

Comparative clinical study of *Triphala Ghrita Aschyotan* and Alcaftadine (0.25%) eye drops in the management of *Vataj Abhishyanada* w.s.r. to Simple Allergic Conjunctivitis

Research Article

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Abstract

Sushrutacharya has described the 76 types of eye diseases. *Sarvagata Roga* includes '*Netraabhishyanda*'. *Vataja Abhishyanda* is characterized by *Nistodan* (Pricking pain), *Sangharsha* (foreign body sensation), *Shishirashruta* (watery discharge), *Alpa Shophya* (mild chemosis), *Vishushka Bhava* (feeling of dryness), *Parushya* (dryness), and so on, which are very similar to most of the signs and symptoms of Simple Allergic Conjunctivitis. The eyes are exposed to different environmental factors. The eye and eyelids are very common sites for allergic reactions. *Triphala Ghrita Aschyotan* is very effective in relieving the symptoms of *Vataja Abhishyand*. Aim: To study the efficacy of *Triphala Ghrita Aschyotan* in *Vataja Abhishyanda* w.s.r to simple allergic conjunctivitis. Materials and Method: A total 60 patients of the age group 18-60 years presenting with signs and symptoms of *Vataja Abhishyanda* w.s.r to simple allergic conjunctivitis were selected randomly from OPD of the department of *Shalakyatantra*. The 30 patients of trial group were treated with *Triphala Ghrita Aschyotana* and 30 patients of control group were subjected to alcaftadine (0.25%) eye drop. Results: *Triphala Ghrita Aschyotana* is more effective as compared to alcaftadine eye drop. Conclusion: *Triphala Ghrita Aschyotan* is an effective, safe and potent treatment of *Vataja Abhishyanda* w.s.r. to Simple allergic conjunctivitis.

Key Words: *Vataja Abhishyanda*, Simple Allergic Conjunctivitis, *Triphala Ghrita*, *Aschyotana*, Alcaftadine (0.25%) Eye drops

Introduction

Ayurveda, the ancient science of India has described the importance of eye, without which life is miserable. *Netra* is the most important organ among the organs of special senses. Functioning of it is very essential for one's life. *Shalakyatantra* can be defined as that branch of *Ayurveda*, in which there is a provision for prevention and management of disorders of the parts situated above the level of the clavicles (*Urdhwajatrugata Vikara*), namely that of Ear- Nose Throat (*Shravana Vadana Ghranadi*). *Abhishyanda* is considered as root cause of almost all the eye diseases. It is considered as *Aupasargika Rog* (1). If the disease is untreated it leads to many serious complications like *Adhimantha*, *Akshipakatyaya*, *Avrana shukla* etc. It has four types-*Vataja*, *Pittaja*, *Kaphajaa* and *Raktaja*.(2) Among these *Vataja Abhishyanda* is characterized by symptoms of *Toda*, *Sthambha*, *Romaharsha*, *Sangarsha*, *Parushya*, *Shiroabhitapa*, *Vishushkabhava* and *Shishirasruta*.(3)The causative factors of *Vataja Abhishyanda* include, *Dhooma*, *Raja*,

Aatapa, variation in seasons, unhygienic conditions, and irregular sleeping habits. It can be correlated with Simple Allergic Conjunctivitis having symptoms like Clear, watery discharge is the most commonly seen discharge and is usually bilateral with minimal crusting in the mornings. Eyelid edema and chemosis are not uncommon and can be quite marked. (4) Now a day's, due to busy life style, patients does not have time to think and act for the healthy life and not able to follow the proper instruction or care of the eye. In *Ayurveda*, *Snehana*, *Mridu svedana*, *Siravyadhana*, *Virechana* and *Netra Kriyakalpas* like *Ashchyotana*, *Seka* and *Anjana* are mentioned in the treatment of *Abhishyanda* (5). Out of these, *Aschyotan* is a simple procedure, which is indicated in the initial stage of eye diseases.

Sharangdhara has quoted *Triphala* as drug of choice to treat effectively for *Abhishyanda* and all types of attributes (6). *Gayadasacharya* stated that *TriphalaGhrita* is *Vyadhipratyanik Dravya* (7). *Triphala* and *Ghrita* are the *Chakshushya Dravya* (i.e.beneficial for eyes). These *Chakshushya Dravyas* by its action nourishes the eyes and gives *Bala* to the most vital *Indriya* i.e., *Chakshurendriya*. *Triphala* was mentioned repeatedly in different compound preparations by *Acharya*.

