



Research Article

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EFFECT OF SHIRISHA DROPS IN ALLERGIC CONJUNCTIVITIS: A CLINICO-PATHOLOGICAL EVALUATION

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Received on: 07/01/17 Accepted on: 17/02/17

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DOI: 10.7897/2277-4343.08134

ABSTRACT

Despite various advances in the management of allergic conjunctivitis the effective control is still a challenge. In Allergic conjunctivitis (*Kaphaja abhisyanda*) Recent works have shown that *Shirisha* (*Albezzia lebbeck*) might be topically beneficial in allergic conjunctivitis. Materials & Methods: Study was conducted on 60 eyes equally divided into two groups, Group I (Control) was intervened by sodium cromoglycate 2% eye drop while Group II (Treated) was intervened with *Shirisha* (*Albezzia lebbeck*) eye drops 2 drops 3 times a day for 30 days. The results were assessed with graph pad instate 3 software before and after treatment in regards to clinical signs and symptoms, improvement in conjunctival impression cytological grade. It was found that the *Shirisha* eye drop has significantly reduced congestion, itching, foreign body sensation and pain but with less relapse rate but relieved the symptoms of watering, discomfort, secretion, burning sensation, photophobia and lid heaviness with equal significance as sodium cromoglycate eye drop. The onset of effect of *Shirisha* drop was not as fast as sodium cromoglycate but the relief was more sustained. Both the groups showed positive effect on the health of conjunctival epithelial cells. *Shirisha* (*Albezzia lebbeck*) has analgesic, anti-inflammatory, mast cell stabilizing and immunomodulatory properties. It acts as antiallergic due to Vishaghna property, It is *Kashaya* in nature, thus does *Kapha shoshana* and *Rukshana* which causes decongestion. It overall alleviates disease due to *Tridosahara Karma*. *Shirisha* may be used as a effective drug in Allergic Conjunctivitis.

Key words: *Kaphaja Abhisyanda*, Allergic conjunctivitis, *Shirisha* (*Albezzia lebbeck*)

INTRODUCTION

The conjunctiva is ten times more sensitive than skin to allergens as it contains more mast cells. Allergic conjunctivitis is inflammation of conjunctiva due to allergy. Symptoms consist of redness, edema of conjunctiva, itching and increased lacrimation. Allergic conjunctivitis is treated mostly by elimination of allergens, topical mast cell stabilizers, vasoconstrictors, artificial tears and steroid eye drops.

According to *Ayurveda* the diseases presenting with the features of allergy are usually *Kapha* predominant. The conjunctival allergic disorders also are due to involvement of *tridosha* with predominance of *Kapha dosha*. On the basis of similarities in clinical presentation *Kaphaja abhisyanda*¹ is the nearest possible disease which can be correlated with allergic disorder of eye. Despite of various advances in the management of allergic conjunctivitis the effective control is still a challenge. There is a great need to find out a drug which can be beneficial for the management of allergic conjunctivitis without any adverse effect. In *Ayurveda* various drugs having *vishaghna*² (alleviate toxic materials from body) and *kandughna* (relieving itching sensation) property may be used for the management of allergic ocular disorders. *Gada nigrha*³ mentioned that the juice of *Shirisha* mixed with honey should be used as *Anjana* (collyrium) in *tivra abhisyanda*. Thus to evaluate the efficacy of *Shirisha* (*Albezzia lebbeck*) on allergic conjunctivitis (*Kaphaja abhisyanda*), *Shirisha* (*Albezzia lebbeck*) bark prepared drops were chosen for intervening with control drug sodium cromoglycate 2% eye drop.

MATERIALS AND METHODS

The clinical study was carried out in the department of *Shalaky tantra* and department of Ophthalmology with collaboration of department of pathology, Institute of medical sciences, Banaras Hindu University, Varanasi. Prior to clinical study an experimental study on rabbit eyes was also done as drug tolerance test for safety measures. The present study was carried out in accordance with ethical principles laid by Banaras Hindu University, Varanasi.

Aim of study

Present research was carried out for the following purpose:

- To evaluate the efficacy of *Shirisha* eye drop *Shirisha* (*Albezzia lebbeck*) bark extract mixed with honey in Allergic Conjunctivitis for topical administration.
- To Compare with standard drug treatment sodium cromoglycate 2% eye drop to evaluate efficacy.

