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RESEARCH ARTICLE

Clinical Efficacy and Safety of *Mahatriphaladya Ghrita* in the Management of Allergic Conjunctivitis: A Prospective Open Label Multicenter Study

[1]Alok Srivastav, [2]Deepa Makhija, [3]Sanjaykumar Singh, [4]Shruti Khanduri, [5]Pradeep Dua, [6]Babita Yadav, [7]Rakesh Rana [8]Richa Singhal, [9]Vanmala B Wakode, [10]Gaddam K Swamy, [11]Narayanam Srikanth, [12]Madan M Padhi, [13]Kartar S Dhiman

ABSTRACT

Introduction: Allergic conjunctivitis is a mild, nonspecific inflammation of the conjunctiva due to allergy with symptoms of conjunctival congestion, mild papillary response, and intense itching without any known specific condition for pathology to develop or with undetermined etiology that is mostly and easily attributed to allergy.

Aims and objectives: To evaluate the efficacy and safety of *Mahatriphaladya Ghrita* and *Triphala Kwath (Aschyotana)* in patients suffering from allergic conjunctivitis.

Materials and methods: A prospective, open label multicenter study was carried out at two peripheral centers of the Central Council for Research in Ayurvedic Sciences (CCRAS). Totally, 54 patients satisfying the selection criteria were enrolled from the outpatient department (OPD) of these centers and were administered *Mahatriphaladya Ghrita* (15 mL) twice daily on an empty stomach in the morning and 3 hours before meals in the evening with lukewarm water for 12 weeks and *Triphala Kvatha (10 drops) Aschyotana* twice daily for 12 weeks. All the participants were subjected to complete physical and ophthalmic examination along with blood investigations. Follow-up was done finally after 2 weeks without medication. Laboratory parameters, viz., absolute eosinophil count (AEC), liver function tests, kidney function tests, lipid profile, total leukocyte count (TLC) were assessed at baseline and at the end of the treatment period of 12 weeks (i.e., 84th day). Paired sample t-test was used to compare mean change from baseline to the 84th day on the outcome variables assessed by visual analog scale (VAS, 0–100 mm) and on the laboratory examination. A p-value of <0.05 was considered significant.

Results: At the end of 12 weeks, compared with baseline, statistically significant improvement was observed in symptoms, viz., redness, anxiety, lacrimation, photophobia, burning, and foreign body sensation ($p < 0.001$). The treatment was found to be safe and effective in the subjects of allergic conjunctivitis as all the safety parameters were within the stipulated range. No adverse drug reactions or adverse events were reported during the trial period.

Conclusion: *Mahatriphaladya Ghrita* and *Triphala Kwath (Aschyotana)* administered in the above-mentioned dose were found effective and safe in patients suffering from allergic conjunctivitis.

Keywords: Allergic conjunctivitis, *Mahatriphaladya Ghrita*, *Triphala Kwath*.

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INTRODUCTION

Allergic conjunctivitis is a mild, nonspecific inflammation of the conjunctiva due to allergy with symptoms of redness (mainly due to vasodilatation of the peripheral small blood vessels), edema (swelling) of the conjunctiva, itching (most typical symptom of ocular allergy), and increased lacrimation (production of the tears) without any known specific condition for pathology to develop or with undetermined etiology that is mostly and easily attributed to allergy.[1,3] Symptoms are usually worse for patients when weather is warm and dry, whereas cooler temperatures and rain tend to minimize symptoms.[2] It is a very common ocular problem in routine ophthalmic practice.[3] Conjunctiva is highly sensitive of about ten times more than skin.[1] It has been reported that allergic conjunctivitis alters patient's routine limiting certain activities such as going outdoors, reading, sleeping and driving in addition to the physical discomfort.[4] The symptoms are due to release of histamine and other active substances by mast cells, which, in turn, stimulate dilatation of blood vessels, irritate nerve endings, and increase tear secretion. Therefore, treating patients with allergic conjunctivitis may improve their everyday quality-of-life.