Most of the conjunctivitis in minor forms are self-limiting and does not cause any serious harm (8). Allergic conjunctivitis is one of the most common forms of conjunctivitis. In a report from the National Health and Nutrition Examination Survey studying the epidemiology of allergic conjunctivitis, 6.4% and 29.7% of 20,010

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patients reported ocular symptoms and combined ocular and nasal symptoms, respectively. 40% of the population reported experiencing at least 1 occurrence of ocular symptoms in the past 12 months. (9) Treatment is needed in this disease to reduce the morbidity by shortening the course of the disease, to restore patient comfort by relieving discomfort and pain, and to lower the risk of sight threatening complications like corneal ulcer, iritis and eliminating the risk of wide spread ocular disease. It is one of the most common eye problems requiring early attention. The major constituents of the *Triphala* are tannins, gallic acid, ellagic acid, and chebulinic acid, which are potent antioxidants that may account, at least in part, for the observed immunomodulatory activity of the formula (10). Hence a comparative study is planned, to search for a permanent, cost-effective, safe, and effective remedy for the treatment of *Vataj Abhishyanada*.

Aim

Comparative clinical study of *Triphala ghrita aschyotan* and alcaftadine (0.25%) eye drop in the management of *vataj abhishyanada* w.s.r. to simple allergic conjunctivitis.

Objectives

- To study the effect of *Triphala ghrita aschyotan* in *Vataj Abhishyanada*.
- To compare Clinical presentation of *Vataj Abhishyanada* as well as Simple Allergic conjunctivitis in detail.

Material and methods

A total 60 patients of the age group 18-60 years presenting with signs and symptoms of *Vataj Abhishyanada* w.s.r to Simple allergic conjunctivitis were selected randomly from OPD of the department of Shalakyatantra) within inclusion criteria and were treated in two groups. The 30 patients of trial group were treated with *Triphala Ghrita Aschyotana* and patients of control group in similar number were subjected to alcaftadine 0.25% eye drop.

Criteria for selection of patients

Diagnostic Criteria

Patients were diagnosed which were having signs and symptoms of *Vataj Abhishyanada* given in *Ayurveda* and Simple Allergic Conjunctivitis in modern literature as like Itching, Congestion, F. B. Sensation, Watering.

Inclusion criteria

- Patients having classical signs and symptoms of *Vataj Abhishyanada* w.s.r allergic conjunctivitis like itching of eyes, irritation and foreign body sensation, dryness of eyes, congestion of eyes i.e., redness will be selected irrespective of sex, religion or occupation.
- Any individual of Age between 18-60 years.

Exclusion criteria

- Patients not willing for trial and follow up.
- Patient having Viral and Bacterial conjunctivitis.
- Cases complicated with superadded infections corneal opacities and corneal ulcers.

- Patients recently operated for eye disease, one eyed patient.
- Patient suffering from systemic disease like uncontrolled HTN, Diabetes Mellitus Cancer, Leprosy, T.B, Cardiac disorder.
- Patients suffering from Vernal Kerato-conjunctivitis, Atopic Kerato-conjunctivitis.
- Patient having complicated eye diseases and Trachoma, Chalazion, Styte, Pterygium, Dacryocystitis, Trichiasis etc.

Table 1: Assessment criteria

Parameters	Symptoms	Grade
Sangharsh (i.e., itching of eyes)	Absent (No itching)	0
	Mild (Itching on exposure)	1
	Moderate (Itching during work)	2
	Severe (Itching all time)	3
Nistodana (i.e., irritation and foreign body sensation of eyes)	Absent (No irritation and FB sensation)	0
	Mild irritation and FB sensation on exposure	1
	Moderate (Irritation during work)	2
	Severe (Irritation at rest)	3
Raaga (i.e., Congestion of eyes)	Absent (no congestion)	0
	Mild (Only hyperaemia of conjunctiva)	1
	Moderate (Congestion without chemosis of eyes)	2
	Severe (Congestion with chemosis of eyes)	3
Shopha (Swelling)	No swelling	0
	Mild swelling	1
	Moderate swelling	2
	Severe swelling	3
Vishushkabhava (i.e., Dryness of eyes)	Absent (20-35)	0
	Mild (15 - 20 mm)	1
	Moderate (5 - 15 mm)	2
	Severe (< 5 mm)	3

Follow ups: 7th, 14th, 21st day of treatment.

