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STUDY OF EFFECT OF *KUSHTADI TAILA NASYA* IN *KSHAVATHU* WITH SPECIAL REFERENCE TO THE CLINICAL ALLERGIC RHINITIS

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ABSTRACT

Introduction: Allergic rhinitis is defined as symptoms of sneezing, nasal pruritus, airflow obstruction, and mostly clear nasal discharge caused by IgE-mediated reactions against inhaled allergens and involving mucosal inflammation driven by type 2 helper T (Th2) cells. Indian study reported that prevalence of allergic rhinitis was 11·3% in children aged 6–7 years, and 24.4% in children aged 13–14 years**. Material and Method:** Total 60 patients were registered in the study. 30 in each group. Group A (Trial group)– In Group A, patients were given *Kushtadi Taila Nasya*, 2-2 drops/nostril twice a day for 7 days. Group B (Control Drug) – In Group B, patients were given *Tila Taila Nasya*, 2-2 drops/nostril twice a day for 7 days. **Result:** Out of 30 patients of group A, 26 patients got relief while 4 didn't get relief and 23 patients out of 30 patients of group B got relief while 7 patients were not relieved. Chi-square test at 5% level of significance indicates that the relief rate group A and group B are not significantly different (P-value = 0.05). **Conclusion:** The study can be concluded by saying that *Kushtadi Taila Nasya* formulation is better choice of treatment in case of *Kshavathu* and *Tila Taila Nasya* formulation also can be adopted by considering the convenience of the patients.

KEYWORDS: *Kushtahadi Taila*, *Kshavathu*, Allergic Rhinitis

1. INTRODUCTION

Allergic rhinitis is defined as symptoms of sneezing, nasal pruritus, airflow obstruction, and mostly clear nasal discharge caused by IgE-mediated reactions against inhaled allergens and involving mucosal inflammation driven by type 2 helper T (Th2) cells.[i] Allergic Rhinitis is a common problem among all age groups and can occur in both the sexes. The incidence is almost same in India. An Indian study reported that prevalence of allergic rhinitis was 11.3% in children aged 6–7 years, and 24.4% in children aged 13–14 years. The selected location, being known for Industrial population, factories, fields etc; respiratory infections report a large number of cases. Approximately 30-40% of the total ENT patients attending *Shalakya* O.P.D, Complains of this Allergic Rhinitis. This Allergic Rhinitis is too difficult to drain out completely. It remains as a focus for infections and inflammations in a sinus causing recurrent sinusitis, leading to complications like serous otitis media, bronchial asthma, orthodontic problems. When gone through other systems of medicine, it can be observed that they fail to offer a complete cure and prevention of this disease.

Nose is a sense organ which performs two functions i.e. olfactory and Respiratory. Due to its direct contact with external environment, it is exposed to lot of microorganisms & pollutants present in the atmosphere. Due to the increased environmental pollution and busy life, rhinitis is a common disease in this present era. If this stage is not properly treated, it will cause the spread of infection to sinuses and result into sinusitis and later on chronic sinusitis.

The features of Allergic Rhinitis is similar to that of *Kshavathu Vyadhi* explained in Ayurveda classics. [ii]This disease is characterised by sneezing, nasal discharge, nasal blockage, itching in nose, headache, loss in smell etc. In *Uttaratantra*, Acharya Sushruta has explained *Kshavathu* one among 31 *Nasa Roga*.[iii] This fact itself shows that *Kshavathu* has been a major problem to the physicians since long back. *Kshavathu* is a recurrent attack and can precipitate even due to minute etiological factors. *Vata* and *Kapha* are the doshas responsible mainly. Improper management of *Kshavathu* may lead to many complications which will be difficult to treat. Considering all these facts, a clinical trial in *Kshavathu* was carried out to find out a treatment protocol for the management of the same.

"*Nasya*" is a prime therapy for maintaining the health of "*Urdhwajatru*", because *Nasya Karma* is the only karma, which finds a place in simple references like "*Dinacharya*" and the most sophisticated places like *Panchakarma*. Out of all *Karmas*, *Nasya* Karma is the best therapy for *Urdhvajatrugata Rogas* and specially *Nasagata Rogas*, according to all Ayurvedic scholars and literatures (Ch.Chi.30/294; Ch.Si.9/93; Su.Chi.40/23). In maximum *Urdhvajatrugata Rogas*, medicated oil is used. The reason is that it not only protects the nasal mucosa from foreign bodies but also potentiates immunity to Nasa Pradesh as well as *Urdhwajatru*.