[1-6,9]Research Officer (Ayurveda), [7]Statistical Officer, [8]Statistical Assistant, [10]Director [11]Deputy Director General, [12,13]Director General

[1,3]Regional Ayurveda Research Institute for Eye Diseases Lucknow, Uttar Pradesh, India

[2,10]Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, India

[4-9,11-13]Central Council for Research in Ayurvedic Sciences New Delhi, India

Corresponding Author: Shruti Khanduri, Research Officer (Ayurveda), Central Council for Research in Ayurvedic Sciences New Delhi, India, e-mail: drshruticcras@gamil.com

Modern trend of management of such conditions advocates avoidance of the allergen[1] and treatment with either topical or systemic steroids/decongestant drops/mast cell stabilizers along with antihistamine and anti-inflammatory agents.[5] This management is not satisfactory and seems to be temporary, used only during exacerbations and also has its side/adverse effects.[2] Considering this, it becomes necessary to find out a safe and effective drug, which could treat such conditions. There is a vivid description of many Ayurvedic formulations and procedures in Ayurveda classics, which are beneficial in the treatment of such conditions.

Oral administration of Ayurveda medicines and *Netra Kriya*, such as *Aschyotana*, *tarpana*, etc., are advocated in Ayurveda classics for the management of conjunctivitis. *Mahatriphaladya Ghrita* and *Triphala Kwatha Aschyotana* are the most commonly used regimens for the treatment of such conditions and an open label multicenter study was carried out at OPD level at two CCRAS institutes on 54 cases. Results were analyzed and assessed using appropriate statistical tools on various clinical parameters.

OBJECTIVES

To evaluate the efficacy and safety of two classical Ayurvedic formulations *Mahatriphaladya Ghrita* and *Triphala Kwath Aschyotana* in the patients of allergic conjunctivitis.

MATERIALS AND METHODS

Study Design

The study was a prospective open label multicenter trial executed at two peripheral centers of CCRAS, Ministry of AYUSH. The study was approved by the Institutional Ethics Committee of both the participating centers and was done in accordance with the World Health Organization—Good Clinical Practice Guidelines. The clinical trial has also been registered in Clinical Trial Registry of India (CTRI/2012/07/002777).

Study Participants

A total of 54 participants were enrolled at the two centers, viz., Regional Ayurveda Research Institute for Infectious Diseases, Patna and Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, India, in the trial after obtaining the written informed consent. Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria

Patients of either sex aged between 16 and 35 years, presenting with signs and symptoms of allergic conjunctivitis who are willing and able to participate for a period of 14 weeks were included in the study.

Exclusion Criteria

Patients having any complications with corneal involvement, conjunctivitis other than allergic, disease of lachrymal system/genetic predisposition to allergy/concurrent serious hepatic disorder, renal disorders, abnormal lipid profile, severe pulmonary dysfunction/uncontrolled diabetes mellitus or poorly controlled hypertension/pregnant or lactating females/patients on steroids, oral contraceptive pills or estrogen replacement therapy/smokers/alcoholics/drug abusers/patients on long-term drug treatment as in rheumatoid arthritis, psycho-neuro-endocrinal disorders/hypersensitivity to any of the ingredients of the trial drug/patients who have undergone any clinical trial during past 6 months were excluded from the study.

Study Interventions

The study medications included quality-assured *Mahatriphaladya Ghrita*[6] in the dose of 15 mL twice daily, which was given with lukewarm water (empty stomach in the morning and 3 hours before meals in the evening) for a period of 12 weeks and topical instillation *(Aschyotana)* of 10 drops of *Triphala Kwath* in the conjunctival sac in supine position was done twice a day using all aseptic measures for 12 weeks.

