

THE OCULAR ECOSYSTEM IN THE DISCOID LUPUS ERYTHEMATOSUS

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ABSTRACT

Introduction: The tear film consists of a set of heterogeneous substances (lipids, proteins, mucin and water) combined in order to form a highly organic tropism structure specialized in the defense of the ocular surface. Discoid lupus erythematosus (DLE) is a chronic photosensitive dermatosis characterized by scarring and atrophy. Several researchers have observed that DLE occurs infrequently with more severe systemic organ involvement.

Material and methods: We studied 40 patients affected by DLE (28 F-12 M mean age 51.5 ± 11.1) with signs of distress and/or dry eyes (burning, foreign body sensation, dryness and itching). Patients were treated with ophthalmic solution with liposome, vitamin A, vitamin E and amino acids for 28 days. Subjective symptoms and objective signs were seen in the first visit and 5 days after the end of therapy.

Results: We considered the results of different tests, such as Schirmer I, Schirmer II, breakage of the film tears (BUT) and conjunctiva swab for the detection of aerobic and anaerobic bacteria. For each tests we evaluated mean and standard deviation. We confronted the data obtained before, and after treatment with a tear substitute next-generation ophthalmic solution obtaining significantly statistical results in each confront. The total number of bacteria isolations occurred before and after treatment showed a reduction of both aerobic (from 33 to 25) and anaerobic strains (from 21 to 12).

Conclusion: These results show that ophthalmic solution has a good regulatory activity and its clinical efficacy is confirmed by an activity aimed to normalize clinical parameters of tears.

Key words: Dry eye, tear, ecosystem eye, liposome, vitamin A, vitamin E and amino acids.

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Introduction

Dry eye disease (DED) represents a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with damage to the ocular surface^(1,2,3). Epidemiological studies have demonstrated that DED has a prevalence of 5-35% depending on the criteria applied, the population studied and geographic location^(4,5,6,7).

The tear film consists of a set of heterogeneous substances (lipids, proteins, mucin, and water) combined in order to form a highly organic tropism structure specialized to defend the ocular surface. The tear film is transparent and has an aqueous/mucin phase,

decreasing in mucin concentration towards as distinct superficial lipid layer. The quality of the tear film was shown to be affecting the visual acuity, while artificial tears were reported to improve vision of dry eye patients^(8,9). The tear film is a vital structure whose main roles are to protect the ocular surface from desiccating caused by the tear film evaporation and bacterial infections among others⁽¹⁰⁾.

The dry eye syndrome is certainly the most important disorder. It is characterized by hypo secretion of a fragmented tear film that leads to altered metabolism of the corneal epithelium and dehydration of the corneal epithelium and conjunctiva. In patients with DLE as autoimmune disease, one can observe an alteration of the tear film resulting in pos-

sible damage to the ocular surface associated with symptoms of ocular discomfort^(11,12,13,14,15,16). We hypothesized that DLE would have a negative effect on the some components. DLE is a chronic photosensitive dermatosis characterized by scarring and atrophy. Several researchers have observed that DLE occurs infrequently with more severe systemic organ involvement^(8,9). The DLE lesion is characterized by erythema, telangiectasia, adherent scale, which varies from fine to thick, follicular plugging, dyspigmentation and atrophy and scarring. The lesion are sharply demarcated and can be round, thus giving rise to the term discoid or disc-like⁽⁵⁾.

Several other authors have observed that in the subgroup of Systemic Lupus Erythematosus (SLE) with active discoid lesions, patients tended to have a more benign disease course. Based on these earlier observational data many clinicians have effected prognostic information to the patient with SLE, who present with discoid lesions as part of the SLE clinical phenotype^(10,17,18,19,20). Based on this knowledge in this study we set out to assess the possible therapeutic role played by ophthalmic solution with liposome, vitamin A, vitamin E and amino acids.

Material and methods

Fifty-five patients with DLE were recruited, but only 40 patients were admitted to the study (28 females and 12 males, mean age 51.5 ± 11.1 , table 1) presenting signs of discomfort and/or dry eyes (burning, foreign body sensation, dryness and itching).

Patients n°	Sex		Age	Range
	Man	Woman	(mean)	
40	12	8	51.5	25-68

Table 1: Demographic characteristics of patients who completed the study.

None of the patients had infections of the ocular surface in the last 30 days. We excluded patients with previous eye surgery, lachrymal disorders, and medical therapy with systemic or topical medications that alter the tearing and/or topical steroids during the 4 weeks preceding the start of the study. In all patients, the subjective symptoms and objective signs at the time of enrollment visit and after 28 days of treatment were considered. Five days after discontinuation of treatment (washout) clinical parameters were re-evaluated. At the time of enrollment and at the end of the treatment, five days after

washout, all patients received Schirmer I test, Schirmer II test, breakage of the film tears (B.U.T.) test and bacteriological research.

Schirmer I test

It was applied a strip of absorbent graduated paper long 35 mm to the outer third of the lower eyelid and it was asked to the patient to glance up. After 5 minutes, the strips were removed and it was estimated the length of wet paper (normal values between 10 and 15 mm).

Schirmer II test

We administered one drop of anesthetic (novesine) every three minutes for three times and we proceed as Schirmer I test. After 3 minutes the strips were removed, and it was estimated the portion of paper soaked (normal >10 mm).

BUT

Small quantity of fluorescein was introduced into the conjunctiva sac and, by the use of a blue filter on a slit lamp bio-microscope, was evaluated the time necessary for the appearance of the first break or dry spot on pre corneal tear film (normal values range 10-15 sec.)

Bacteriological analysis

It was carried out testing of conjunctiva swab Hess, to search for aerobic and anaerobic bacteria.