Plan of study

Method of preparation of Drug

The freshly prepared *Shirisha* bark *swaras* (small pieces of bark soaked overnight in sterile water, expressed extract from bark with fine cloth in the morning, mixed with honey in equal amount) was selected for the proposed study. This freshly prepared *Shirisha* eye drop was sent to the Department of Microbiology, IMS, BHU for culture, to rule out the possibility of any growth of any microorganism in the drug. It was observed that no growth of organism was seen up to day 5th and

pH of prepared drug was recorded 7.0, pH was also remained unchanged up to 5th day from the day of preparation. So, patients were strictly advised to use the freshly prepared drug up to day 5 and then discard it.

Grouping of patients

Sixty eyes of thirty patients were equally divided into two groups.

Group I (Control Group)- Thirty eyes received sodium cromoglycate (2%) eye drop, 2 drops three times a day for 30 days.

Group II (Treated Group)- Thirty eyes received *Shirisha* drop (equal parts of juice of bark of *Shirisha* and honey- freshly prepared in every 5 days) 2 drops 3 times a day for 30 days.

Duration of therapy-Duration of therapy was for 30 days.

Follow up study

Results were recorded on the basis of the response of the various clinical manifestations after 15 days of treatment (AT1), after 30 days of treatment (AT2). The relapse rate after 15 days (F1) and 30 days after completion of treatment (F2) were also recorded. Impression cytology was done to study about the changes of the morphology of the epithelial cells and goblet cell population.

Inclusion Criteria

1. All the patients were of 2-35 years of age irrespective of sex, caste, religion etc. presenting with signs and symptoms of Allergic conjunctivitis.
2. Patients willing to participate in the study.

Exclusion criteria

1. Corneal involvement with ulcers.
2. Any type of injury to eye.
3. Any type of ocular surgery
4. Infection like conjunctivitis
5. Chemical burns
6. Associated with Glaucoma

CRITERIA FOR ASSESSMENT

Clinical improvements of signs and symptoms were carried out in this study by the following scoring pattern:

Kandu (Itching)

1.	Absent	0
2.	Intermittent	1
3.	Intermittent desire to rub eye	2
4.	Constant rubbing	3

Srava (Watering)

1.	Absent	0
2.	Fullness of conjunctival sac without overflowing	1
3.	Intermittent watering from eye	2
4.	Constant watering from eye	3

Foreign body sensation

1.	Absent	0
2.	Fine dust powder sensation	1
3.	Coarse dust powder sensation	2
4.	Hot ember sensation	3

Discomfort

1.	Absent	0
2.	Awareness present difficult to describe	1
3.	Moderate discomfort with description present	2
4.	Severe discomfort require analgesic	3

Picchil Srava (Secretion)

1.	Absent	0
2.	Not requiring moping	1
3.	Causing stickiness of lids in morning	2

Photophobia

1.	Absent	0
2.	During exposure to sun light	1
3.	Intermittent	2
4.	Constant	3

Burning sensation

1.	Absent	0
2.	On exposure to sun	1
3.	Intermittent	2
4.	Constant	3

Heaviness of lids

1.	Absent	0
2.	Intermittent	1
3.	Constant	2

Congestion (Palpebral Conjunctiva)

1.	Absent	0
2.	With clear pattern of blood vessels	1
3.	With poorly visible pattern of blood vessels	2
4.	Velvety conjunctiva or loss of blood vessels pattern	3

Congestion (Bulbar Conjunctiva)

1.	Absent	0
2.	Muddy color of conjunctiva	1
3.	In palpebral aperture	2
4.	In whole of bulbar conjunctiva	3

Conjunctival hypertrophy (Palpebral)

1.	Absent	0
2.	Diffuse hypertrophy	1
3.	Giant cobble stone papillae	2
4.	Giant papillae with copious mucus	3

Conjunctival hypertrophy (Bulbar)

1.	Absent	0
2.	Slight heaping in one or two quadrants	1
3.	Heaping in all over bulbar conjunctiva	2
4.	Heaping with Tranta's spot	3

Impression Cytology

1.	Epithelial cells are small and round, nuclei are large, nucleocytoplasmic ratio 1:2, goblet cells are abundant	0
2.	Epithelial cells are slightly larger and polygonal, nuclei are smaller, nucleocytoplasmic ratio 1:3, less goblet cells	1
3.	Epithelial cells-larger and polygonal, nuclei-small, nucleocytoplasmic ratio-1:4/1:5, goblet cells-markedly decreased	2
4.	Epithelial cells-large,polygonal, nuclei-small pyknotic, nucleocytoplasmic ratio-1:6, goblet cells- absent	3

Readings of all parameters after treatment were compared with the before treatment (base line) readings in each group. Finally, the overall changes of group II (treated) cases were compared with group I (control).