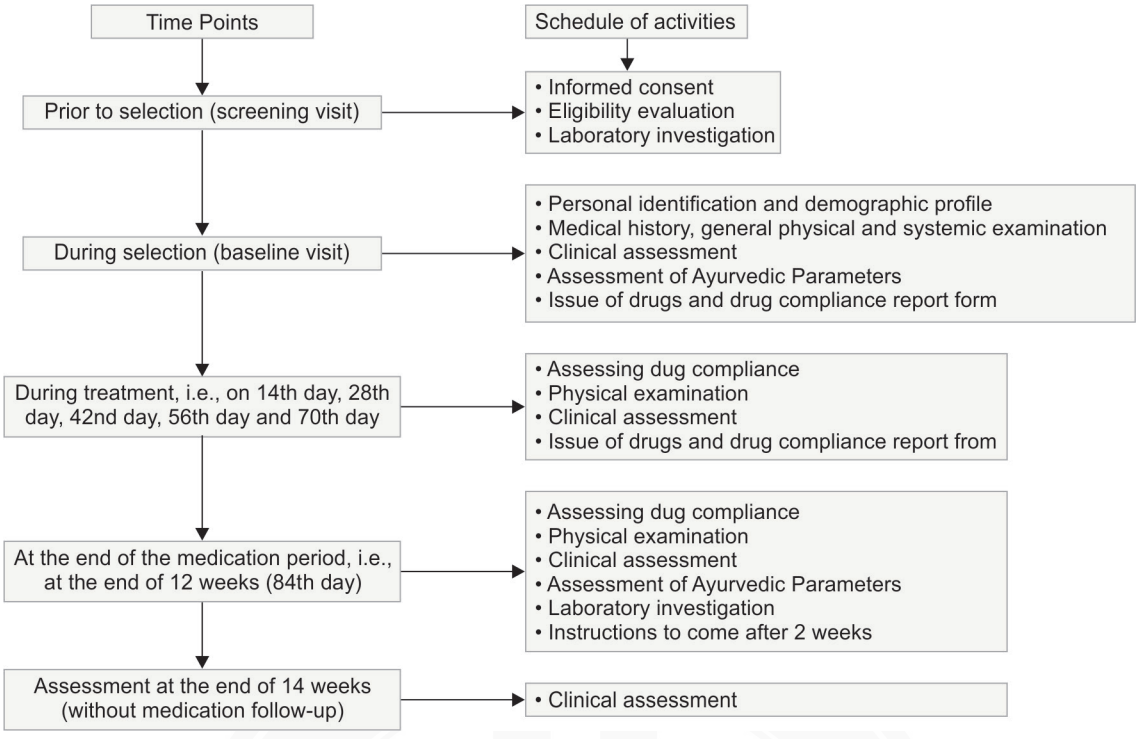
Before treatment, all subjects were subjected to a preparatory phase comprising *Dipana* for 3 days with *Hingvastaka Churna* 3 to 5 gm (based on assessment of Agni) orally before meal twice a day with lukewarm water followed by *Virechana* with *Avipattikar Churna* 5 gm once at bedtime with lukewarm water. The patients were also guided regarding pathya–apathya and about hygienic conditions.

Study Procedure

On the enrolment day at baseline (Visit 1), the patient's demographic profile, medical history, general and systemic examination, and ophthalmic examination were done and recorded. Subsequent visits were planned at an interval of 2 weeks [14th day (Visit 2), 28th day (Visit 3), 42nd day (Visit 4), 56th day (Visit 5), 70th day (Visit 6), and 84th day (Visit 7)]. Patients were assessed and given study medications at each subsequent visit until the 84th day. There was also a without-medication follow-up after 2 weeks of the 84th day visit. Details of clinical assessment and study schedule are given in Flow Chart 1.

At the study site, data of all the patients were recorded in predesigned case report forms (CRFs) and were also

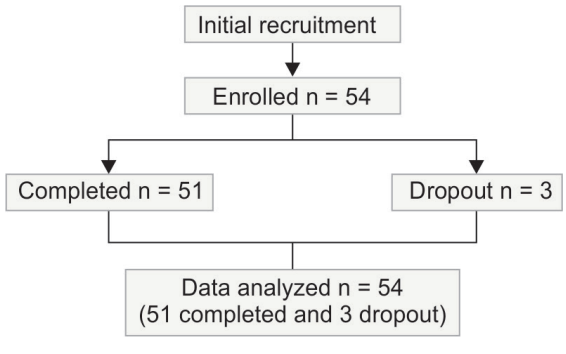
Flow Chart 1: Study schedule



entered in electronic formats (e-formats) designed in MS Excel with many data validation checks to ensure correct data entry. The e-formats and Xerox of the CRFs along with the laboratory investigations reports of the patients were sent by the participating centers to the Council's headquarters on a weekly basis for the purpose of clinical trial monitoring.

Out of the total 54 patients enrolled in the study, 3 dropped out during the course of the study. Intention-to-treat analysis was done and the data of all those patients who have completed at least 14th day visits were imputed by last observation carried forward (LOCF) method. Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total of 54 patients were used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

Flow Chart 2: Outflow of the patients in the study



Efficacy Evaluation through Outcomes

The outcome of the study was symptomatic improvement in redness, anxiety, lacrimation, photophobia, burning sensation, foreign body sensation assessed by VAS (0–100 scale) at every follow-up, i.e., baseline, 14th day, 28th day, 42nd day, 56th day, 70th day, 84th day, and 98th day.

