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Management of VATAJA ABHISHYANDA (SIMPLE ALLERGIC CONJUNCTIVITIS) with SHIGRU-HARIDRADI EYE DROP AND RASAYANA YOGA - An Open Labelled randomized comparative Clinical Trial."

Title: Further study on efficacy of *Shigru-Haridradi* Eye Drop and *Rasayana Yoga* in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis)- An open labelled randomized comparative clinical trial."

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ABSTRACT:

Background: In *Ayurveda* according to *Acharya Sushruta*, *Abhishyanda* is the main cause for all the *Netra Vyadhi* (eye diseases) and it is *Aupasargika Roga*. *Vataja Abhishyanda* is one among the *Sarvagata Netraroga*. Clinically *Vataja Abhishyanda* can be corelated with Allergic Conjunctivitis in Modern science. It is a non-infective type of conjunctivitis in which inflammation of conjunctiva occurs due to allergic or hypersensitive reactions which may be immediate (humoral) or delayed (cellular) characterised by itching, stickiness, hyperaemia and mild papillary response.

Aim: To assess and compare the efficacy of *Shigru-Haridradi* Eye Drop and *Rasayana Yoga* in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis).

Material and Methods: Patients were selected from the O.P.D. of *Shalakya Tantra* and also referred from OPD of other Departments, I.P.G.T. & R.A. Hospital, Jamnagar on the basis of signs and symptoms of the disease *Vataja Abhishyanda* (Simple Allergic Conjunctivitis).

Results: In group B, statistically significant result was found with p<0.05 in the symptoms of *Nistoda* (Pricking pain), *Sangharsha* (Foreign body sensation), *Ragata* (Redness), *Vishushka Bhava* (Dryness Feeling), *Achchashruta* (Clean/Watery Discharge), *Alpa Sopha* (Mild Chemosis), *Chala Ruja* (Referred Pain) and *Kandu* (Itching), *Daha* (Burning sensation) in compare to group A in both subjective and objective parameters of the study.

Conclusion: Group B (*Shigru-Haridradi* Eye Drop with *Rasayana Yoga*) showed better percentage of relief on all signs and symptoms of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis) in comparison to group A (*Shigru-Haridradi* Eye Drop).

Keywords: Vataja Abhishyanda, Shigru-Haridradi Eye Drop, Rasayana Yoga

INTRODUCTION:

Inflammation or infection of the conjunctiva is known as conjunctivitis and is characterized by dilatation of the conjunctival vessels, resulting in hyperemia and edema of the conjunctiva, typically associated with discharge.ⁱ It is most commonly due to an allergic reaction or an infection (usually bacterial or viral).

Allergic Conjunctivitis (Prevalence 5-22 % of the general population; Recurrence in 41-62 % cases) has an equal distribution more or less throughout the world, without any exception to the developed and under developed countries.ⁱⁱ

According to Modern science there are several forms of Allergic conjunctivitis. Simple Allergic Conjunctivitis is a mild and nonspecific. Allergic conjunctivitis is characterized by itching, hyperemia and mild papillary response. Basically, it is an acute or subacute urticarial reaction.

AIM AND OBJECTIVE:

AIMS: To assess and compare the efficacy of *Shigru-Haridradi* Eye Drop and *Rasayana Yoga* in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis).

OBJECTIVE:

- To assess the efficacy of *Shigru-Haridradi* Eye Drop in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis).
- To assess the efficacy of *Rasayana Yoga* in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis).

CRITERIA OF SELECTION

INCLUSION CRITERIA:

- 1. Patients presenting with typical signs and symptoms of Vataja Abhishyanda (Simple Allergic Conjunctivitis) i.e., Nistoda (Pricking Pain), Sangharsha (Foreign body sensation), Ragata (Redness), Vishushka Bhava (Dryness feeling), Achchashruta (Clean/Watery discharge), Alpa Shopha (Mild Chemosis), Chala Ruja (Referred Pain), Kandu (Itching), Daha (Burning sensation)
- 2. Patients between 16 years to 40 years of age.