Considering all the above literature work, this study was initiated to study the effect & access the principle of *Kushtadi Taila Nasya* on *Kshavathu*. The drugs mentioned in *Kushtadi Taila* are *Kushta, Bilwa, Shunthi, Pippali, Draksha Kalka* and *Tila Taila*. These two drugs were selected by considering its *Tridoshahara* properties with special action in *Nasaroga* and *Shirahshoola*.[iv]

1.2 MATERIAL AND METHOD

Criteria of selection of patients & diagnosis

Inclusion Criteria- 1. Uncomplicated patients with signs & symptoms of Allergic Rhinitis, attending O.P.D & I.P.D. of *Shalakya* Dept, were selected irrespective of age, sex, religion, caste, educational status, socioeconomic status & occupation etc. 2. Age group of 10 to 50 years. 3. Patients who give written consent for study & drug trial after reading about the ideas of the project, before drug trials.

Exclusion criteria- 1. Patient aged below 10 and above 50 years. 2. Patients with other major systemic diseases like Hypertension, Diabetes Mellitus, Asthma, Tuberculosis and HIV. 3. Patients other than allergic Rhinitis like Atrophic Rhinitis, Nasal polyp, Rhinoliths, Ca Nasopharynx, Rhinitis Sicca, Hypertrophic Rhinitis etc.

Discontinuation Criteria 1. Any adverse effect of the medicine seen in the patient. 2. Patients not willing to continue the treatment & follow-up.

Investigations-

Haematological Examination : ESR : Absolute Eosinophil Count

Grouping - The selected patients were randomly placed and studied under 2 groups.

Group A (Trial group)– In Group A, patients were given *Kushtadi Taila Nasya*, 2-2 drops/nostril twice a day for 7 days

Group B (Control Drug) – In Group B, patients were given *Tila Taila Nasya*, 2-2 drops/nostril twice a day for 7 days

Follow up study - Follow up were recorded in the O.P.D on 1st, 3rd, 5th, 7th, 15th, 22nd & 30th day. Haematological Investigations recorded on 1st and 15th day.

Criteria of Assessment: Assessment of the effect of treatment was done on the basis of relief of subjective & objective signs & symptoms of Allergic Rhinitis through statistical analysis & other tests. The following general evaluating scale was used for the same.

Kshavathu **(Sneezing)**	***Nasa Sraava*** **(Rhinorrhoea)**
0- No sneezing	0- No discharge.

1– 1 to 10 sneezing 2– 10 to 15 sneezing 3– 15 to 20 sneezing 4- >20 sneezing	1– Occasional Rhinorrhoea with a feeling of running nose without visible fluid. 2- Rhinorrhoea with occasional running nose with visible fluid. 3– Rhinorrhoea with running nose which needs moping but controllable. 4- Severe Rhinorrhoea with copious fluid needs continuously moped.
***Nasavarodha* (Nasal Obstruction)** 0 - No obstruction. 1 – Inhalation & exhalation with effort with feeling of mild obstruction. 2 – Inhalation & exhalation with effort with feeling of moderate obstruction. Inhalation & exhalation to be supplemented with mouth breathing. 3 - Complete nasal blockage with total mouth breathing.	***Nasa Kandu* (Itching)** 0 - No itching. 1 – Mild itching. 2 – Moderate & occasionally. 3 - Severe with scratching the nose very frequently.
***Shirah Shoola* (Headache)** 0 - No headache. 1 – Mild Headache. 2 – Moderate Headache. 3 – Severe headache patient restless & able to carry routine work with great difficulty. 4 - Severe crippling headache that renders patient bed ridden	***Bhutwa Bhutwa*** 0 – No attacks 1 – Period between attacks more than 2 days 2 – Period between attacks 1- 2 days 3 – Period between attacks 12-24 hrs. 4- Attack within 12 hrs

Statistical analysis: For analysis of quantitative parameters t test was used. For intra-group comparison "Paired t test" and for intergroup comparison "Two sample t test". As grading used for the some of the parameters were ordinal in nature, "Wilcoxon Signed Rank test" was used for intra-group comparison. (i.e. before and after treatment of a group) while for inter-group comparison, (i.e. for comparing two groups with each other) "Mann-Whitney U test" was used. Chi-square test (for proportion) was used to compare cure rate of two groups. Hypothesis for each parameter was tested and result was interpreted accordingly. The level of significance was kept at 0.05.

