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A clinical study to assess the efficacy of *Triyushnadi Anjana* in *Kaphaja Abhishyanda* with special reference to vernal keratoconjunctivitis

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Abstract

Vernal keratoconjunctivitis / spring catarrh is a variety of exogenous allergic conjunctivitis, which is a very troublesome ocular disease of childhood and in the adolescent age group. The child suffers from intense itching, grittiness, discharge, redness, lacrimation, photophobia, and so on, thereby, decreasing his learning hours. The troublesome features are aggravated in the spring season / hot climate that lasts for years together and rarely persists after adolescence. Mast cell stabilizers, topical Nonsteroidal anti-inflammatory drugs (NSAIDs), and steroids are the available treatment options that too with symptomatic relief and potential side effects, which limits the long-term use of these medicines. The clinical picture of vernal keratoconjunctivitis / spring catarrh is very similar to *Kaphaja Abhishyanda*, and *Triyushnadi Anjana* Bhaishajya Ratnavali (B.R.), and its treatment was clinically tried on the patients attending the Netra Roga OPD of the R.G. Government P.G. Ayurveda College Hospital at Paprola (H.P.). A proper protocol and performa was adopted with strict inclusion and exclusion criteria. In the first phase, a pilot study was conducted on 38 clinically diagnosed patients with vernal keratoconjunctivitis, and it gave 100% relief in photophobia, foreign body (FB) sensation, and lacrimation, with marked relief in other features. Encouraged by this pilot work, *Triyushnadi Anjana* (TA) and 2% sodium cromoglycate (mast cell stabilizer) eye drops in the second-phase clinical trial on 32 patients were tried clinically to evaluate the comparative efficacy. In the second clinical trial, the patients were randomly divided into two groups and Group I was given sodium cromoglycate 2% eye drops and Group II was given TA. The outcome of this study verified the results of the first phase pilot study, and on comparison of the results of the two groups in the second clinical study it was observed that the TA-treated group showed better results. Transient irritation in the eyes was reported by all patients after application of TA, which was relieved by keeping the eyes closed for a few minutes. None of the patients reported any adverse action of the trial drug. Thus, it can be concluded that TA is a safe, cost-effective, and potent Ayurvedic alternative in the treatment of vernal keratoconjunctivitis / spring catarrh.

Key words: *Kaphaja Abhishyanda,* vernal keratoconjunctivitis (VKC), *Triyushnadi Anjana* (TA)

Introduction

Awareness, environment, and health are so closely interlinked that ignoring any one of them will lead to a disturbed ecosystem as well as the well-being of the society as a whole. Ayurveda, a perfect life science has laid its full emphasis on nature, natural resources, and environment, for the maintenance of a healthy life as well as for combating the disease condition. Thus, the key to man's health lies largely in the environment one lives in; and the study of the disease is really the study of man and its environment. In fact, much of a man's ill-health can be traced to environmental factors. Adverse environmental factors disturb the natural rhythmic circadian and seasonal rhythms leading to an altered homeostasis. This disharmony directly / adversely affects the immune system of the body and the disease resistance power.

In such circumstances, even minor exo- and endogenous etiological factors cause the human body to suffer serious disease. The skin, eyes, and respiratory tract show immediate

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response to the exogenous factors called allergens. The oral cavity being continuously flushed with saliva is at the least risk. Sensitivity to allergies may develop any time in life, although greater propensity for the development of allergic diseases appears to occur in childhood and adolescence.[1,2]

Allergic conjunctivitis in childhood and adolescent age is common and often mistaken for infective conjunctivitis. Among the different varieties of allergic conjunctivitis, vernal keratoconjunctivitis (VKC) is the most troublesome, wherein, the child suffers from intense itching grittiness, mucoid discharge, redness, lacrimation, photophobia, and so on. The disease is chronic / refractory and becomes worse during the warm months.[1] Pollens are considered to be the main allergens, but recent observations show that VKC appears perennially, and that the pollens are not the sole cause behind it.[3]

Although the disease does not affect the vision, it is an extremely discomforting disease of childhood, decreasing the learning hours of the child, and may last for years. Rarely it may cause corneal ulcer[3] or keratoconus effecting vision.[4]

Mast cell stabilizers (e.g. sodium cromoglycate), NSAIDs and topical corticosteroids are the treatment options, but only symptomatic relief is the outcome.[5] On the other hand, drug sensitivity, increasing resistance, preservative-induced dry eye, as well as the complications of the corticosteroids, for example, cataract, glaucoma, and increased risk of bacterial and fungal infections restrict the long-term use of these medicines.[6]

With this background profile about the disease and keeping in view the high number of patients with this problem in Paprola (H.P.), it is felt that it may be due to the high vegetative flora and pollen. A study was planned, to search for a permanent, cost-effective, safe, and effective remedy for the treatment of spring catarrh-VKC.