Statistical Analysis

Statistical Analysis was done for clinical sign and symptoms and improvement in conjunctival impression cytological grade by using graph pad instat 3 Software.

RESULT

This clinical study clearly indicating that sodium cromoglycate eye drop relieves all clinical features of allergic conjunctivitis

rapidly; however almost all these symptoms relapsed after completion of treatment. It means it gives only symptomatic relief temporarily. Whereas the *Shirisha* eye drop though slowly relieved the symptoms, the relapse rate is very slow and relief is somehow persistent.

Effect on impression cytology grades showed returning of cellular pattern towards normal in respect to size and shape of epithelial cells and slight increased number of goblet cells within 30 days' period of treatment. Both group showed statistically significant improvement but progress was more evident in control group. *Shirisha* eye drop proved its effectiveness towards improving the grades of impression cytology to reasonable extent.

Table 1: Relieved and Relapsed Patients and not Relapsed (Percentage and No. of Patients) in Treated and Control Group

Symptom	Group	Relieved Pts. on 15 th Day AT1 (No. of Pts) %	Relieved Pts. on 30 th Day AT2 (No. of Pts) %	Relapsed Pts. After 15 th Day of completing AT2 (No. of Pts) %	Relapsed Pts. After 30 th Day of completing AT2 (No. of Pts) %	Not Relapse Cases (No. of Pts) %
Congestion	I (n=30)	22 (73.3)	8 (26.6)	16 (53.3)	8 (26.6)	6 (20)
	II (n=30)	16 (53.3)	14 (46.6)	12 (40.0)	2 (6.6)	16 (53.3)
Itching	I (n=30)	24 (80.0)	6 (20.0)	16 (53.3)	14 (46.6)	0 (0)
	II (n=30)	16 (53.3)	14 (46.6)	8 (26.6)	12 (40.0)	10 (33.3)
Watering	I (n=28)	18 (64.2)	10 (35.7)	12 (42.8)	4 (14.2)	10 (35.7)
	II (n=28)	10 (35.7)	14 (50.0)	6 (21.4)	10 (35.7)	14 (50.0)
Discomfort	I (n=16)	14 (87.5)	2 (12.5)	10 (62.5)	4 (25.0)	2 (12.5)
	II (n=22)	12 (54.5)	10 (45.4)	10 (45.4)	6 (27.2)	6 (27.2)
Secretion	I (n=20)	14 (70.0)	6 (30.0)	10 (50.0)	4 (20.0)	6 (30.0)
	II (n=16)	6 (37.5)	8 (50.0)	4 (25.0)	8 (50.0)	4 (25.0)
Burning Sensation	I (n=16)	16 (100.0)	0 (0)	10 (62.5)	6 (37.5)	0 (0)
	II (n=18)	12 (66.6)	6 (33.3)	4 (22.2)	12 (66.6)	2 (11.1)
Photophobia	I (n=16)	16 (100.0)	0 (0)	6 (37.5)	4 (25.5)	6 (37.5)
	II (n=18)	12 (66.6)	6 (33.3)	2 (11.1)	6 (33.3)	10 (55.5)
F.B. sensation	I (n=14)	14 (100.0)	0 (0)	12 (85.7)	0 (0)	2 (14.2)
	II (n=10)	6 (60.0)	4 (40.0)	2 (20.0)	2 (20.0)	6 (60.0)
Pain	I (n=6)	6 (100.0)	0 (0)	4 (66.6)	0 (0)	2 (33.3)
	II (n=12)	12 (100.0)	0 (0)	4 (33.3)	0 (0)	8 (66.6)
Lid heaviness	I (n=2)	2 (100.0)	0 (0)	2 (100.0)	0 (0)	0 (0)
	II (n=6)	6 (100.0)	0 (0)	2 (33.3)	2 (33.3)	2 (33.3)
Elevations	I (n=30)	12 (40.0)	18 (60.0)	8 (26.6)	14 (46.6)	8 (26.6)
	II (n=30)	8 (26.6)	18 (60.0)	2 (6.6)	8 (26.6)	20 (66.6)
Eosinophil in conjunctival smear	I (n=30)	12 (40.0)	18 (60.0)	16 (53.3)	14 (46.6)	0 (0)
	II (n=30)	20 (66.6)	10 (33.3)	8 (26.6)	10 (33.3)	12 (40.0)