Statistical Analysis

The data of enrolled participants for whom the values for baseline visit and at least one subsequent visit after taking the study medication were available have been used for analysis.

The LOCF method was used for handling the missing data. Demographic profile and baseline characteristics of the patients for all the discrete variables have been expressed as frequency and percentage. The data for all the continuous variables have been represented as mean and standard deviation (SD). Before and after treatment, data of the patients have been analyzed using paired sample t-test on the outcome variables assessed by VAS and on the laboratory examination. The p-value of <0.05 has been considered as significant.

RESULTS

Data of a total of 54 patients (32 male and 22 female) were used for statistical analysis, out of which the maximum patients were in the age group of 16 to 20 years. Table 1 shows the demographic profile of the patients. Totally, 24 (44.4%) patients were of vataja–pittaja sharirik prakriti.

Table 1: Baseline characteristics of study participants

Demographic profile (n = 54)	
Age group	
16–20	29 (53.6)
21–25	7 (13.0)
26–30	7 (13.0)
31–35	11 (20.4)
Sex	
Male	32 (59.2)
Female	22 (40.8)
Educational status	
Illiterate	4 (7.4)
Read and write	50 (92.6)
Socioeconomic status	
Above poverty line	49 (90.7)
Below poverty line	5 (9.3)
Habitat	
Urban	41 (75.9)
Semiurban	2 (3.7)
Rural	11 (20.4)
Shariri Prakriti	
Vataja	2 (3.7)
Pittaja	9 (16.7)
kaphaja	0 (0.0)
Vata-Pittaja	24 (44.4)
Vata-Kaphaja	1 (1.9)
Pitta-Kaphaja	11(20.4)
Sannipataja	7 (13.0)

Values are expressed as n (%)

It was also observed from data that the maximum number of patients [35 (64.8%)] were in desk work and 7 (13.0%) were in field work/field work with physical labor. Maximum numbers of patients 41 (75.9%) were residing in urban area.

It was observed that 38 patients (70.4%) were allergic to some material and 29 (76.3%) of these patients had dust allergy.

It was also noticed that 42 (77.8%) patients were nonvegetarian; addiction of any kind was not found in 96.3% of cases, while chewing tobacco was observed in 3.7% of cases.

Oral administration of *Mahatriphaladya Ghrita* and *Triphala Kwath Aschyotana* for 84 days revealed significant improvement in the common complaints of patients suffering from allergic conjunctivitis. The complaint of redness was observed in 56.48% patients at baseline, which was reduced to 5.09% patients at the end of treatment (<0.001). Complaint of anxiety was observed in 32.41% patients at baseline, which was reduced to 4.63% patients at the end of treatment (<0.001), lacrimation was observed in 49.07% patients at baseline, which was reduced to 5.56% patients at the end of treatment (<0.001), photophobia was observed 41.2% patients at the baseline, which was reduced to 4.63% patients at the end of treatment (<0.001), burning was observed in 43.98% patients at the baseline, which was reduced to 6.48% at the end of treatment (<0.001), and foreign body sensation was observed 39.35% at baseline, which was reduced to 3.24% at the end of treatment (<0.001). Effect of the treatment on chief complaints/Outcome parameters are given in Graph 1.

Effect of the study medications was also assessed by paired t-test on hematological parameters compared at baseline and at 84th day. Table 2 shows the results of the analysis on hematological parameters.

Effect of the Drugs on Safety Parameters

The effect of *Mahatriphaladya Ghrita* was assessed using liver function tests and kidney function tests at baseline and at the end of 84th day to establish the clinical safety. Lipid profile was also assessed at baseline and at the end of 84th day. The values of these biochemical tests were found to be within the normal range during the assessment period (Table 3). These observations validate that these classical drugs are safe for human use. Further, no adverse events or adverse drug reactions were reported during the treatment period.

