

Shadbindu Taila Nasya in Allergic Rhinitis: a Controlled Clinical Trial to Compare its Efficacy with Topical *Azelastine hydrochloride* Nasal Spray

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Submission: November 30, 2016; **Published:** December 15, 2016

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Abstract

With the aim to evaluate the efficacy of *shadbindu taila Nasya* and topical *Azelastine hydrochloride nasal spray* in the management of Allergic Rhinitis, a Single blind randomized clinical study was done. For the clinical study of Allergic Rhinitis 60 subjects was selected and studied. Subject's fulfilling the criteria of diagnosis was studied irrespective of their religion, caste, sex and socio-economic status from shalakra-tantra (ENT) department of the institute after thorough scrutiny and proper consent in his/her language. The Subject's having age between 20-60 yrs was selected for the clinical study. Detail history of the patient were elicited, pathological investigation including Hb, TLC, DLC, RBS and required radio logical investigation were done in a diagnostic Centre.

The examination of the Nose is also carried out with the help of modern viewing techniques like Anterior Rhinoscopy, Posterior Rhinoscopy and Spatula Test etc. After observation and analytical study with the help of Wilcoxon sign rank test and Man-whitney test it was concluded that in Allergic Rhinitis treatment with *shadbindu taila Nasya* shows more effective and long lasting Result in relieving sign and symptoms of Allergic Rhinitis than *Azelastine hydrochloride nasal spray*.

Keywords: Shadbindu taila; Nasya; Azelastine hydrochloride; Rhinitis

Introduction

The human life is full of competition due to which his life style has been completely changed, we has to face excessive exposure to pollution, cold Along with these factor consumption of chilled foods, cold drinks, ice cream etc. produces phlegm diseases which gives rise to respiratory tract diseases. As respiration is soul of physiological activity, Pranvaha strotas has its special importance. Dushti of Pranvaha Strotas may disturb the physiological activity of body. Nasa is commencement of pranvaha strotas. Nasa protects pranvaha strotas by adhering the harmful factors like pollen, dust to the mucous membrane, also humidifies air entering the nose and regulate the temperature of air entering the nose. Hence Pranvaha Strotas will be affected if physiological activity of protection of nose is not performed well. The pollution and the above said factors affect the nose and its mucosal membrane leading to various nasal diseases. Allergic Rhinitis is also a disease among them which is described by all Ayurvedacharya' [1-4].

In modern medical science, there is medical treatment for Allergic Rhinitis. Complete cure of these diseases is not yet possible by medical treatment. So looking towards the

importance of above said points, there is a great need to look forward for the Ayurvedic management of Allergic Rhinitis. There are number of references in Ayurvedic texts suggest various regimes of treatment for Allergic Rhinitis. All these management have one common concept and this is nasya karma. Ayurvedacharya have already praised the role of nasya Karma in urdhav jatrugat vikar [5,6].

Aims and Objectives

- i. To study efficacy of *shadbindu taila Nasya* in Allergic Rhinitis.
- ii. To study efficacy of *Azelastine hydrochloride nasal spray* in Allergic Rhinitis.
- iii. Comparing the efficacy of *shadbindu taila Nasya* and *Azelastine hydrochloride nasal spray* in the management of Allergic Rhinitis.

Taking above said point in consideration, we have plan to study and compare *shadbindu taila Nasya* and *Azelastine hydrochloride nasal spray* in the management of Allergic Rhinitis which includes patients' history, sign, symptoms , diagnosis

,clinical examination and management by above said trial drugs [7].

Hypothesis

- a) H₀-*shadbindu taila Nasya* and Azelastine hydrochloride nasal spray do not have any effect on Allergic Rhinitis.
- b) H₁-*shadbindu taila Nasya* and Azelastine hydrochloride nasal spray do have effect on Allergic Rhinitis.

Materials and Method

Patients having signs and symptoms of Allergic Rhinitis was randomly enrolled from the OPD of department of Shalakya-Tantra (ENT) of the institute after thorough scrutiny, proper consent and permission from ethical committee [8,9].

Composition of trial drug (Tables 1 & 2).

Table 1: Shadbindu Taila.