Table 2: Statistical Significance of Symptomatic Parameters

Symptom	Grp	BT	F1	F2	AT1	AT2	Intra grp comparison BT-AT2	Remark	Inter grp comparison BT-AT2
Congestion	I	2.47±0.63	0.53±0.90	0.0±0.0	0.93±0.94	1.27±0.87	1.20±0.76	p<0.001 HS	p<0.01 VS
	II	2.33±0.71	0.87±0.97	0.0±0.0	0.47±0.63	0.53±0.63	1.80±0.85	p<0.001 HS	
Itching	I	2.47±0.63	0.33±0.71	0.0±0.0	0.80±0.85	1.47±0.63	1.0±0.64	p<0.001 HS	p<0.001 HS
	II	2.53±0.63	0.87±1.04	0.0±0.0	0.33±0.61	0.73±0.58	1.80±0.85	p<0.001 HS	
Watering	I	1.53±0.63	0.33±0.48	0.0±0.0	0.53±0.73	0.80±0.76	0.73±0.78	p<0.001 HS	p>0.05 NS
	II	1.53±0.73	0.73±0.69	0.13±0.35	0.27±0.45	0.47±0.51	1.07±0.78	p<0.001 HS	
Discomfort	I	0.06±0.62	0.07±0.25	0.0±0.0	0.33±0.48	0.40±0.50	0.20±0.41	p<0.02 S	p>0.05 NS
	II	0.87±0.63	0.33±0.48	0.0±0.0	0.33±0.48	0.53±0.51	0.33±0.48	p<0.01 VS	
Secretion	I	1.0±0.83	0.20±0.41	0.0±0.0	0.33±0.48	0.47±0.51	0.53±0.63	p<0.001 HS	p<0.001 HS

	II	0.80± 0.85	0.33± 0.48	0.07± 0.025	0.20± 0.41	0.40± 0.50	0.40± 0.49	p<0.001 HS	
Burning Sensation	I	0.87± 0.90	0.0± 0.0	0.0± 0.0	0.20± 0.41	0.33± 0.48	0.53± 0.63	p<0.001 HS	p<0.001 HS
	II	1.0± 0.91	0.20± 0.41	0.0± 0.00	0.31± 0.35	0.53± 0.51	0.47± 0.51	p<0.001 HS	
Photophobia	I	0.87± 0.90	0.0± 0.0	0.0± 0.0	0.20± 0.41	0.33± 0.48	0.53± 0.63	p<0.001 HS	p<0.001 HS
	II	0.93± 0.87	0.20± 0.41	0.0± 0.00	0.071± 0.25	0.27± 0.45	0.67± 0.61	p<0.001 HS	
F.B. sensation	I	0.73± 0.87	0.0± 0.0	0.0± 0.0	0.53± 0.82	0.67± 0.88	0.07± 0.25	p>0.05	p<0.05 S
	II	0.40± 0.62	0.13± 0.35	0.0± 0.00	0.071± 0.25	0.13± 0.35	0.27± 0.45	p<0.01	
Pain	I	0.20± 0.41	0.0± 0.0	0.0± 0.0	0.13± 0.35	0.13± 0.35	0.07± 0.25	p>0.05	p<0.05 S
	II	0.40± 0.50	0.0± 0.0	0.0± 0.00	0.13± 0.35	0.13± 0.35	0.27± 0.45	p<0.01	
Lid heaviness	I	0.13± 0.51	0.0± 0.0	0.0± 0.0	0.07± 0.25	0.07± 0.25	0.07± 0.25	p>0.05	p>0.05 NS
	II	0.33± 0.71	0.07± 0.25	0.0± 0.00	0.07± 0.25	0.13± 0.35	0.20± 0.41	p<0.02	

Table 3: Changes of grades of Impression Cytology (IC)

