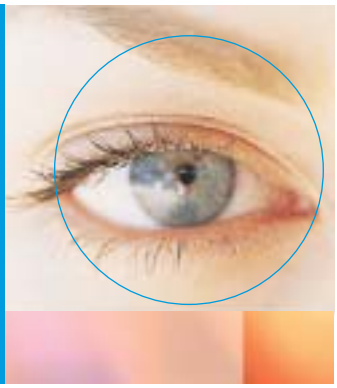
The Treatment of Conjunctivitis with Antihomotoxic Preparations
Results of a prospective controlled cohort study

Reinhard W. Küstermann, M.D. - Reprint from Medicina Biologica, Vol. 2, April-June 2002, 36-42.



In general terms, conjunctivitis can be of bacterial or viral origin. Conjunctivitis due to allergy, irritation, and toxic reactions constitutes the more frequent, non-bacterial causes of the condition. The incidence of conjunctivitis from allergy is approximately 20% of cases, and is usually accompanied by rhinitis and intense tearing of the eye, hyperemia, lacrimation, congestion of the upper respiratory passages, and sneezing.

Traditionally, anti-inflammatory agents, vasoconstrictors, and antihistamines are used for these conditions. Alternatively, the use of homeopathic preparations, and specifically in this instance, the antihomotoxic preparation OCULOHEEL (manufactured by HEEL GmbH, Baden-Baden, Germany) is applicable to the treatment and management of conjunctivitis, blepharitis and dacryocystitis. The individual homeopathic components of OCULOHEEL are anti-inflammatory and detoxifying, especially targeted to the eye.

OBJECT

The object of this study is to investigate the efficacy, safety and specific application of the product OCULOHEEL in ophthalmic practice. A prospective controlled cohort study was designed to compare the efficacy and safety of the antihomotoxic preparation to that of conventional treatment with the allopathic drug tetryzoline in the treatment of conjunctivitis.

PATIENTS AND TREATMENT REGIME

Results are based on a case-by-case-study, using clinical cases. No real criteria limit the inclusion of candidates; that is, they are patients being treated for conjunctivitis, not limited to a particular cause, and thus each case is based on its particulars, taking into consideration the associated symptoms of conjunctivitis that may be present. The underlined parameter is to compare the efficacy of the homeopathic medication with conventional medication, such as vasoconstrictors. Those candidates included in the study have been treated with Oculoheel (which contains Euphrasia officinalis D5, Cochlearia officinalis D5, Pilocarpus jaborandi D5, Echinacea angustifolia D5) or with a dose of tetryzoline (0.5 mg) as the only therapy. Oculoheel does not contain preservatives.

Only patients over 6 years of age were included in the study. At the start of this study, two over-the-counter ophthalmic drops could be bought in Germany as monodoses, containing 0.5 mg of tetryzoline (Berberil R N® and Yxin R®). Participating physicians were free to choose their preference for the comparison study.

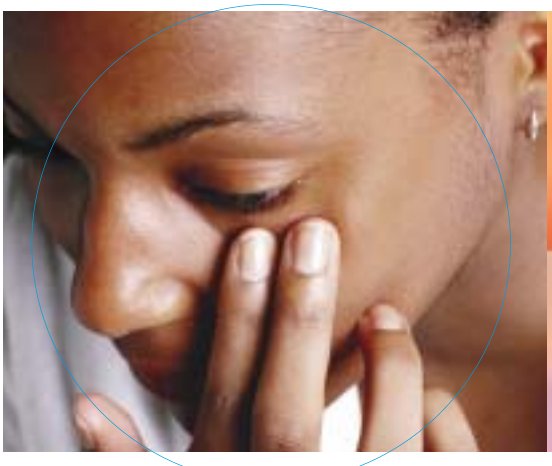
The patient data corresponds to the initial and final consultation. The duration of the treatment generally lasted 2 weeks. In certain cases, when deemed necessary, there were intermediate interventions and the data recorded. The results documented in this study are those from the treatment of conjunctivitis as the principal symptom.

Throughout the initial examination, the following criteria were recorded: date, demographics, possible factors contributing to redness and conjunctivitis, diagnosis, specifics of ocular irritation. In order to document the aforementioned criteria as data, values were given to the efficacy of the treatment as follows: low, moderate, severe; the nature of the condition was also valued as: acute, chronic or minor. The severity of the condition was also evaluated as: insignificant, low, moderate, severe, very severe, especially for the following symptoms: pain, pruritis, redness, tearing, grating (sensation of foreign object in the eye) retrobulbar pain. Other indicative data, if any, obtained prior to the initial exam could be referred to in cases of concomitant conditions.

During the final examination, the effectiveness of the treatment was assessed according to the current symptoms and any secondary reactions that might have occurred. The efficacy of the treatment was rated by a 5-point system: very good (no symptoms), good (significantly better); moderate (improved) no results (no improvement) or exacerbation. To determine the tolerability of the study, a 4-point system was established for the patients to rate as: very good, good, moderate, ineffective.

Treatments were compared by an analysis of variance with baseline values of efficacy parameters as covariates based on a 5-point system of values: mean, deviation, standard, minimum and maximum. The demographic data and all of the reference parameters were treated with the Fisher test. Efficacy parameters were the mean symptom score and the sum of 5-point rating scale scores of 9 specific conjunctivitis symptoms and the global assessment of the investigators.

For both the mean symptoms score and the sum of score, the intensity of the baseline symptoms was reduced significantly during the treatment. The analysis of variance revealed with a probability of 95% that the difference between the treatments was less than 5% of the maximum score range.