EXCLUSION CRITERIA:

- 1. Patients having complications like corneal involvement like Marginal Corneal Ulcer, Dacryocystitis, Trachoma, Keratoconjunctivitis sicca, Vernal keratoconjunctivitis, Giant papillary conjunctivitis, Atopic keratoconjunctivitis.
- 2. Patients below 16 years and above 40 years of age.
- 3. All types of Conjunctivitis (Acute and Chronic) which are non-allergic in nature are excluded from the Study.

INVESTIGATIONS:

- a. Hematological Examination: (Hb %, TC, DC, ESR, AEC (Absolute Eosinophil Count), has been carried out before and after treatment to rule out any systemic disease and after treatment to note any changes in these parameters.
- **b.** Biochemical: FBS has been carried out before treatment to rule out any systemic disease.

GROUPING: All the patients have been divided into two groups by open labelled randomized comparative clinical trial.

Group - A

Shigru-Haridradi Eye Drop (Anubhuta)

Route of administration: Local

Dose: 1 drop 4 times per day (every 4 hours)

Duration: 1 month Minimum Patients: 15

Group – B

Shigru-Haridradi Eye Drop (Anubhuta)

Route of administration: Local

Dose: 1 drop 4 times per day (every 4 hours)

Duration: 1 month Minimum Patients: 15

Rasayana Yoga (Anubhuta)

Route of administration: Oral

Dose: 2 *Vati* (1*Vati* = 500 mg) after meal 3 times per day with Luke water.

Minimum Patients: 15

FOLLOW UP:

After completion of the treatment, the patients were followed for one month at 15 days interval.

STATISTICAL ANALYSIS: The data obtained in clinical study were arranged in Excel sheet and prepared the master chart. Statistical tests were performed with sigma stat software. Subjective parameters: The effect of therapy in the subjective parameters within the group were analysed by paired t test.

- 1) Objective parameters: The effect of therapy in Objective parameters within the group were analysed by paired 't' test.
- 2) Comparison between the groups: The effect of therapy in subjective and objective parameters between the group were evaluated by unpaired 't' test.

The results obtained are considered highly significant for P<0.001, significant for P<0.05, and insignificant for P>0.05.

OBSERVATION: Demographic data, clinical data and observations have been presented for 30 patients (i.e.15 patients in each group) who completed the trial.

CLINICAL STUDY:

Demographic data observations (Maximum value):

Age group	>32-40 Year	43.34%	
Sex	Female	66.67%	
Religion	Hindu	93.33%	
Occupation	Housewife	50.00%	
Socio-Economic	Middle	83.34	
Status			

Distribution Chief complains of 30 patients of *Vataja Abhishayanda* – (Simple Allergic Conjunctivitis).

Sr. No	Chief Complaints	No. of Patients (N=30)		Total	%
		Group-A	Group-B	Total	70
	Nistoda (Pricking Pain)				
1.		12	14	26	86.66
	Sangharsha				
2.	(Foreign body sensation)	13	14	27	90
	Ragata (Redness)	1.5	1.5	20	100
3.		15	15	30	100
	Vishushka Bhava				

	(Dryness - feeling)				
4.		03	04	07	23.33
5.	Achchashruta (Clean/ Watery discharge)	15	14	29	96.66
6.	Alpa Shopha (Mild Chemosis)	07	03	10	33.33
7.	Chala Ruja (Referred Pain)	02	04	06	20
0	Kandu (Itching)			20	02.22
8.		14	14	28	93.33
9.	Daha (Burning Sensation)	03	06	09	30

Distribution of Objective parameters in 30 patients of *Vataja Abhishyanda* – (Simple Allergic Conjunctivitis).

Objective Parameters	Group A (B/L Eye)	Group-B (B/L Eye)	Total	%
Papillary Changes	12	14	26	86.66
Chemosis	08	05	13	43.33
Congestion	15	15	30	100
Stickiness	14	15	29	96.66

EFFECT OF THERAPY

Effect of Shigru-Haridradi Eye Drop on chief complaints in the Group- A.

Nistoda (**Pricking Pain**): Right eye before treatment mean score was 1.167 which was reduced to 0.33 after treatment thus provide 71.43 % relief.

Left eye before treatment mean score was 1.083 which was reduced to 0.33 after treatment. Thus provided 69.23 % relief which was statistically highly significant at the level of P<0.001.