Grades of IC	Group I (n=30)						Group II (n=30)					
	0 day		15 days		30 days		0 day		15 days		30 days	
	No	%	No	%	No	%	No	%	No	%	No	%
0	4	13.3	10	33.3	12	40.0	2	6.6	6	20.0	10	33.3
1	14	46.6	10	33.3	12	40.0	12	40.0	12	40.0	12	40.0
2	10	33.3	8	26.6	6	20.0	14	46.6	10	33.3	8	26.6
3	2	6.6	2	6.6	0	0.0	2	6.6	2	6.6	0	0.0

Table 4: Statistical Significance of Impression Cytology

Groups	Grades on IC (mean and SD)			Within the group comparison (Initial-30 days)
	0 day(Initial)	15 days	30 days	
Group I (n=30)	1.53±0.73	1.07±0.94	0.87±0.90	0.67±0.61 p<0.001 HS
Group (n=30)	1.33±0.80	1.07±0.94	1.0±0.91	0.33±0.48 p<0.01 VS

Between the group comparison (Initial- 30 days) : p>0.05 NS

DISCUSSION

According to Ayurveda generally allergic diseases are due to vitiation of *kapha*. But in all allergic conjunctivitis along with vitiation of *kapha*, *pitta* and *vata* also takes important role in the causation of diseases. Among the four types of *abhisyanda*, *kaphaja abhisyanda* was taken into account as the disease is very closely resembles to allergic conjunctivitis in terms of clinical features.

According to Ayurveda possible mechanism of action of drug *Shirisha* may be as follows

Acharya Charaka classify this drug under *Vishaghna* (similar to Antihistaminic/Antiallergic effect) *Ayurveda* considers *visha* as toxic (antigen) which provokes allergic responses. By eliminating toxic materials from the body *Shirisha* lowers allergic reaction of the body. It is included in *Kashaya skandha*⁴ (astringent tasting group of herbs), *Kashaya* has *Ruksha guna* and does *Shoshana Karma*(drying), thus act as a decongestant on mucosa. It has *Tridosha shamaka*⁵ karma, which is cause of every disease. Allergic conjunctivitis is also due to vitiation of *tridosha* with *kapha* predominance thus *tridosha shamaka* effect of *Shirisha* helps in alleviating disease.

Recent works on *Shirisha* have shown its immunomodulatory effect⁶, steroidogenic effect⁷, mast cell stabilizing activity or cromoglycate like action⁸. Analgesic & Anti-Inflammatory Activity of *Shirisha* (*Albizia lebeck*) was also proved by many studies⁹ Methanolic extract of bark of *Albizia lebeck*

possess.¹⁰ In oral administration a clinical study of 29% of *ghansatva* of *Albizia lebeck* bark and 500 mg capsule of *Albizia lebeck* showed very favorable response in all kinds of allergic conjunctivitis.¹¹ Other results support that *Albizia lebeck* at different concentrations has got potent mast cell stabilizing property. This inhibitory potential of catechin from *Albizia lebeckis* perhaps due to modulation of two important effector's functions, histamine release and cytokine expression of antigen -IgE activated mast cells.¹²

Above mentioned few researches and present study suggests that the drug *Shirisha* may be used as effective agent in Allergic Conjunctivitis. It is a good local anti-allergic drug and more over it is easily available, cheap and free from side effects.

CONCLUSION

Shirisha eye drop has significantly reduced congestion, itching, foreign body sensation and pain with less relapse rate as compared to sodium cromoglycate eye drop. It relieved the symptoms of watering, discomfort, secretion, burning sensation, photophobia and lid heaviness as relieved by sodium cromoglycate eye drop. The onset effect of *Shirisha* eye drop was not as fast as sodium cromoglycate but the relief was more sustained. Both the groups showed positive effect on the health of conjunctival epithelial cells as showed by the improvement in the grades of impression cytology as improvement in the population of goblet cells. Thus *Shirisha* eye drop may be used as effective agent in Allergic Conjunctivitis.

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Cite this article as:

Haramohan Moharana et al. Effect of Shirisha drops in allergic conjunctivitis: A clinico-pathological evaluation. Int. J. Res. Ayurveda Pharm. 2017;8(Suppl 1):35-39 <http://dx.doi.org/10.7897/2277-4343.08134>

Source of support: Nil, Conflict of interest: None Declared

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