The spring catarrh nomenclature of the disease is indicative of seasonal (*Vasanta Ritu*) incidence, and as per the Ayurvedic principles, it is the *Kapha Prakopa* period of the year.[7] Childhood age group is the *Kapha* dominating period of life[8] and the clinical features of the disease simulate those of *Kaphaja Abhishyanda*. The *Lekhana* type of therapeutic procedure is the main line of treatment forn *Kaphaja Netra Rogas* in the classics.[9]

The literature of the *Shalakya Netra Roga Chikitsa* (ophthalmology) was therefore explored, to select a classical formulation indicated in the treatment of the *Kaphaja* type of eye disease, having *Lekhana* therapeutic values. The contents of the drug had to be easily available, and had to have no controversy. *Triyushnadi Anjana Gutika*, a collyrium that is mentioned in the *Bhaishajya Ratnavali Netra Chikitsa* chapter fulfilled our criteria for drug selection,[10] and was selected for the trial.

Aims and Objectives

1. To study the conceptual relation of *Kaphaja Abhishyanda* with that of VKC / spring catarrh.
2. To study effect of TA in patients of spring catarrh and to compare its efficacy with sodium cromoglycate 2% eye drops.
3. To see the side effects / toxic effects of the drug, if any.

Study design

To fulfill the above aims and objectives, a prospective randomized and clinical trial was designed in two phases:

Phase I: First, a clinical study was conducted to see the efficacy of TA only.

Phase II: Second, a clinical study was conducted to compare the efficacy of TA with sodium cromoglycate 2% eye drops.

Material and Methods

Selection of patients

This clinical study was conducted on outpatients attending the Netra Roga OPD of the Shalakya Tantra Department of R.G. Government Postgraduate Ayurvedic College and Hospital Paprola (Himachal Pradesh). The patients were selected irrespective of caste, creed, race or religion, in the age group of 5 – 20 years.

Criteria of diagnosis

Patients were diagnosed on the basis of signs and symptoms of spring catarrh and those mentioned in Ayurvedic classics with reference to *Kaphaja Abhishyanda*, such as:
Kandu (itching)
Pichchil Srava (mucus ropy secretion)
Muhurmuhur Srava (repeated lacrimation)
Guruta (heaviness of lids)
Photophobia
Foreign body (FB) sensation
Burning sensation
Conjunctival congestion
Conjunctival hypertrophy (cobble stone)
Gelatinous opacification at the limbus
Trantas spots
Subepithelial keratitis

Inclusion criteria

All patients in the age group of 5 – 20 years presenting with signs and symptoms of spring catarrh and *Kaphaja Abhishyanda*, as mentioned in classical text, were taken into account.

Exclusion criteria

i) Patients not willing for trial.
ii) Cases complicated with trachoma.
iii) Spring catarrh associated with other forms of allergic conditions like skin rash, allergic bronchitis to exclude the atopic and systemic allergic problems.
iv) Cases complicated with superadded infections and corneal ulcers.

Investigational criteria

For the purpose of assessing the general condition of the patient and to exclude other pathologies, the following investigations were performed in all the selected patients:

Routine examination

i) Blood: Hemoglobin percentage, total and differential leucocyte count, and erythrocyte sedimentation rate.
ii) Urine: Routine and microscopic.
iii) Stool: For ova and cyst.

Specific investigations

Conjunctival smear examination in the first study and conjunctival biopsy in the second study were planned.

After arriving at the diagnosis, the clinical proforma was filled up, which incorporated all the signs and symptoms based on both Ayurvedic as well as modern descriptions. All the points related to examination from the Ayurvedic viewpoint, that is, *Dosha*, *Dushya*, *Srotas*, *Agni* and the like, were also included in the proforma. A detailed clinical history was taken initially and a complete physical and ocular examination of each patient was carried out on the basis of the proforma.