Sangharsha (Foreign Body Sensation): Right eye before treatment mean score was 1.615 which was reduced to 0.615 after treatment thus provide 61.9 % relief.

Left eye before treatment mean score was 1.615 which was reduced to 0.692 after treatment. Thus provided 57.1 % relief which was statistically highly significant at the level of P<0.001.

Ragata (**Redness**): Right eye before treatment mean score was 1.60 which was reduced to 0.467 after treatment thus provide 70.83 % relief.

Left eye before treatment mean score was 1.533 which was reduced to 0.467 after treatment. Thus provided 69.57 % relief which was statistically highly significant at the level of P<0.001.

Vishushka Bhava (**Dryness Feeling**): Right eye before treatment mean score was 1.33 which was reduced to 1.00 after treatment thus provide 25 % relief.

Left eye before treatment mean score was 1.33 which was reduced to 1.00 after treatment. Thus provided 25 % relief which was statistically Insignificant at the level of p>0.05.

Achchashruta (Clean/Watery Discharge): Right eye before treatment mean score was 1.467 which was reduced to 0.400 after treatment thus provide 72.7 % relief.

Left eye before treatment mean score was 1.467 which was reduced to 0.467 after treatment. Thus provided 68.2 % relief which was statistically Highly significant at the level of P<0.001.

Alpa Shopha (Mild Chemosis): Right eye before treatment mean score was 1.286 which was reduced to 0.571 after treatment thus provide 55.6 % relief.

Left eye before treatment mean score was 1.286 which was reduced to 0.714 after treatment. Thus provided 44.4% relief which was statistically significant at the level of P<0.05.

Chala Ruja (**Referred Pain**): Right eye before treatment mean score was 1.33 which was reduced to 0.66 after treatment thus provide 50 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.66 after treatment. Thus provided 33.3 % relief which was statistically Insignificant at the level of P>0.05.

Kandu (Itching): Right eye before treatment mean score was 1.786 which was reduced to 0.429 after treatment thus provide 76 % relief.

Left eye before treatment mean score was 1.786 which was reduced to 0.500 after treatment. Thus provided 72 % relief which was statistically Highly significant at the level of P<0.001.

Daha (Burning sensation): Right eye before treatment mean score was 1.33 which was reduced to 0.66 after treatment thus provide 50 % relief.

Left eye before treatment mean score was 1.33 which was reduced to 0.66 after treatment. Thus provided 50 % relief which was statistically Insignificant at the level of P>0.05.

Effect of Shigru-Haridradi Eye Drop on Slit Lamp Examination in the Group-A.

Papillary Changes: Right eye before treatment mean score was 1.417 which was reduced to 0.417 after treatment thus provide 70.58 % relief.

Left eye before treatment mean score was 1.417 which was reduced to 0.417 after treatment. Thus provided 70.58 % relief which was statistically Highly significant at the level of P<0.001.

Chemosis: Right eye before treatment mean score was 1.125 which was reduced to 0.375 after treatment thus provide 66.66 % relief.

Left eye before treatment mean score was 1.125 which was reduced to 0.375 after treatment. Thus provided 66.66 % relief which was statistically significant at the level of P<0.05.

Congestion: Right eye before treatment mean score was 1.733 which was reduced to 0.533 after treatment thus provide 69.23 % relief.

Left eye before treatment mean score was 1.667 which was reduced to 0.533 after treatment. Thus provided 68 % relief which was statistically Highly significant at the level of P<0.001.

Stickiness: Right eye before treatment mean score was 1.33 which was reduced to 0.533 after treatment thus provide 60 % relief.

Left eye before treatment mean score was 1.267 which was reduced to 0.533 after treatment. Thus provided 57.89 % relief which was statistically Highly significant at the level of P<0.001.

Effect of Shigru-Haridradi Eye Drop and Rasayana Yoga on chief complaints in the Group-B.

Nistoda (Pricking Pain): Right eye before treatment mean score was 1.143 which was reduced to 0.214 after treatment thus provide 81.25 % relief.

Left eye before treatment mean score was 1.143 which was reduced to 0.214 after treatment. Thus provided 81.25 % relief which was statistically Highly significant at the level of P<0.001.