Samples from patients were seeded in the appropriate culture medium and incubated in aerobic and anaerobic atmosphere for the isolation and identification of bacteria, with separate counts for aerobic and anaerobic bacteria. After the identification of bacteria has been confirmed through Vitek (Biomerieux, Mercy l'Etoile, Francia) in case of aerobic bacteria and through API 20A (Biomerieux) in case of anaerobic bacteria, all subjects were treated with a tear substitute next-generation ophthalmic solution with liposome, vitamin A, vitamin E and amino acids (Lacrisek plus - Bioos Italy) 1 drop 3 times / day for 28 days.

Statistical analysis

The data of clinical parameters (Figure 1) Schirmer I test, Schirmer II test and BUT obtained before and after discontinuation of treatment with ophthalmic solution with liposome, vitamin A, vitamin E and amino acids before and after treatment are expressed as mean and standard deviation (SD). The statistical significance of differences between

the group before and after treatment was calculated by applying the statistical test “t” student. Statistical significance in contingency tables was evaluated using the chi square and Fisher exact test. Student’s test for unpaired data, one way ANOVA, and Mann-Whitney rank sum test were used for comparisons of continuous variables.

Statistical analysis was performed using tests for repeated measures as well by controls for multiple comparisons with correction by Duncan Procedure.

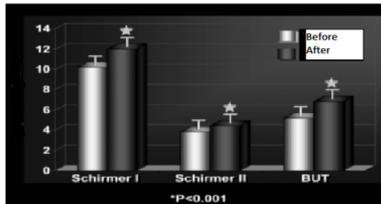


Figure 1: Statistical analysis of clinical parameters in discoid lupus erythematosus subjects expressed the first “A” and after “B” treatment with ophthalmic solution (the fifth day after discontinuation of treatment).

Results

The data obtained before and after the treatment were respectively the following: Schirmer I 8.7 ± 0.2 vs. 13.6 ± 0.4 ($p < 0,001$); Schirmer II 3.6 ± 0.1 vs. 4.6 ± 0.2 ($p < 0,001$); BUT 4.3 ± 0.3 vs. 6.5 ± 0.2 ($p < 0.001$).

Culture test showed initial bacterial growth in 35 out of 80 eyes tested, corresponding to 43.7%. After treatment positive cultures were found in 29 tests equal to 36.2% (table 2). The total numbers of isolations of aerobic and anaerobic bacteria found before and after treatment are shown in table 3. A reduction of 33 to 25 strains of aerobic and anaerobic isolates from 21 to 12 was found.

Table 4 shows the species of aerobic and anaerobic bacteria found in DLE patients before and after treatment on the fifth day after discontinuation of therapy: *S. epidermidis* from 26.4% to 51.3%, *S. aureus* from 16.9% to 8.2%, while the other isolates showed a reduction of almost homogeneous aerobic Gram-negative before and after treatment. The same table lists the species of anaerobic bacteria isolated before and after treatment: for *Peptococcus* spp. from 20.8 to 24.3%, for *Peptostreptococcus* from 9.4 to 5.4%; for *Propionibacterium* from 5.7 to 2.7% and for *Bacteroides* ssp. from 1.9 to 0%.

N° pazients (40)	N°. Eyes (80)	before		after	
		N°.	%	N°.	%
Culture test	80	35	43.7	29	36.2

Table 2: Overall incidence of culture positivity of bacteriological tests before and after treatment.

Microrganisms	Before	After
Aerobes	33	25
Anaerobes	21	12
Total strains	53	37

Table 3: Total number of aerobic and anaerobic isolates of cultures before and after treatment.

Microorganism	before		After	
	N°	%	N°	%
<i>S. epidermidis</i>	14	26.4	19	51.3
<i>S. aureus</i>	9	16.9	3	8.2
<i>S.pneumoniae</i>	3	5.7	1	2.7
<i>S.pyogens</i>	35.7	5.7	1	2.7
<i>H. influenzae</i>	2	3.7	1	2.7
<i>E. coli</i>	1	1.9	-	-
<i>P. vulgaris</i>	1	1.9	-	-
<i>Peptococcus</i> spp.	11	20.8	9	24.3
<i>Peptostreptococcus</i> spp.	5	9.4	2	5.4
<i>Propionibacterium</i> spp.	3	5.7		2.7
<i>Bacteroides</i> spp.	1	1.9	-	-
Total strains	53	100	37	100

Table 4: Overall incidence of culture positivity of bacteriological tests before and after treatment.

Discussion and conclusion

DLE is a chronic photosensitive dermatosis characterized by scarring and atrophy. Several researchers have observed that DLE occurs infrequently with more severe systemic organ involvement^(21, 22, 23, 25, 26). Numerous studies have shown that in patients with DLE there is an alteration of the tear film demonstrated by Schirmer and BUT tests^(4,5,6).

Other authors have also demonstrated microangiopathic complications in patients without symptoms of dry eye and normal Schirmer test with degrees of squamous metaplasia^(27, 28, 29, 30, 31, 32).

In our study it was observed that treatment with ophthalmic solution with liposome, vitamin A, vitamin E and amino acids induces physiological activity recovery of tear film production. The indirect activity of this molecule in the restoration of the normal microbiota of the eye, characterized by the increase in the percentage of bacteria normally present on ocular surface, seems to restore a good physiological ecology of the ocular surface. The data of our study confirm a good activity of ophthalmic solution with liposome, vitamin A, vitamin E and amino acids in enhancing the defense system of the ocular surface damage and chronic hyperglycemia probably responsible of alteration of the physiological components of the tear film^(33, 34, 35). The ophthalmic solution with liposome, vitamin A, vitamin E and amino acids exerts both a direct activity that leads to normalization of clinical parameters of tear film and an indirect activity in restoring the ocular surface microbial ecology.

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