Drug

The criteria for the selection of the drug have been discussed in the introductory part of the article. *Shunthi* (*Zingiber officinale* Rosc.), *Marich* (*Piper nigrum* Linn.), *Pippali* (*P. longum* Linn.), *Haritaki* (*Terminalia chebula* Retz.), *Bhibhitaka* (*T. bellerica* Roxb.), *Aamalaki* (*Emblica officinalis* Gaertn.), *Tagara* (*Valeriana wallichii* DC.), *Saindhava Lavana* (Rock salt), and *Manashila* (Realgar-As_2 S_2) were collected from the market through a college pharmacy and were sent to *Dravyaguna* and *Rasashastra* experts for identification. *Manashila* was purified by triturating it seven times in fresh lemon juice and then dried. All the contents of the formulation were powdered to the finest possible level and an equal quantity of each ingredient was taken in a pestle and mortar and again triturated / ground for three days. This compound was then percolated through a double-layered muslin cloth and a micro fine powder of the TA was obtained which qualified the *Varitar* (can float on the stagnant water), *Rehkha Poorana* (can stay in the creases of fingers) qualities.

Although the classical dosage form of TA is *Varti*, which is applied by instant pasting with honey, this method is inconvenient and also invites contamination while rubbing on a plate. Honey causes a lot of irritation on the ocular surface and washes away the *Anjana* due to hyperlacrimation. Honey is also reported to be *Kaphahara*, therefore, to know the exact / individual action of this *Anjana* it was used without any vehicle. The mode of application was also modified to avoid contamination as well as the additive effect of the applicator, that is, *Shalaka*. The fine powder of *Anjana* (mesh value was not measured as the facility was not available) was put into the lower fornices of the eye, preferably in the supine lying position, by pressing a collapsible plastic vial. The guardian of the patient was instructed to keep the eyes of patient closed for five minutes to avoid irritation of the medicine.

The cumulative pharmacological action of the *Anjana* as per Ayurveda classics is *Kapha–Pitta–Shamaka*, *Raktashodhaka*, *Chakshushya*, *Rasayana*, *Shothahara*, and *Vedanasthapana*. The anti-inflammatory, antimicrobial, antioxidant, analgesic, bioavailability enhancing, and immunomodulatory actions of the contents of this compound are reported in the pharmacological studies.[11]

Method of study

All the patients selected for trial were explained the nature of the study and their consent was obtained on the proforma before inclusion in the study.

In the first study

A total of 38 patients selected for the present study, who fulfilled the criteria of the diagnosis and consented for the study, were given TA for local application.

In the second study

A total of 32 patients were selected and randomly divided into two groups:

Group I — Control group, was given sodium cromoglycate 2% eye drops.
Group II — Trial group, was treated with TA.

Dose and duration of the trial

Dose: TA 10 mg, twice daily, in the lower fornix.

Sodium cromoglycate 2% eye drops — two drops, four times, topically into the conjunctival sac.

Duration: The trial of the therapy was carried on for 30 days.

Follow-up: Thirty days, with an interval of 15 days.

Criteria for assessment

In this study, the results were assessed with regard to the clinical signs and symptoms (on the basis of the grading and scoring system) and the overall improvement.

Clinical assessment

The signs and symptoms were assessed by adopting a suitable scoring method. The details are as follows:

***Kandu* (Itching)**
- No *Kandu* 0
- Occasional *Srava* on exposure to sun light not effecting the *routine work* 1

***Muhurmuhur Srava* (Lacrimation)**
- No *Srava* 0
- Occasional *Srava* (on exposure to sunlight) not affecting routine work 1
- Continuous *Srava* affecting routine work 2

***Pichchil Srava* (Mucus ropy discharge)**
- No *Pichchil Srava* (no discharge) 0
- *Pichchil Srava with* no moping required 1
- *Pichchil Srava* causing sticking of lids in morning 2

***Guruta* (Heaviness of Lids)**
- No *Guruta* 0
- Occasional *Guruta* of eyes 1
- Continuous *Guruta* of eyes 2

Photophobia
- No photophobia 0
- Photophobia only during exposure to sunlight 1
- Intermittent photophobia 2
- Continuous photophobia 3

Foreign body (FB) sensation
- No FB sensation 0
- Occasional FB sensation 1
- Intermittent FB sensation 2
- Continuous FB sensation 3