Sangharsha (Foreign Body Sensation): Right eye before treatment mean score was 1.357 which was reduced to 0.429 after treatment thus provide 68.42 % relief.

Left eye before treatment mean score was 1.357 which was reduced to 0.429 after treatment. Thus provided 68.42 % relief which was statistically Highly significant at the level of P<0.001.

Ragata (**Redness**): Right eye before treatment mean score was 1.267 which was reduced to 0.33 after treatment thus provide 73.68 % relief.

Left eye before treatment mean score was 1.267 which was reduced to 0.33 after treatment. Thus provided 73.68 % relief which was statistically highly significant at the level of P<0.001

Vishushka Bhava ((**Dryness Feeling**) Right eye before treatment mean score was 1.00 which was reduced to 0.750 after treatment thus provide 25 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.500 after treatment. Thus provided 50 % relief which was statistically Insignificant at the level of P>0.05.

Achchashruta (Clean/Watery Discharge): Right eye before treatment mean score was 1.214 which was reduced to 0.214 after treatment thus provide 82.35 % relief.

Left eye before treatment mean score was 1.214 which was reduced to 0.214 after treatment. Thus provided 82.35 % relief which was statistically Highly significant at the level of P<0.001

Alpa Shopha (Mild Chemosis): Right eye before treatment mean score was 1.00 which was reduced to 0.33 after treatment thus provide 66.66 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.33 after treatment. Thus provided 66.66 % relief which was statistically Insignificant at the level of P>0.05

Chala Ruja (**Referred Pain**): Right eye before treatment mean score was 1.00 which was reduced to 0.600 after treatment thus provide 40 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.600 after treatment. Thus provided 40 % relief which was statistically Insignificant at the level of P>0.05

Kandu (Itching): Right eye before treatment mean score was 1.267 which was reduced to 0.200 after treatment thus provide 84.21 % relief.

Left eye before treatment mean score was 1.267 which was reduced to 0.200 after treatment. Thus provided 84.21 % relief which was statistically Highly significant at the level of P<0.001

Daha (Burning sensation): Right eye before treatment mean score was 1.00 which was reduced to 0.167 after treatment thus provide 83.33 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.167 after treatment. Thus provided 83.33 % relief which was statistically significant at the level of P<0.05

Effect of Shigru-Haridradi Eye Drop and Rasayana Yoga on Slit Lamp Examination in the Group-B.

Analysis of above table after the administration of *Shigru-Haridradi* Eye Drop and *Rasayana Yoga* reveals the following point:

Papillary Changes: Right eye before treatment mean score was 1.357 which was reduced to 0.286 after treatment thus provide 78.94 % relief.

Left eye before treatment mean score was 1.357 which was reduced to 0.286 after treatment. Thus provided 78.94 % relief which was statistically Highly Significant P<0.001

Chemosis: Right eye before treatment mean score was 1.00 which was reduced to 0.200 after treatment thus provide 80 % relief.

Left eye before treatment mean score was 1.00 which was reduced to 0.200 after treatment. Thus provided 80 % relief which was statistically Significant P<0.05

Congestion: Right eye before treatment mean score was 1.267 which was reduced to 0.200 after treatment thus provide 84.21 % relief.

Left eye before treatment mean score was 1.267 which was reduced to 0.200 after treatment. Thus provided 84.21 % relief which was statistically Highly Significant P<0.001

Stickiness: Right eye before treatment mean score was 1.067 which was reduced to 0.267 after treatment. thus provide 75 % relief.

Left eye before treatment mean score was 1.067 which was reduced to 0.267 after treatment. Thus provided 75 % relief which was statistically Highly Significant P<0.001

Comparative therapy of Group-A and Group-B on Chief Complaints- Right Eye.

In the comparative study of Right Eye of Group-A and Group-B, it is revealed from the above table that:

- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Nistoda* (Pricking Pain) with t value 0.462, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Sangharsha* (Foreign Body Sensation) with t value 0.418, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Ragata* (Redness) with t value 1.342, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Vishushka Bhava* (Dryness Feeling) with t value 0.205, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Achchashruta* (Clean/Watery Discharge) with t value 0.00, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Alpa Shopha* (Mild Chemosis) with t value 0.135, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Chala Ruja* (Referred Pain) with t value 0.655, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Kandu* (Itching) with t value 1.638, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on *Daha* (Burning sensation) with t value 0.509, it is statistically Insignificant P>0.05

Comparative therapy of Group-A and Group-B on Slit Lamp Examination- Right Eye:

- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on Papillary Changes with t value 0.520, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on Chemosis with t value 0.192, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on Congestion with t value 1.058, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of right eye between Group-A and Group-B on Stickiness with t value 000, it is found statistically Insignificant P>0.05.