Criteria for overall assessment- The total effect of therapy was assessed considering the following criteria.

Complete remission	100% Relief in the signs and symptoms
Markedly improvement	More than 76% and less than 99% relief in the signs and symptoms
Moderately improvement	More than 51% and less than 75% relief in the signs and symptoms
Mild improvement	More than 26% and less than 50% relief in the signs and symptoms
Unchanged	Below 25% relief in the signs and symptoms

1.3 OBSERVATION

In the present study total 60 patients were registered and were categorized into two groups of 30-30 patients each.

Observation on demographic data: In group A, there was 4 patients (13%) having age between 10 – 19 years, 13 were (43%) having age between 20 – 29 years, 8 patients (27%) were in range 30 – 39 years while 5 patients (17%) were having age 40 – 49 years. In group B, there was 2 patients (7%) having age between 10 – 19 years, 11 were (37%) having age between 20 – 29 years, 9 patients (30%) were in range 30 – 39 years while 8 patients (27%) were having age 40 – 49 years. In group A, there were 14 males (47%) and 16 patients were female (53%). In group B, 21 patients were male (70%) and 9 were female (30%). In group A, 5 patients (17%) were factory worker, 9 were farmer (30%), 3 were housewife (10%), 9 were student (30%) and 4 were teacher (13%) while in group B, 6 patients (20%) were factory worker, 11 were farmer (37%), 1 patient was housewife (3%), 11 were student (37%) and 1 was teacher (3%).

1.4 RESULT

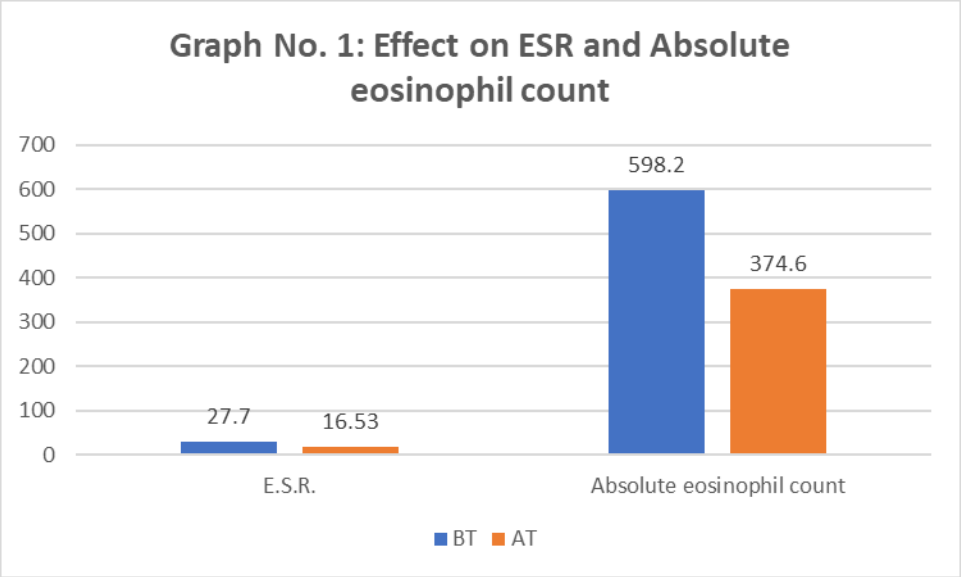
1. **ESR**: Using paired t test for ESR, p – value is less than 0.01 i.e. the difference between mean ESR before and after treatment is significant at 5% level of significance. i.e. there is reduction in ESR for trial group. The mean reduction in ESR for group A and mean reduction of group B wasn't significant (P-value =0.655) at 5% level of significance. Thus trial drug and control drug can be considered as equally effective in reducing ESR. (Graph No. 1)
2. **Absolute Eosinophil Count:** By using paired t test, p – value is less than 0.01 i.e. the difference between mean ESR before and after treatment is significant at 5% level of significance. i.e., there is reduction in Absolute Eosinophil Count for trial group. The mean reduction in Absolute Eosinophil Count for group A and mean reduction of group B wasn't significant (P-value =0.224) at 5% level of significance. Thus trial drug and control drug can be considered as equally effective in reducing Absolute Eosinophil Count. (Graph No. 1)
3. ***Kshavathu***: For group A, the median reduction in *Kshavathu* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Kshavathu* for Group A. For group B, the median reduction in *Kshavathu* after treatment is significant (P-value < 0.001) at 5%

