

Evaluation of Effect and Safety Profile of Systemic Omega-3 Fatty Acids in Treatment of Dry Eye Over a Period of 3 Months: An Institutional Based Study

Harshraj Nehra^{1*}, KPS Malik², Charu Jain³

^{1*}Assistant Professor, Department of Ophthalmology, SGT Medical College, Gurugram, Haryana, India.

²Visiting Professor, Department of Ophthalmology, AIIMS, Rishikesh, Uttarakhand, India.

³Professor, Department of Ophthalmology, Subharti Medical College, Merrut, Uttar Pradesh, India.

ABSTRACT

Background: Dry eye is a symptom complex resulting from alteration in composition, stability and tonicity of the tear film. Dry eye affects millions and substantially altering the productivity and quality of life. The aim of the present study was to evaluate the effect and safety profile of systemic omega-3 fatty acids in treatment of dry eye over a period of 3 months.

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. Group B: Patients were given tear substitutes only q.i.d. (carboxy methyl cellulose 0.5%). Follow up examination was done after two weeks, six weeks and twelve weeks. OSDI 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 total no. of patients was 40 in which 4 patients drop out. Patients were followed up for 12 weeks. The maximum cases were in the age group 40-50 yrs (52.77%) Mean age of patients were 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 OSDI score showed improvement on the successive follow-ups i.e. from 70.5±15.5 to 20.2 ± 13.8. In group B (lubricant eye drops) the mean and

standard deviation showed slight improvement on the first follow up i.e. from 70.2±15.2 to 53.31±14.9, then no significant improvement on further follow-ups i.e. 68.73±15.0 on the second follow up and 69.77±15.1 on the third follow up. On comparing OSDI 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 OSDI score improved among participants of Group A 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 OSDI score.


Keywords: Dry Eye, Omega-3 Fatty Acids, OSDI Test.

*Correspondence to:

Dr. Harshraj Nehra,
Assistant Professor,
Department of Ophthalmology,
SGT Medical College, Gurugram, Haryana, India.

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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 discomfort.¹ Dry eye is among the most frequently established diagnosis in ophthalmology.² Between 14% and 33% of the population worldwide suffers from dry eye, making it a significant public health problem. Upto 25% of patients consulting eye care practitioners present with dry eye symptoms.³⁻⁵ The very first documentation of tear film abnormalities was done by Schmidt.⁶

Historically, the term “dry eye” can be attributed to the Swedish ophthalmologist Henrik SC Sjogren.⁷ The modern definition of dry eye disorder is based on the concept of the three layers of the tear film devised by Holly F and Lemp MA⁸ - lipid, aqueous and mucin layers that are secreted by the meibomian glands, lacrimal glands and goblet cells respectively. The normal tear film may be viewed as hydrated mucin gel with an outer lipid layer that limits evaporation and enhances lubrication.^{9,10} Deficiency of the lipid layer gives rise to ‘Evaporative’ form of dry eye.¹¹

The usual cause of lipid layer deficiency is obstruction of the meibomian glands, blepharitis, atopic keratoconjunctivitis and generalized dysfunction of sebaceous glands, such as acne rosacea or seborrhoeic dermatitis.¹²

The underlying causes of inflammation vary; 'neurogenic inflammation' of the lacrimal glands in response to environmental irritation is the key mechanism in the pathogenesis of dry eye. The inflammation occurs when efferent nerve stimulation triggers the release of neuropeptides including calcitonin gene - related peptide (CGRP) and substance P, thereby resulting in epithelial cell antigen presentation.¹³

The aim of the present study was to evaluate the effect and safety profile of systemic omega-3 fatty acids in treatment of dry eye over a period of 3 months.

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%).

Inclusion Criteria

Patient were diagnosed on the basis of Ocular Surface Disease Index (OSDI).

Exclusion Criteria

1. External disease including active ocular infection
2. Contact lens wearers
3. Previous history of herpetic keratitis
4. Degenerative corneal disease
5. Pregnant and lactating females
6. Patients on systemic drugs like beta-blockers, anti-cholinergics, halothane etc.

Follow up examination was done after two weeks, six weeks and twelve weeks. OSDI 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 total no. of patients was 40 in which 4 patients drop out. Patients were followed up for 12 weeks. The maximum cases were in the age group 40-50 yrs (52.77%) Mean age of patients were 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 OSDI score showed improvement on the successive follow-ups i.e. from 70.5±15.5 to 20.2±13.8. In group B (lubricant eye drops) the mean and standard deviation showed slight improvement on the first follow up i.e. from 70.2±15.2 to 53.31±14.9, then no significant improvement on further follow-ups i.e. 68.73±15.0 on the second follow up and 69.77±15.1 on the third follow up. On comparing OSDI 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).

Table 1: Age Distribution of Patients

Age Groups (Yrs)	No. of patients	Percentage
40-50	19	52.77
50-60	17	47.22

Table 2: Genderwise Distribution of Patients

Sex	No. of patients	Parentage
Male	15	41.66
Female	21	58.33

Table 3: Mean and Standard Deviation of OSDI Score

S. No.	Groups	Mean ± S.D			
		First Day	2 weeks	6 weeks	12 weeks
	Group A	70.5±15.5	53.42±15.2	38.12±14.7	20.2±13.8
	Group B	70.2±15.2	53.31±14.9	68.73±15.0	69.77±15.1

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

S.No.	Groups	Probability of Independent "t" Test		
		2 Weeks	6 Weeks	12 Weeks
1	Group A & Group B	.0264* (P<.05) SIG.	.0028* (P<.05) SIG.	.0001* P<.05) SIG.

*Shows a Significant Difference at 0.05 Level of Significance. (P<0.05)

** Shows No Significant Difference at 0.05 Level of Significance. (P>0.05)

DISCUSSION

The present study has been undertaken to study the effect and safety profile of systemic omega-3 fatty acids for treatment of patients with dry eye disorder in Indian population. 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. The age incidence in our study is similar to that reported by Mc Carty CA et al¹⁴ and Yazdani C¹⁵ who have postulated the increasing prevalence of dry eye with age. In the present study 41.66% of the cases were males and 58.33% were females. Our results were similar to that of the previous studies by McCarty CA et al¹⁴, Yazdani C¹⁵, Schaumberg DA et al¹⁶ who found a higher prevalence of dry eye in females especially postmenopausal or of perimenopausal age.

A significant improvement in OSDI score ($p < 0.05$) was noted in group A in which mean OSDI score improved from 70.5 (S.D.=15.5) to 53.42 (S.D.=15.2) at the end of 2 weeks. This improvement was also seen after 12 weeks of treatment with mean of 20.2 (S.D =13.8) and was significant ($p < 0.05$), while in Group B there was no improvement in OSDI score.

Our result also matched with a study done by Kangari H et al¹⁷ who found that short term consumption of oral omega-3 fatty acids showed improvement in dry eye syndrome. Initially the OSDI score mean was 38.7(S.D.=16.5) and finally it became 29.3 (S.D.=15.9). Changes in the treatment and placebo groups were 26% and 4% respectively for OSDI score ($p=0.004$).

Our result was also similar to the study done by Wojtowicz JC et al¹⁸ who found that treatment of dry eye with omega-3 fatty acids improved tear production which was confirmed by OSDI score. In this study 70% of patients became asymptomatic.

Our result was also similar to a study done by Pinheiro MN et al¹⁹ 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 OSDI score.

CONCLUSION

Our study concluded that OSDI score improved among participants of Group A 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 OSDI score.

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