DISCUSSION

Almost all the eye disorders have been caused by *Abhishyanda* and must be treated as soon as possible, otherwise its complications will become severe and will lead to difficulty in saving the eyesight.[7]

Table 2: Effect of the treatment on hematological parameters

Parameters	*Baseline (mean ± SD)*	*84th day (mean ± SD)*	*t-value*	*p-value*
Hemoglobin (gm/dL)	12.507 ± 1.5312	12.541 ± 1.7064	0.228	0.821
TLC/cu mm	7287.04 ± 1891.994	7542.59 ± 2229.020	0.883	0.381
N%	54.43 ± 11.452	56.39 ± 10.832	1.293	0.201
E%	6.35 ± 6.150	6.15 ± 5.611	0.291	0.772
L%	36.61 ± 11.136	34.83 ± 10.147	1.217	0.229
M%	2.61 ± 1.071	2.81 ±1.199	1.132	0.263
ESR (mm) at the end of 1st hour	23.09 ±14.006	22.17 ± 14.346	0.607	0.546
Blood sugar fasting (mg/dL)	84.19 ± 12.028	82.50 ± 8.750	0.986	0.329
*AEC cells	450.46 ± 466.761	444.15 ± 382.035	0.111	0.912

ESR: Erythrocyte sedimentation rate; N: Neutrophils; E: Eosinophils, L: Lymphocytes, M: Monocytes; *Absolute Eosinophil Count Minimum values at Baseline—46, Maximum value at baseline—2565; *Absolute Eosinophil Count Minimum value at 84th day—84, Maximum value at 84th day—1920

Table 3: Effect of the trial drugs on safety parameters

Parameters	*Baseline (mean ± SD)*	*84th day (mean ± SD)*	*t-value*[$]	*p-value*
Blood urea (mg/dL)	25.011 ± 5.9317	25.87 ± 5.863	0.765	0.448
Serum uric acid (mg/dL)	4.7870 ± 0.93369	4.972 ± 0.9205	1.655	0.104
Serum creatinine (mg/dL)	0.8135 ± 0.10029	0.8585 ± 0.11979	2.810	0.007
SGOT (AST) (IU/L)	20.80 ± 5.318	22.96 ± 7.400	2.413	0.019
SGPT (ALT) (IU/L)	34.20 ± 10.164	38.24 ± 17.234	1.843	0.071
Total protein (gm/dL)	7.541 ± 0.5053	7.608 ± 0.4624	0.767	0.446
Serum albumin (gm/dL)	4.299 ± 0.3407	4.280 ± 0.2872	0.313	0.756
Serum globulin (gm/dL)	3.242 ± 0.4421	3.30 ± 0.373	0.916	0.364
Conjugated bilirubin (mg/dL)	0.5015 ± 0.17336	0.5146 ± 0.15456	0.617	0.540
Unconjugated bilirubin (mg/dL)	0.313 ± 0.0728	0.3381 ± 0.13190	1.589	0.118
Serum alkaline phosphatase (U/L)	275.31 ± 206.964	230.85 ± 169.968	2.617	0.012
Serum cholesterol (mg/dL)	185.03 ± 26.766	185.90 ± 25.871	0.363	0.718
Serum triglycerides (mg/dL)	108.13 ± 32.912	106.24 ± 33.673	0.385	0.701
Low-density lipoprotein (mg/dL)	115.208 ± 18.8845	116.97 ± 18.943	0.994	0.325
High-density lipoprotein (mg/dL)	51.039 ± 4.6542	50.45 ± 4.497	0.818	0.417
Very low density lipoprotein (mg/dL)	21.159 ± 6.5590	20.678 ± 6.7372	0.490	0.626

