8.25 seconds (S.D =3.51) and was significant ($p < 0.001$), while in Group B there was no improvement in TBUT test score.

Our result also matched with a study done by Kangari H et al¹¹ who found that short term consumption of oral omega-3 fatty acids showed improvement in dry eye syndrome. Initially the TBUT test score mean was 3.9 seconds (S.D.=1.7) and finally it became 5.67sec (S.D.=2.6). Changes in the treatment and placebo groups were 71% and 3.3% respectively for TBUT score ($p=0.001$).

Our result was also consistent with a study done by Pinheiro MN et al¹² who in his study found the role of oral flaxseed oil in the treatment of dry eye patients. In his study he found p value to be significant i.e. ($p < 0.005$) for TBUT test score.

CONCLUSION

Our study concluded that in Group A Schirmer's test showed significant improvement from a mean value of 2.57 ± 1.387 mm to 8.99 ± 3.688 mm at 12 weeks. TBUT scores also increased from a $2.95 \pm .76$ seconds to 8.25 ± 3.51 seconds at 12 weeks and this improvement was found to be statistically significant ($p < 0.001$). No significant improvement was seen in Group B. Dietary intervention with Omega-3 fatty acid not only causes symptomatic improvement but also improves clinical markers of dry eye as evidenced by a positive drift in Schirmer's test score, TBUT.

Probably, there is improvement in inherent stability of tear film as evidenced by a larger TBUT drift and Schirmer scores. However, these tests are not a specific marker for any subtype of dry eye and further studies of changes in meibum quality and quantity may broaden the usefulness of Omega-3 fatty acids. Systemic omega-3 fatty acids is an effective and safe modality for treatment of patients with severe dry eye. However, more studies should be conducted to assess its long-term effect on tear film and other parameters of dry eye. A curative treatment for severe dry eye still remains elusive.

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