Comparative therapy of Group-A and Group-B on Chief Complaints – Left Eye.

In the comparative study of Left Eye of Group-A and Group-B, it is revealed from the above table that: -

- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on.
- Nistoda (Pricking Pain) with t value 1.247, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Sangharsha* (Foreign Body Sensation) with t value 0.029, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Ragata* (Redness) with t value 0.983, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Vishushka Bhava* (Dryness Feeling) with t value 0.378, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on Achchashruta (Clean/Watery Discharge) with t value 0.00, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Alpa Shopha* (Mild Chemosis) with t value 0.253, it is found statistically Significant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Chala Ruja* (Referred Pain) with t value 0.164, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Kandu* (Itching) with t value 1.273, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on *Daha* (Burning sensation) with t value 0.509, it is statistically Insignificant P>0.05.

Comparative therapy of Group-A and Group-B on Slit Lamp Examination - Left Eye.

• On comparisons of overall effect of treatment of left eye between Group-A and Group-B on Papillary Changes with t value 0.520, it is found statistically Insignificant P>0.05

- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on Chemosis with t value 0.192, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on Congestion with t value 0.447, it is found statistically Insignificant P>0.05
- On comparisons of overall effect of treatment of left eye between Group-A and Group-B on Stickiness with t value 0.418, it is found statistically Insignificant P>0.05.

Total effect of therapy of Group-A and Group-B:

Table represents the data pertaining to overall effect of therapy in 30 patients.

Group-A, out of 15 patients, 11 (73.33%) patients got marked improvement, 03 (20%) patients got complete improvement and 01 (6.67%) patients got Moderate improvement after Completion of treatment.

Group-B, out of 15 patients, 08 (53.33%) Marked improvement, 07 (46.67%) patient got complete improvement after completion of treatment.

DISCUSSION:

FLOW CHART OF PROBABLE MODE OF ACTION OF SHIGRU-HARIDRADI EYE DROP:

Topical administration of Shigru-Haridradi Eye Drop in the eye

Drug absorption through various layers of the eye

Spread drug in deeper tissues through Sira, Srotas and Sandhi of Netra

Due to properties of Shigru-Haridradi Eye Drop like Vata-Kaphashamaka, Ushna Virya Chakshusya, and Krimihara

Bring Dosha towards Netra, eliminates through Aushadha Prabhava

Due to anti-inflammatory, antihistamine and antimicrobial properties of the drugs

Effective in the signs and symptoms of Vataja Abhishyanda-

(Simple Allergic Conjunctivitis)

Rasayana Yoga orally Anti-Inflammatory, Works at different system of Anti- Bacterial, the Body and acts into two Immuno-modulator ways by the virtue of its action **Decreases Papillary** changes, Congestion, Rasayana, Dhatu Vardhaka, Deepana and Pachana Chamacic and Stickings Balya, Brimhaniya, Ojovardhaka Agni Vardhana Increase the Relief in the signs and symptoms of Vataja Abhishyanda-

(Simple Allergic Conjunctivitis)

FLOW CHART OF PROBABLE MODE OF ACTION OF RASAYANA YOGA ORALLY:

CONCLUSION:

After analysis of all the data, it can be concluded that group A shows statistically significant result than that of group B that was Administration of *Shigru-Haridradi* Eye Drop topically along with administration of Rasayana Yoga orally is more effective than that of administration of Shigru-Haridradi Eye Drop topically alone in the management of *Vataja Abhishyanda* (Simple Allergic Conjunctivitis). The duration of the treatment is short; so, further long-duration studies are needed. It is recommended that the study should be carried out on a large number of patients with longer duration to evaluate and analyse the efficacy of drugs.

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Conflicts of interest: There are no conflicts of interest

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