The graded values were later totally and individually scored and assessed statistically to find out the rate of effect of treatment. The age, gender, occupation, habitat wise distribution of patients with socioeconomic status was also recorded and assessed statistically. The effect of treatment in each group was assessed separately by analysing the pre-treatment and post treatment data, scores and values. The comparison of the effect of therapy of two groups done by statistical analysis.

Ingredients of drug and preparation of *Triphala Ghrita (11)(12)*

1. *Triphala Kalka*: 1 Pala (40 gm)
2. *Triphala Kwatha*: 64 Tola (640 ml)
3. *Goghrita*: 1/2 Prastha (320 gm)
4. *Godugdha*: Quantity same as *Kwatha* (640 ml)

All the above ingredients are taken into utensils along with stirrer and kept on gas stove or burner. The above mixture is heated till "*Snehasiddhi Lakshana*" appears in mixture or 320 ml of *Ghrita* remains in utensil.

Table 2: Drug Regimen

Subject	Group A	Group B
Number of patients	30	30
Age group	18-60 yrs	18-60 yrs
Drug name	<i>Triphala Ghrita Aschyotan</i>	Alcaftadine(0.25%)eye drop
Dose of drug	A dose of 2 Bindu. twice a day	A dose of 2 drops. Once a day
Route of administration	Local	Local
Duration	3 weeks	3 weeks
Follow up	0th,7th, 14th, 21th	0th,7th, 14th, 21th

Data thus collected during the study, summarized and statistically analyzed as per protocol.

Table 3: Statistical Analysis for Group A (Trial Group) for subjective criteria by Wilcoxon Signed Rank test

Sr. No.	Variables	Number of Pairs (N)	Sum of all Ranks (W)	BT Mean	SD	AT Mean	SD	P
1	<i>Sangharsh</i>	30	365	1.867	0.8604	0.5333	0.5713	<0.0001 Highly significant
2	<i>Nistodan</i>	30	120	0.6667	0.6065	0.1667	0.3790	<0.0001 Highly significant
3	<i>Raaga</i>	30	153	1.367	0.4901	0.6333	0.5561	<0.0001 Highly Significant
4	<i>Shopha</i>	30	171	1.367	0.4901	0.6000	0.5632	<0.0001 Highly Significant

Table 4: Statistical Analysis for Group A (Trial Group) for Objective criteria, *Vishushkabhava*, by Paired “t” test

Sr. No.	Variables	Number of Pairs (N)	t value	BT Mean	SD	AT Mean	SD	P
1	<i>Vishushkabhava</i>	30	6.911	1.567	0.5040	0.6333	0.5561	<0.0001 Highly significant

Table 5: Statistical Analysis for Group B (Control Group) by Wilcoxon Signed Rank test- (subjective criteria)

Sr. No.	Variables	Number of Pairs (N)	Sum of all Ranks (W)	BT Mean	SD	AT Mean	SD	P
1	<i>Sangharsh</i>	30	276	1.867	0.5074	1.100	0.4026	<0.0001 Highly significant
2	<i>Nistodan</i>	30	55	0.7000	0.5960	0.3667	0.4901	0.0020 significant
3	<i>Raaga</i>	30	120	1.333	0.4795	0.8333	0.6477	<0.0001 Highly Significant
4	<i>Shopha</i>	30	190	1.400	0.4983	0.7000	0.5960	<0.0001 Highly Significant

Table 6: Statistical Analysis for Group B (Control Group) for Objective criteria, *Vishushkabhava*, by Paired “t” test

Sr. No.	Variables	Number of Pairs (N)	t value	BT Mean	SD	AT Mean	SD	P
1	<i>Vishushkabhava</i>	30	6.679	1.467	0.5074	0.8000	0.4842	<0.0001 Highly significant

Table 7: Statistical analysis in between the trial and control group subjective parameters (by Mann Whitneys U test)

Parameters	Group	Mean	SD	U	P
<i>Sangharsha</i>	Trial	1.333	0.8023	236	0.0003 S
	Control	0.7667	0.4302		
<i>Nistodan</i>	Trial	0.5000	0.5085	375	0.2949 NS
	Control	0.3333	0.4795		
<i>Raaga</i>	Trial	0.7333	0.7397	382.5	0.2590 NS
	Control	0.5000	0.5085		
<i>Shopha</i>	Trial	0.7667	0.7279	435.5	0.8409 NS
	Control	0.7000	0.5960		