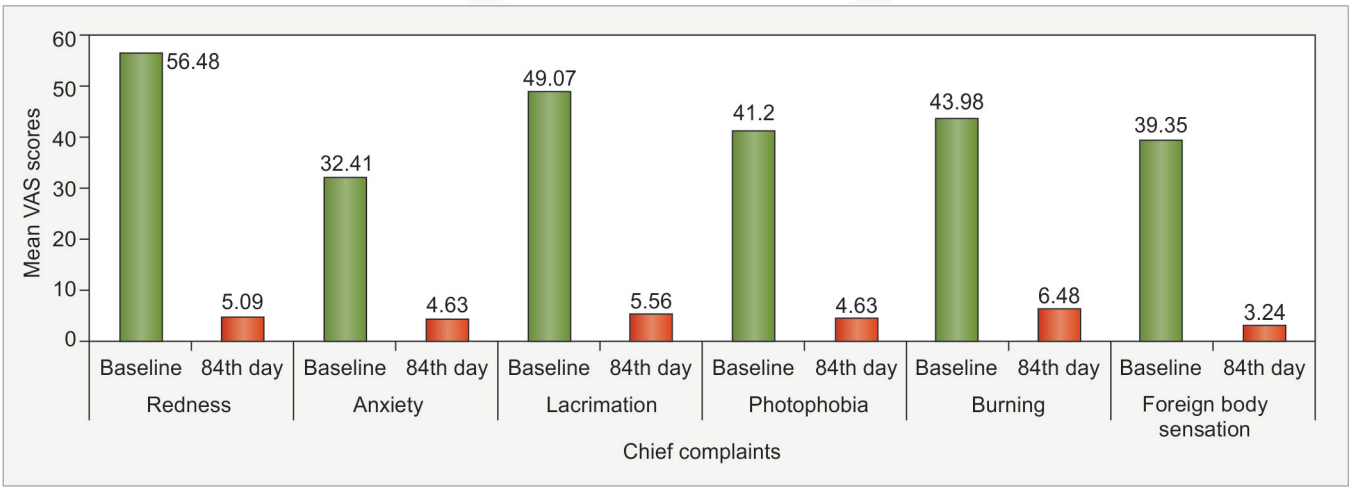
Values are expressed as mean (SD), [$]Compared using paired t-test at baseline and 84th day. SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase; AST: Aspartate transaminase; ALT: Alanine transaminase

A highly polluted environment has an effect on lifestyle. Simple allergic conjunctivitis is one of the outcomes of this changing lifestyle, food habits, and polluted environment. Simple allergic conjunctivitis has an equal distribution, more or less, throughout the world, without any exception to the developed and underdeveloped countries.[8]

In the present study, a total of 54 patients of allergic conjunctivitis were included in the trial and studied on OPD basis. The observations and results of the study revealed that the disease is evenly prevalent in both genders and most patients were in the age of 16 to 20 years. Maximum cases (75.9%) were found to be residing in urban areas. Allergy due to dust, mites, pollens, etc., is attributed as one of the main causative factors of allergic conjunctivitis, which was quite evident in this study also as about 70.4% patients were allergic to some materials. Mostly, patients were of the *Vata–pittaja prakriti* and about 27.8% patients had refractive errors.

The drug interventions, viz., *Triphala Kwath Aschyotana* and *Mahatriphaladya Ghrita* orally showed marked results in the alleviation of symptoms, viz., redness, anxiety, lacrimation, photophobia, burning sensation, foreign body sensation at the end of treatment (84th day), which remained almost persistent after withdrawal of the drug on VAS. There was decrease in the mean value of AEC after the treatment, though insignificant statistically.

Mahatriphaladya Ghrita is one of the most commonly prescribed Ayurveda medications mentioned in Ayurveda classics for different *Netra roga* (eye disorders). Most of the ingredients, such as *Goghrta*[9] (clarified butter from cow's milk), *Haritaki*[10] (*Terminalia chebula*), *Bibhitaki*[11] (*Terminalia belerica*), *Amalaki*[12] (*Emblica officinalis*), *Bhringaraja*[13] (*Eclipta alba*), *Satavari*[14] (*Asparagus racemosus*),



Graph 1: Effect of the treatment on chief complaints/outcome parameters

and *Madhuka*[15] (*Glycyrrhiza glabra*) of this formulation are described for their therapeutic use in eye disorders.

Aschyotana, a Netra kriya karma, is often used for allergic conjunctivitis as it alleviates the inflammation, burning, redness, foreign body sensation, lacrimation, and itching in eyes.[16,17]

Triphala possesses *chakshushya* property and its *Kashaya* is mentioned in Ayurveda texts for Netra roga (eye disorders) particularly in all types of Abhishyanda (conjunctivitis),[18] owing to which *Triphala Kvatha* Aschyotana was used in this clinical study.

Triphala being predominantly *kasayaras* may have contributed in reducing congestion in the eyes.[19] It is also opined that Triphala is helpful in breaking the abhisyandatva of the srotas by virtue of its ushna and ruksha properties. The tridoshahara property of Triphala is helpful in maintaining the homeostasis in the body and eye, thus preventing further pathogenesis.[20] Further, *Triphala* is reported to be a potent free radical scavenger and possesses antioxidant, anti-inflammatory, analgesic, antibacterial, and immunomodulatory properties.[21]

CONCLUSION

This study provides the evidence in support of the potential efficacy and safety of the *Mahatriphaladya Ghrita* and *Triphala Kwath Aschyotana* in the subjects suffering from allergic conjunctivitis. About 12 weeks of treatment significantly reduced the symptoms in subjects suffering from allergic conjunctivitis, which sustained after 2 weeks follow-up also. The test drugs were found to be clinically safe as no significant changes were seen in any of the safety parameters, i.e., kidney function and liver function. No adverse drug reaction or events were also reported during the treatment period. Hence, it can be concluded that these drugs can be safely used in the subjects suffering from allergic conjunctivitis. Further study with a control group is required to corroborate the findings of the study.