Burning sensation
- No burning sensation 0
- Burning sensation on exposure to sunlight 1
- Intermittent burning sensation 2
- Continuous burning sensation 3

Palpebral conjunctival congestion
- No congestion 0

- Congestion with clear pattern of blood vessels 1
- Congestion with poorly visible pattern of blood vessels 2
- Velvety conjunctiva or loss of blood vessels pattern 3

Bulbar conjunctival congestion

- No congestion 0
- Muddy color of bulbar conjunctiva 1
- Conjunctival congestion in palpebral aperture 2
- Conjunctival congestion in the entire bulbar conjunctiva 3

Conjunctival hypertrophy

(i) Palpebral conjunctiva

- No conjunctival hypertrophy 0
- Diffuse conjunctival hypertrophy 1
- Giant cobble stone papillae 2
- Giant papillae with copious mucus 3

(ii) Bulbar conjunctiva

- No heaping 0
- Slight heaping of conjunctiva less than 360° 1
- Heaping of conjunctiva 360° without circumcorneal encroachment 2
- Heaping of conjunctiva with circumcorneal encroachment with Trantas spots 3

***Keratitis:* (Assessed only in second study)**

- No corneal involvement 0
- Subepithelial keratitis 1
- Epithelial ulcer / macro erosions 2
- Plaque 3
- Subepithelial scarring 4

The data thus obtained after treatment was statistically analyzed and the '*t*' value and '*P*' value were presented and logically interpreted after discussion, and conclusions were drawn.

Overall assessment of the therapy

To assess the overall effect of the therapy, the following criteria were laid down:

Grade I: Complete remission / cured: More than 95% relief in symptoms and more than or equal to 80% relief in signs of the disease.

Grade II: Markedly improved: More than 75% relief in symptoms and more than 65% relief in the signs of the disease.

Grade III: Mildly improved: More than 50% relief in symptoms and signs of the disease.

Grade IV: No improvement / unchanged: Less than 50% relief in signs and symptoms of the disease.

Observations

In the first study by Sharma *et al.* 2003,[12] Out of 38 patients, the demographic data showed that the maximum (44.73%) number of patients were in the 5–10 year age group and 81.7% of the patients were male children; 94.73% who participated in this study were school going. All the patients were local, that is, from a rural habitat; 81.71% patients relished a mixed diet, and a majority of the children (97.36%) had no addiction. Only 2.63% patients were found to be smokers. A family history of allergy was not observed in 94.73% of the patients. A majority of the patients suffered from *Mandagani* (low-digestive fire) and *Madhyama Koshtha*, that is, 36.84 and 55.26%, respectively.

A majority of the patients (73.68%) had the history of onset in the summer season followed by the perennial form, in 26.32%. *Kandu* (itching) was found in 100% of the patients, *Pichhila Srava* (mucoid discharge) was observed in 60.52%, whereas, *Muhurmuhar Srava* (Lacrimation) was seen in 84.21%, *Daha* (Burning sensation) in 60.52%, FB sensation in 34.21%, and photophobia in 39.47% of the patients.

In the Second study by Singh *et al.*, 2006[13] on 32 patients, 62.50% of the patients were in the 5–10 year age group, males dominated this study, that is, 84.3% patients, 90.62% were students, wherein 37.50% were in primary classes. In the present study, 75% patients were vegetarian and 25% were with mixed dietetics habit. Fifty percent of the patients were found with *Madhura Rasa*, 53.13% of the patients enjoyed a good appetite, 93.75% of the patients reported no addiction, and 6.25% of the patients were habituated to smoking. A negative family history of allergic disorders was observed in 84.37% patients. *Madhyama Koshtha* (84.38%), *Samagani* (81.25%), *Madhyama Dehabala* (71.87%), *Kapha–Pittaja Prakriti* (71.87%), and *Nirama Avastha* (Chronic phase) of the disease condition (81.27%) were observed in the present study. In this study, 50% of the patients reported onset of the disease in the summer season and the rest had a history of perennial onset. The incidence of clinical signs and symptoms are presented in Figure 1.

Effect of therapy in first study by Sharma *et al.* (2003)

The patients were given TA for local use and the following results were observed [Table 1].

A conjunctival smear could only be carried out with routine blotting paper in our college laboratory, due to the nonavailability of cellulose blotting paper. Three-to-four eosinophils per 50 objective fields were seen on an average. This could be a local variation in the clinical presentation of the disease. As the standard method of this test could not be carried out in the after-treatment period, it was not analyzed.