Table 8: Statistical analysis in between the trial and control group objective parameters (by unpaired “t” test) *Vishushkabhava*

Group	No of patients	Mean	SD	t value	P
Trial	30	0.7667	0.7279	0.6017	0.5497 NS
Control	30	0.6667	0.5467		

Table 9: Overall Assessment criteria

Sr.No	Assessment	Trial	%	Control	%	X ² 16.7283
1	Marked Improvement	12	40	1	3.33	
2	Moderate Improvement	2	6.66	12	40	P 0.0008 S (p<0.05)
3	Mild Improvement	11	36.66	13	43.33	
4	No Improvement	5	16.66	4	13.33	
5	Total	30	100	30	100	

Observations

A majority of patients (53.33%) were reported in age group of 31-45 yrs. The observed M: F ratio was 3.3:1. The businessmen were 46.66% as consideration with occupation. The habitat wise distribution of patients shows 53.33% cases from urban and 46.66% cases from rural area from both groups.

Results

By statistical analysis, it was proved that, *Sangharsha* (i.e., itching sensation of eyes), *Nistodana* (i.e. irritation and foreign body sensation of eyes), *Raaga* (i.e. Congestion of eyes) and *Shopha* (Swelling) were improved in both groups. Wilcoxon signed rank test was highly significant in subjective criteria of both the groups. Paired t test was applied to objective parameter i.e., *Vishushkabhava*, in both the groups it was highly significant. That means both the drugs are effective in reducing symptoms of *Vataj abhishyanda*. Mann Whitney U test was applied for subjective parameters to compare the efficacy of both the drugs, there was insignificant difference between efficacy of both the groups except *sangharsha* symptom. It suggests that, both the drugs are equally effective but mean difference is more in trial group drug than control group drug so, *Triphala Ghrita Aschyotan* was more effective *Vataj Abhishyanda*. Considering *Sangharsha* symptom, trial group drug was highly significant in reducing *Sangharsha* symptom as compared to control group drug. Unpaired “t” test was applied to objective parameter i.e., *Vishushkabhava*, there was insignificant difference between efficacy of both the drugs.

In overall assessment, out of 60 patients 12 and 01 patients showed Marked Improvement in trial and control group respectively. So, trial group drug is much more effective than control group drug. In trial group 40% patients showed marked improvement compared to control group i.e., only 3.33 %. 2 and 12 patients moderately improved in trial and control group respectively. 11 and 13 patients showed mild improvement in trial and control group respectively. 5 and 4 patients showed no improvement from trial and control group. It is clearly seen from table that trial group drug is more effective than control group drug in *vataj abhishyanda* patients. The Chi-Square Statistic is 16.7283. The p-value is 0.0008. There is significant difference in overall assessment in both the groups as p<0.05. Hence trial group drug is more effective than control group drug as per overall assessment is concerned.

Discussion

Triphala consists of *Haritaki*, *Amalaki* and *Bibhitaka* (13). *Sharangdhara* stated that *Triphala* is a drug of choice for all types of *Netrabhishyanda*. *Acharya Gayadasa* cited in *Dalhana*

commentary that *Triphala Ghrita* is a *Vyadhipratyanik Dravya*. *Triphala* and *Ghritha* are *Chakshushya Dravya* i.e., both provides *Bala* to *Chakshurendriya* (14). *Triphala* have balancing and rejuvenating effect on the three constitutional elements in *Ayurveda* viz. *Vata*, *Pitta* & *Kapha*. *Ghritha* has lubricating action by *Snigdha Guna* and also as it is *Samskaranuvarti* (15). Also, the topical conventional remedies available in the market are topical decongestants used for a long period actually worsen the symptoms, overuse of topical antihistamines causes dryness and topical steroids overuse can cause elevated intra ocular pressure (IOP), leads to visual damage, increased risk of cataract and clouding of lens that can lead to impairment of vision. So, it was decided to instill *Triphala Ghrita Aschyotan* in *Vataj Abhishyanda* w.s.r to simple allergic conjunctivitis. *Aschyotan* was selected for the trial because it was easy and prime treatment in all types of eye diseases (16). *Aschyotan* significantly reduces the congestion of eyes, itching, pricking sensation of eyes, etc. *Aschyotan* can also be given in *Samavastha* of the eye diseases so, the *Aschyotan* was decided for the trial.