Sr. No.	Name of Dravya	Family	Latin Name	Proportion
1.	Bhrunga raja	Compositae	<i>Eclipta alba</i>	1
2.	Yashtimadhu	Leguminasae	<i>Glycyrrhiza glabra</i>	1
3.	Sunthi	zingiberaceae	<i>Zinziber Officinale</i>	1
4.	Kushta	Compositae	<i>Saussurea lappa</i>	1
5.	Lavan	-	-	1
6.	Tila taila	-	-	4

Table 2: Azelastine Hydrochloride nasal spray.

Sr no.	Drug	Content (%)	Per spray dose
1.	Azelastine Hydrochloride	0.15%	205.5mcg

Drug Analysis (Table 3).

Table 3: Drug Analysis.

Sr. No.	Test	Result
1.	Description Brown colour oil	-
2.	pH(2gm in 100ml water) Method :by pH Meter	4.86
3.	Refractive Index at 40°C Method: as per IS-548	1.465
4.	Viscosity at 40°C Method : by Ostwald viscometer cps	77.44
5.	Iodine value Method : as per IS-548 gl/100gm	116
6.	Acid value Method : as per IS-548 mgkoh/gm	5.53
7.	Saponification value Method : as per IS-548 mgkoh/gm	182

Grouping: 2 groups

- i. Group A: The Subjects of this group was treated with *shadbindu taila Nasya*
- ii. Group B: The Subjects of this group was treated with Azelastine hydrochloride nasal spray (Table 4) [10-15].

Table 4: Study Design.

Grouping	Group A	Group B
Sample size	30	30
Intervention	<i>shadbindu taila Nasya</i>	<i>Azelastine hydrochloride nasal spray</i>
Duration	21 days	21 days
Follow up	7 days	7 days
Dosage	6 drops in each nostrils	One spray in each nostril (205.5mcg)
Timing	Once daily in a morning	Once daily in a morning
Interval	3 days after every 7 days	3 days after every 7 days

Examination of the patient

Nasal examination of the patient includes.

- a) Examination of external nose.
- b) Examination of Vestibule.
- c) Anterior Rhinoscopy
- d) Posterior Rhinoscopy
- e) Functional examination of nose [16].

Criteria of diagnosis

- a) Foul Smell
- b) Anosmia
- c) Dryness of Nose
- d) Crusting
- e) Nasal discharge
- f) Blocking of Nose

Grading (0-Absent, 1-occasional, 2-frequent, 3-continuous)

A. Investigation

- a) Pathological: CBC, BSL, HIV
- b) Radiological: x-ray PNS
- c) Endoscopic: Functional nasal endoscopy (Rigid) [17-19].

Criteria for assessment:

Criteria for selection:-

- a) Diagnosis of Allergic Rhinitis was based on clinical examination which will be supported with Radiological and pathological investigation [20-22].
- b) Age group between 20 to 50 years [23-27].
- c) Both male and female subjects, having sign and symptoms of Allergic Rhinitis, irrespective of their socio-economic status, educational status, caste and religion [27-32].

Criteria for rejection

- a) Subjects having previous history of nasal surgery.
- b) Subjects suffering from nasal polyposis, nasal carcinoma, epistaxis.

The data collected from all the 60 Subjects of both groups was summarized and statistically represented in terms of Vital Statistics, Observations during study, Results of the study and Statistical comparison of both the groups [33-37].

Result

In the Group A the Mean Foul Smell of Nose was observe to be 2.133 before treatment that reduced to 0.9333 after treatment (p value <0.05), the Mean Anosmia of Nose was observe to be 1.633 before treatment that reduced to 1.567 after treatment (p value >0.05), the Mean Dryness of Nose was observe to be 2.5 before treatment that reduced to 0.6667 after treatment (p value <0.05), the Mean Crusting of Nose was observe to be 2.467 before treatment that reduced to 0.7000 after treatment (p value <0.05), the Mean Nasal Discharge of Nose was observe to be 1.333 before treatment that reduced to 0.5667 after treatment (p value <0.05), the Mean Blocking of Nose was observe to be 2.133 before treatment that reduced to 0.9000 after treatment (p value <0.05) [38,39].