Effect of therapy in Group I in second study by Singh *et al.* (2006)

The clinical data presented here is based on 28 patients (14 in Group I and 14 in Group II), because four patients in Group I could not complete the trial.

The efficacy of the standard therapy, that is, sodium cromoglycate 2% eye drops in Group I with 14 patients was adjudged on various clinical features and the results were derived after executing statistical analysis. The effect of therapy

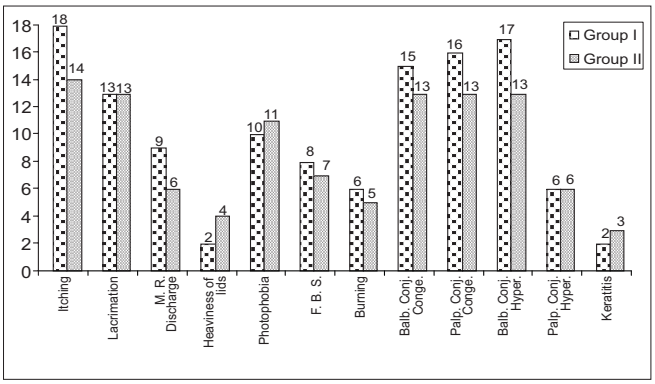

Figure 1: Incidence of signs and symptoms in 32 patients

on the criteria assessed has been presented in Table 2:

Effect of therapy in Group II of the second study in second study by Singh *et al.* (2006)

The clinical data of 14 patients who completed the study is presented in Table 3. Conjunctival biopsy could only be performed in eight patients of the trial group. Biopsy was not performed in the standard group, as most of the parents were not ready to allow conjunctival tissue excision for biopsy from their kids eye.

After the treatment, none of the parents had cooperated in this investigation. The outcome of the pre-treatment biopsy showed that there were hypertrophic changes in the epithelial

Table 1: Effect of therapy of TA after local use in study of Sharma *et.al.*

Signs and symptoms	Mean		% relief	SD	SE	*'t'*	*P* value
	B.T.	A.T.					
Kandu (Itching)	1.66	0.26	84	0.498	0.090	15.55	< 0.001
Pichchil Srava (Discharge)	1	0.1	90	0.803	0.146	6.164	< 0.001
Muhurmuhur Srava (Lacrimation)	0.83	0	100	0.355	0.064	13.01	< 0.001
Burning sensation	0.9	0.1	88.88	0.761	0.138	5.797	< 0.001
FB sensation	0.466	0	100	0.681	0.124	3.758	< 0.001
Photophobia	0.466	0	100	0.507	0.092	5.065	< 0.001
Palpebral conjunctival congestion	1.416	0.433	69.41	0.482	0.088	11.17	< 0.001
Bulbar conjunctival congestion	1.7	0.85	50	0.527	0.096	8.854	< 0.001
Palpebral conjunctival hypertrophy	0.63	0.06	89.47	0.612	0.111	5.04	< 0.001
Bulbar conjunctival hypertrophy	1.56	0.53	65.95	0.586	0.106	9.716	< 0.001

SD - Standard Deviation, BT - Before Treatment, AT - After Treatment, SE - Standard Error

Table 2: Effect of therapy in Group I in study of Singh *et.al.*

Symptoms and signs	n	Mean		d	% relief	S.D.	S.E.	*'t'*	*P* value
		B.T.	A.T.						
Itching	14	1.35	0.57	0.78	57.77	0.65	0.17	4.48	< 0.01
Lacrimation	10	1.1	0.50	0.60	60	0.51	0.16	3.75	< 0.01
Ropy discharge	8	1	0.37	0.50	63	0.53	0.17	2.94	< 0.05
Heaviness of lids	2	1	0.50	0.50	50	0.70	0.49	1	> 0.05
Photophobia	9	1.22	0.22	1.10	81.96	0.62	0.20	5.31	< 0.001
FB sensation	8	1	0.25	0.75	75	0.80	0.28	2.65	< 0.05
Burning sensation	6	1	0.16	0.83	84	0.41	0.16	4.09	< 0.01
Conjunctival congestion Bulbar	11	1.36	0.72	0.63	47	0.51	0.15	4.20	< 0.01
Palpebral	12	1.16	0.58	0.58	50	0.52	0.16	3.62	< 0.01
Conjunctival Hypertrophy Bulbar	13	1.61	1.46	0.15	9.31	0.37	0.10	1.50	> 0.05
Palpebral	4	1.25	1	0.25	20	0.50	0.25	1	> 0.05
Keratitis	2	1	0.50	0.50	50	0.70	0.49	1.02	> 0.05