PATIENTS AND METHODS

769 patients with conjunctivitis were treated either with OCULOHEEL (n= 456) or tetryzoline (n=313) in a prospective controlled cohort study. The treatments were compared by an analysis of variance with baseline values of efficacy parameters as covariates. Efficacy parameters were the mean symptom score and the sum of a 5-point rating scale for 9 specific conjunctivitis symptoms and the global assessment of the investigators.

TABLE 1

Reference parameters for the patients included in the study. The data represents the number and percentage of patients. OCULOHEEL: n = 456; TETRYZOLINE: n = 313; n can be smaller due to patient data loss. Multiple assignment was possible for the parameters: location / specification and cause of conjunctivitis. SD = standard deviation.

		Oculoheel	Tetryzoline
Demographic data	Age (year)		
	■ Average	39.1	44.3
	■ Range	6-89	6-94
	■ SD	19.8	18.6
	Gender		
	■ Male	162 (35.5)	147 (47.0)
	■ Female	292 (64.0)	164 (52.4)
	■ Unspecified	2 (0.4)	2 (0.6)
Location and specification	Conjunctivitis		
	■ With redness	389 (88.0)	283 (92.8)
	■ Without redness	38 (8.6)	16 (5.2)
	■ Unspecified	15 (3.4)	6 (2.0)
	Marginal blepharitis		
	■ With redness	64 (58.7)	68 (68.0)
	■ Without redness	44 (40.4)	30 (30.0)
	■ Unspecified	1 (0.9)	2 (2.0)
Cause of conjunctivitis	Irritation	167 (36.6)	147 (47.0)
	Allergic inflammation	165 (36.2)	125 (39.9)
	Infection	99 (21.7)	45 (14.4)
	Systemic illness	8 (1.8)	2 (0.6)
	Others	37 (8.1)	13 (4.2)
Type of conjunctivitis	Acute	218 (47.8)	234 (74.8)
	Chronic	144 (31.6)	33 (10.5)
	Recurrent	76 (16.7)	31 (9.9)
	Unspecified	18 (3.9)	15 (4.8)
Intensity of conjunctivitis	Light	188 (41.2)	94 (30.0)
	Moderate	239 (52.4)	196 (62.6)
	Severe	25 (5.7)	21 (6.7)
	Unspecified	3 (0.7)	2 (0.6)
Duration of conjunctivitis (weeks)	< 1	187 (41.0)	196 (62.6)
	1 - 2	97 (21.3)	74 (23.6)
	2 - 4	59 (12.9)	12 (3.8)
	> 4	102 (22.4)	19 (6.1)
	Unspecified	11 (2.4)	12 (3.8)

790 patients with conjunctivitis participated in this prospective controlled study of which 21 were excluded because of age or loss of data. Interruption of treatment occurred in 24% of the Oculoheel group and 16% of the tetryzoline group. In 5% of the Oculoheel group and 1% of the tetryzoline group interruption of treatment was necessary due to the appearance of side effects or inefficacy on that particular patient (1% Oculoheel, 1% tetryzoline).

The average age in the Oculoheel group was 39.1 years compared to 44.3 years for the tetryzoline group. More women than men participated in the study.

The most common symptom was redness of the eye and this was graded as either moderate or high. The duration of the condition was regarded as being acute or

chronic conjunctivitis. Additionally, a considerable number of recurring conditions were taken into consideration.

The group treated with Oculoheel had more candidates with chronic conditions than the group treated with tetryzoline (32% to 11% respectively). Treatment periods varied from one week to three weeks. In the Oculoheel group some patients extended treatment to 4 weeks. Most of the patients had not had previous ophthalmic treatment before participating in this study.

TREATMENT

The treatment regimen was one drop of medication in each eye three times per day. Changes in the dosage occurred throughout the study as a reduction of the frequency of application in general and more so in the Oculoheel group (41% in the Oculoheel group compared with 14% in the tetryzoline group).

The average treatment period was 12.5 days in the Oculoheel group and 15.9 days in the tetryzoline group. The average duration of treatment for both groups was 8-14 days (Oculoheel 55%; tetryzoline 49%).

EVALUATION

The investigators evaluated the intensity of symptoms of conjunctivitis. From this data, they proceeded to calculate the average treatment required to reduce symptoms by a 4-point system (ranging from 0-4).

The evaluation revealed a linear reduction of symptoms in both groups. The average value assigned to the symptoms was 1.45 for the Oculoheel group.

During the course of treatment, the value was reduced from 0.36 down to 0.1 by the end of the treatment. In the tetryzoline group, values were compared: (1.712, 0.7 and 0.3 respectively).

TOLERABILITY

The values for tolerability of both groups in this study were excellent: 98% for the Oculoheel group and 100% for the tetryzoline group. Both groups of patients rated the treatment as “very good ”or “good” (in 96% of patients).

Fig. 3: Global assessment of the treatment’s effectiveness

RESULTS

For both the mean symptom score and the sum of score, the intensity of the baseline symptoms was reduced significantly during the treatment. The analysis of variance revealed, with a probability of 95% , that the difference between the treatments was less than 5% of the maximum score range. The global assessment revealed that a treatment with Oculoheel was rated as “very good” or “good” in 88% of the cases (tetryzoline group 95%). Tolerability was excellent for both groups.

CONCLUSION

The data suggests that Oculoheel eye drops are a first-rate option for the treatment of conjunctivitis.