In the Group B the Mean foul smell of Nose was observe to be 2.233 before treatment that reduced to 1.067 after treatment (p value <0.05), the Mean Anosmia of Nose was observe to be 1.500 before treatment that reduced to 1.400 after treatment (p value >0.05), the Mean Dryness of Nose was observe to be 2.333 before treatment that reduced to 1.367 after treatment (p value <0.05), the Mean Crusting of Nose was observe to be 2.300 before treatment that reduced to 1.067 after treatment (p value <0.05), the Mean Nasal Discharge of Nose was observe to be 1.467 before treatment that reduced to 0.8333 after treatment (p value <0.05) [33,40,41], the Mean Blocking of Nose was observe to be 2.033 before treatment that reduced to 1.167 after treatment (p value <0.05).

To examine either the groups differs from each other significantly or not, further data are treated by Mann whiteny U score test. For Foul Smell of Nose the mean difference in value

in group A was 1.200 while that in Group B was 1.167 (p value >0.05). For Anosmia of Nose the mean difference in value in group A was 0.06667 while that in Group B was 0.1000 (p value >0.05). For Dryness of Nose the mean difference in value in group A was 1.833 while that in Group B was 0.9667 (p value <0.05) [42-44]. For Crusting of Nose the mean difference in value in group A was 1.767 while that in Group B was 1.233 (p value <0.05). For Nasal Discharge of Nose the mean difference in value in group A was 0.7667 while that in Group B was 0.6333 (p value >0.05). For Blocking of Nose the mean difference in value in group A was 1.233 while that in Group B was 0.8667 (p value <0.05).

Discussion and Conclusion

In this series, 60 patients of Allergic Rhinitis were studied out of which 36.66% patients found in Aged group between 20-30 yrs and 40-50 yrs respectively, No any difference in sex ratio is found i.e. both male to female ratio is equal, 73.33% patients belonging to Hindu religion, maximum number of patient are educated up to mid school and high school i.e. 26.66% each. 80% of patients are from lower socio-economic level, 50% patient were suffering from Allergic Rhinitis since more than 5 yrs, 71.66% patient were having *kaphavataj prakriti*, 38.33% patient were having *mandagni*, 78.33% patients were taking sheet *gunatmaka Ahar* while 71.66% patient were taking *rukshagunatmak Ahar*, 48.33% patient were taking dominant *katu rasatmaka Ahar* and 83.33% patients were taking mixed type of diet [44].

In this study 100% patients of both groups were having *vata dosh dushti* while 75% patient were having *kapha dosh dushti*, 100% patients of both groups were having *Rasa dushya dushti* while *Mansa* and *Rakta dushya dushti* were 80% and 71.66% respectively. 85% patients were living in Unhygienic residential area, 58.33% patients were doing labor work and 35% patients were having history of addictions. After doing inference confidently by Wilcoxon Sign Rank Test, it is found that in group A except for Anosmia difference between before treatment and after treatment are statistically highly significant for foul smell, dryness, and crusting, nasal discharge and blocking of nose [42]. Also in group B treatment with Azelastine hydrochloride nasal spray are effective relieving symptoms of Allergic Rhinitis except for symptom anosmia.

After doing Mann-Whitney U Test to examine difference between effect of treatment in both groups it is found that for dryness, crusting and blocking of nose the inference is highly significant. I.e. for above symptoms Group A shows better result than Group B. But for foul smell, anosmia and nasal discharge the inference are in-significant. The properties of *shadbindu taila* i.e. acidic nature, excess of hydrogen ions are useful for capillary circulation. Increased H⁺ ions concentration dilate the capillary. As *shadbindu taila* is having excess of H⁺ ions concentration it causes dilatation of capillary. Irritation of the skin produces vasodilatation in the locality. In neurology this reflex is known as Axon reflex. As *shadbindu taila* is being acidic in nature, it

acts as irritant to nasal mucosal membrane, which produces vasodilatation [23,36]. The acidic nature of *shadbindu taila* also inhibits the photolytic organism and also helps in removing crust. Thus *shadbindu taila* acts as vasodilator and Germicidal which are helpful in minimizing the symptoms of Allergic Rhinitis. From the above discussion, it is clear that Subjects having clinical features of Allergic Rhinitis are more significantly reduced in Group A than Group B which itself prove that treatment with *shadbindu taila Nasya* is better than treatment with Azelastine hydrochloride nasal spray in Allergic Rhinitis.

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