Table 3: Effect of therapy in Group I in study of Singh *et.al.*

Symptoms and signs	n	Mean		d	% relief	S.D.	S.E.	*'t'*	*P* value
		B.T.	A.T.						
Itching	14	1.35	0.14	1.21	89.60	0.59	0.15	7.67	< 0.001
Lacrimation	13	1.15	0.15	1	86.95	0.57	0.15	6.32	< 0.001
Ropy discharge	6	1.16	0.33	0.83	71.55	0.41	0.16	5.18	< 0.01
Heaviness of head	4	1	0.25	0.75	75	0.50	0.25	3	< 0.05
Photophobia	11	1.18	0	1.18	100	0.41	0.12	9.59	< 0.001
FB sensation	7	1.28	0	1.28	100	0.50	0.19	6.73	< 0.001
Burning sensation	5	1.2	0	1.20	100	0.44	0.19	6.09	< 0.01
Conjunctival congestion bulbar	13	1.30	0.23	1.07	82	0.50	0.13	7.75	< 0.001
Palpebral	13	1.53	0.46	1.07	69.93	0.51	0.14	7.58	< 0.001
Conjunctival hypertrophy bulbar	13	1.50	0.66	0.84	56	0.41	0.16	5.18	< 0.001
Palpebral	6	1.61	0.76	0.83	52	0.37	0.10	8.13	< 0.01
Keratitis	3	1	0.33	0.33	77	0.47	0.27	1.21	> 0.05

tissue, and subepithelial tissue was infiltrated with eosinophils. Occasional mast cells, lymphocytes, and polymorph nuclear cells were also found in the subepithelial tissue. These findings indicated that there were type I and type IV hypersensitivity reactions, which also provided strength to the textual references (Occu. Pharm. by T.Z. Zimmerman).

Discussion

Childhood age is the *Kaphaja Dosha*–dominant period of life, wherein, liking for sweet, curd, excess fluid, and day sleep leads to *Kapha Sanchaya*. The rising atmospheric temperature in the spring season leads to *Kapha Prakopa*. This vitiated *Kapha*, through the blood channels, reaches the supraclavicular region, where the already vitiated *Kapha* dominating parts of the eye, that is, *Shweta Mandala* and lids (*Mansa*) lead to features like *Shotha*, itching, *Upadeha Srava*, and so on.

The vitiated *Kapha* being carried through the *Sira Marga* (blood vessels) also vitiates the *Rasa–Rakta Dhatu*, thus, the *Rakta* and subsistent *Pitta* also get vitiated. The *Pitta* is vitiated when provoked in the sun or heat, wherein the eyes get reddened and photophobia as well as lacrimation and discharge appear. Limbus, being the junction of the *Kapha* and *Pitta* / *Raktaja-Srotas* derivative structures (*Shweta Mandala* and *Krishna Mandala*), is more involved.

If the *Rakta* / *Pitta* vitiation is more, then the chances of corneal ulcer increase. Therefore, the treatment line should also be anti-*Kapha* and *Pitta* / *Rakta*. Perhaps, this is the reason *Abhishyanda* has been categorized / classified as *Raktaja Roga* on pathological grounds.

The surprising fact came to be noticed when the drug review was critically analyzed and it was found that the present trial drug TA was not only *Kapha Hara*, but had *Pitta Shamaka* and *Rakta Shodhaka* properties too. Such a combination formulated for the treatment was due to the fact that all *Abhishyanda* were *Raktaja* in origin.

Kapha is *Bala – Oja*: "*Prakritastu Balam Shleshma Vikruto Malam Uchyatey*, *Sa Chaiva Ooja Smritah*…….".[14] Vitiated *Kapha* fails to discharge this duty of providing *Bala* / *Oja* immunity to the eye. Therefore, the disease-fighting capacity as well as preventing ability is diminished and whatever comes in contact with the eye ball makes the eye diseased, whether it be allergens or pathogens.