Mode of action of the Drug

Acharya Vagbhata specified the mode of action of *Aschyotan*, as the *Aschyotan* drug goes in *Urdhwajatu* i.e., in region above the collar bone, spreads and brings *Dosha* outside by its *Veerya* (17). *Ghritha* by its *Snigdha Guna* pacifies the *Ruksha Guna* of *Vata*. *Vayu Mahabhuta Pradhana Ruksha Guna* in *Vataj Abhishyanda* was pacified by *Aap Mahabhuta Pradhan Snigdha Guna*. *Snigdha Guna* has soothing property and causes moistening of conjunctival mucosa and increases the stability, *Bala* and *Varna*. *Sheeta* and *Ruksha Guna* together causes the *Sangharsha* i.e., itching sensation of eyes and increases the vasoconstriction and grittiness feeling in the eyes. These *Gunas* were pacified by the lukewarm *Ghritha Aschyotan* procedure which allows more absorption of drug through the vessels and decreases the symptom. So, the parameter of efficacy was fulfilled and experimental group showed results better than he control group. The mucosa of conjunctiva absorbs the drug. So, by virtue of *Madhur Rasa* of the contents in the *Triphala Ghrita* and the *Rasayana* property *Vata Prashamana* occurs. *Chakshushya* property of *Triphala* and *Ghritha* as well as the *Jeevaniya* property of *Godugdha* combinely acts and the *Vata dosha* come to normalcy. The *Swantantra* (independent) *Vata Dosha Dushti* pacified by all these properties. So, the results observed in experimental and control group are nearly same in *Nistodana* i.e., irritation and Foreign Body sensation of eyes. *Ghritha* when instilled in eyes causes some irritation and along with that *Triphala* has its *Kashaya Rasa* which also responsible for the irritation though the *Snigdhatwa* of *Ghritha* overcomes this *Kashaya Rasa* of *Triphala* and

compensate it. Fat soluble factors can penetrate *Krishnamandalam* and *Shuklamandalam*. So, if *Snigdha* drugs especially *Ghrita Kalpana* is applied, it penetrates the *Mandala* so the *Laghu*, *Ruksha Gunas* are counter acted. Thus, the patients feel relief. Now coming to the point of allergy, it was nothing but the *Asatmya Avastha* of the body tissue. Each *Dosha* has its certain tolerance in the body. Whenever external factors disturb these constitutional elements, *Dosha* vitiate in two ways i.e., *Swatantra* and *Paratantra Dosha Dushti* (18). In allergic conjunctivitis *Vata* is a *Swatantra Dosha* vitiated by external factors and the *Paratantra Dosha* are *Kapha* and *Pitta*. Histamines can be correlated with *Pitta Dosha*. So, considering this correlation *Triphala* is a trio of *Tridosahara Prabhava* and a fortified combination of *Haritaki*, *Amalaki*, *Bibhitaki* and *Ghrita* and *Godugdha* (Cow's Milk) removes the intolerance of excess or vitiated *Vata Dosha* by acting virtue of its *Guna* on *Vata Dosha*. Hence in this study the symptoms itching, Foreign Body and irritation sensation of eyes and congestion of eyes are relieved.

Limitations of the study

The tests concerning the diagnosis of allergic eye diseases are expensive like IgE count in tear, skin prick test. Also, the eosinophils to come in smear prerequisite vigorous scraping of conjunctiva. So, this thing needs careful as well as skilful efforts. The other tests are performed in giant hospitals only. It remains a challenge for the future researchers in Ayurveda. Another limitation is that the allergic eye disease is a huge topic and it requires a lengthy duration for study.

Scope of further study

Technical aspect of all the *Kriyakalpas* have been lost in recent years, it's our duty now to renovate the science and technology. Further there is scope to study the complex form of allergic eye diseases like Vernal Keratoconjunctivitis, Atopic Keratoconjunctivitis with the help of other forms of medicines like *kwatha* (decoction). The modern medicines have lacuna in allergic disorders and so an Ayurvedic medicaments can treat these diseases according to *Dosha*, *Dushya*, *Panchabhautik chikitsa* and also can prove it on modern parameter basis. Local therapy along with *Panchakarma* and systemic medicines may be effective.

Conclusion

Thus, from above study it can be concluded that *Triphala Ghrita Aschyotana* is equally effective rather than we can say more effective in some of the symptoms of *Vataj Abhishyanda* as compared to Alcaftadine 0.25% eye drop.

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