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हिन्दी सारांश

एलर्जिक कंजनक्टिवाईटिस में महात्रिफलाद्य घृत की आतुरीय प्रभावकारिता एवं सुरक्षा – एक प्रत्याशित बहुकेन्द्रीय ओपन लेबल अध्ययन

[1]आलोक श्रीवास्तव, [2]दीपा मखिजा, [3]संजयकुमार सिंह, [4]श्रुति खंडूड़ी, [5]प्रदीप दुआ, [6]बबीता यादव [7]राकेश राणा, [8]ऋचा सिंघल, [9]वनमाला बी. वकोड़े, [10]गड्डाम के. स्वामी, [11]नारायणम श्रीकांत [12]मदन एम. पाढ़ी, [13]करतार एस धीमान

परिचयः प्रस्तुत शोधपत्र में एलर्जिक कंजनक्टिवाईटिस पर महात्रिफलाद्य घृत के प्रभाव का एक चिकित्सात्मक अध्ययन क्षेत्रीय आयुर्वेद अनुसंधान संस्थान वर्ष 2012–13 में नई दिल्ली, पटना में किया गया। एलर्जिक कंजनक्टिवाईटिस रोग के लक्षणों की तुलना आयुर्वेद में कफज अभिष्यंद के लक्षणों से की गई हैं।

उद्देश्यः महात्रिफलाद्य घृत एवं त्रिफलाक्वाथ के प्रभाव एवं सुरक्षा को एलर्जिक कंजनक्टिवाईटिस में अध्ययन करना।

साधन एवं विधिः यह एक बहुकेन्द्रीय अध्ययन है जो कि केन्द्रीय आयुर्वेदीय अनुसंधान परिषद् के 2 परिधीय संस्थानों पर 54 रोगियों में चयन प्रक्रिया के अनुसार किया गया। इन रोगियों को महात्रिफलाद्य घृत 15 मि.ली. दिन में दो बार (सुबह खाली पेट ओर शाम में भोजन के 3 घंटे पहले गुनगुने पानी के साथ 12 सप्ताह तक दिया गया) और त्रिफलाक्वाथ का स्थानीय प्रयोग (आश्च्योतन) 10 बूंद दिन में दो बार 12 सप्ताह तक दिया गया। सभी रोगियों में रक्त की जाँच, शारीरिक नेत्र परीक्षण पूर्ण की गई थी। 2 सप्ताह के बाद बिना दवा के जाँच करने के लिए बुलाया गया था। इस अध्ययन में जैव रासायनिक परीक्षण एल. एफ. टी. (L.F.T) और के. एफ. टी. (K.F.T) ईसिनोफिल गणना का पूर्व और पश्चात् परीक्षण किया गया। औषध का प्रतिकूल प्रभाव (ADR), परीक्षण अवधि के दौरान इंगित किया गया। युग्मयुक्त टी–टेस्ट का इस्तेमाल सभी मापदंडो के आधारभूत परिवर्तन से 84वे दिन के बीच तुलना किया गया। सांख्यिकी दृष्टि से चिकित्सा का सार्थक परिणाम ($P>0.05$) प्राप्त हुआ।

परिणामः एलर्जिक कंजनक्टिवाईटिस में पाए गए लक्षणों में सांख्यिकी आधार पर 12 सप्ताह के अंत में सार्थक सुधार देखा गया जो कि 14 सप्ताह के उपरांत भी कायम रहा।

निष्कर्षः एलर्जिक कंजनक्टिवाईटिस में महात्रिफलाद्य घृत एवं त्रिफलाक्वाथ (आश्च्योतन), उपरोक्त मात्रा में प्रभावी एवं सुरक्षित पाया गया।

कुंजी शब्दः एलर्जिक कंजनक्टिवाईटिस, महात्रिफलाद्य घृत, त्रिफलाक्वाथ।