Demographic profile

The incidence of VKC goes on decreasing with advancing age. The fact was also verified in our small sample study, that is, 44.73 and 62.50% in the age group of 5 – 10 years and 36.84 and 28.35% in the 11–15 year age group, respectively, in two studies. None of the patients were reported to have this problem after the third decade. Male patients were 81.57 and 84.37% in two studies, respectively. The occupation of the majority of patients (> 90%) were students. The study also reflected the middle socioeconomic status of the area in which patients dominated. No family history of any allergy was noticed in this study, which reflected that VKC did not have genetic predisposition. Diet, *Koshtha* and *Jatharagni*, and *Dehabala* had no effect on the disease, as in both the studies, opposite findings were observed.

So far as the onset of the VKC is concerned, in the first study, 73.68% of the patients had summer season onset, 26.3% had a perennial form, whereas, in the second study 50% of the patients reported summer season and 50% reported a perennial onset. This observation also verified the fact reported on the shifting nature of the onset of VKC. In both the studies, patients having a *Kapha Pittaja* / *Pitta Kaphaja* temperament dominated in number, which proved our hypothesis that VKC was a *Kapha* dominating (*Raktaja*)recessive disease.

In the first and second studies, the incidence of clinical features, such as, itching (100 and 100%), discharge (60.52 and 46.87%), lacrimation (84.21 and 81.25%), burning sensation (60.52 and 34.37%), photophobia (39.47 and 65.62%), FB sensation (34.21 and 46.87%), conjunctival congestion (100 and 90%), bulbar conjunctival hypertrophy (100 and 93.75%), and palpebral conjunctival hypertrophy (50 and 37.5%) was noted.

In the follow-up period, there was not much variation in the relief profile; however, those patients who continued the *Anjana* after the follow-up period, for two months more, got rid of their problem. VKC being a chronic eye ailment, needed a longer duration for a complete cure.

Itching, discharge, and conjunctival hypertrophy are *Kapha* dominating features, whereas, lacrimation, burning, lacrimation photophobia, and congestion are the *Pitta* / *Rakta* dominating features of the disease. The FB sensation is the *Vata* dominating clinical feature of the disease.

Clinical study

In the first study 100% relief in lacrimation, photophobia, and FB sensation was observed. Ninety percent relief in discharge, 88.88% relief in burning sensation, and 84% relief in itching was reported by the patients. Palpebral and bulbar conjunctival congestion reduced to the extent of 69.41 and 50%, respectively, whereas, palpebral and bulbar hypertrophy got relieved by 89.47 and 65 – 95%, respectively.

By this outcome, it was inferred that the inflammatory features / pathology were most targeted by this compound TA, whereas, hypertrophic changes at the cellular level took a longer time to be reversed.

In the second study, the compound TA was compared with sodium cromoglycate. It was observed that the percentage level of efficacy was better in the TA-treated group (II). In both the groups, the percentage relief in itching was 57.77 / 89.60, lacrimation 60 / 86.95, discharge 63 / 71.85, photophobia 81.96 / 100, burning sensation 84 / 100, and FB sensation 75 / 100, respectively. Other clinical features too had a better level of relief in the case of group II (TA treated group). It was also noted that in both studies TA-treated patients showed almost similar results.

The conjunctival smear examination in the case of the pilot study (i.e., the first study) revealed that three to four eosinophils per 50 objective fields were seen in each patient. The histopathological study of the conjunctival tissue in the second study showed type I and type IV hypersensitivity reactions in the case of VKC, which was also as per the classical references.

Mode of action

As discussed earlier in this section, VKC / spring catarrh is a *Kapha* dominating *Raktaja* ocular surface disorder. Ingredients of TA, by virtue of their combined pharmacological action of *Kapha–Pitta Hara*, *Lekhana*, *Rakta Shodhaka* (blood purifying property), *Shothahara* (anti-inflammatory action), and *Vedana Sthapana*, *Chakshushya*, and *Rasayana* (antioxidants and immunomodulatory actions) has a potency to relieve the clinical features.

Conclusion

Kaphaja Abhishyanda (VKC / spring catarrhal) is a benign, but distressing ailment of childhood, which can be better managed / treated with a simple, safe, non-toxic, cheap, and effective Ayurvedic formulation — TA. Further, change in the dosage form of the drug as well as making it isotonic to tears so as to reduce the irritation and assessment on more objective parameters along with multicentric trials on a large sample, are required to support the claim.

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