level of significance. i.e. There is significant reduction in *Kshavathu* for Group B. Distribution of "reduction in *Kshavathu*" for group A and group B isn't significantly different. (p –value = 0.348) Thus trial drug and control drug can be considered as equally effective in reducing *Kshavathu* at 5% level of significance. (Graph No. 2)

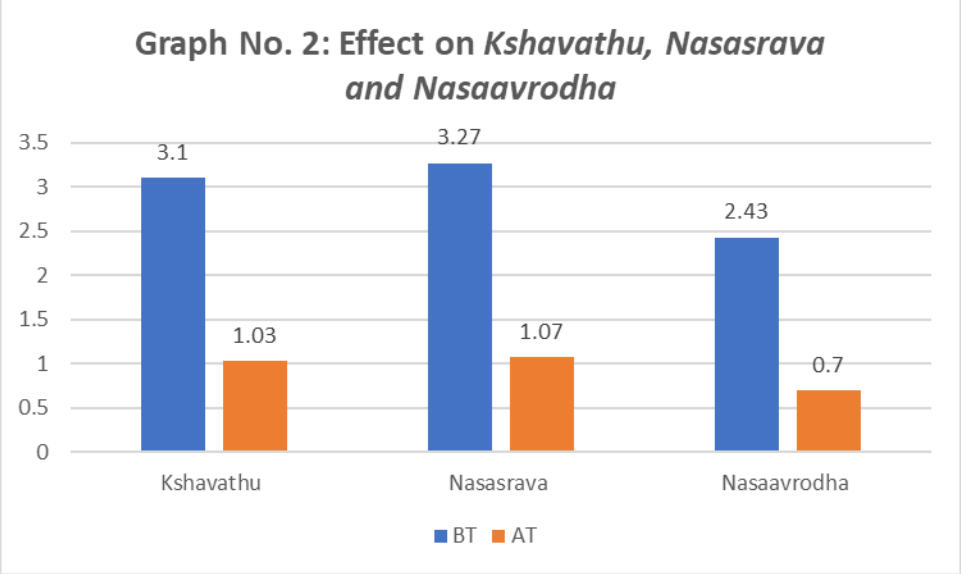
4. ***Nasasraava***: For group A, the median reduction after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Nasasraava* for Group A. For group B, the median reduction in *Nasasraava* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Nasasraava* for Group B. Distribution of "reduction in *Nasasraava*" for group A and group B isn't significantly different. (p –value = 0.439) Thus trial drug and control drug can be considered as equally effective in reducing *Nasasraava* at 5% level of significance. (Graph No. 2)
5. ***Nasavarodha*:** For group A, the median reduction in *Nasavarodha* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. that there is significant reduction in *Nasavarodha* for Group A. For group B, the median reduction in *Nasavarodha* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Nasavarodha* for Group B. Comparative Analysis of Groups. Distribution of "reduction in *Nasavarodha*" for group A and group B is significantly different. (p –value = 0.039) Thus trial drug can be considered as more effective in reducing *Nasavarodha* as compared to control drug at 5% level of significance. (Graph No. 2)
6. ***Nasa Kandu:*** For group A, the median reduction in *Nasa Kandu* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Nasa Kandu* for Group A. For group B, the median reduction in *Nasa Kandu* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e there is significant reduction in *Nasa Kandu* for Group B. Distribution of "reduction in *Nasa Kandu*" for group A and group B isn't significantly different. (p –value = 0.278) Thus trial drug and control drug can be considered as equally effective in reducing *Nasa Kandu* at 5% level of significance. (Graph No. 3)
7. ***Shirahshoola:*** For group A, the median reduction in *Shirahshoola* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Shirahshoola* for Group A. For group B, the median reduction in *Shirahshoola* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. there is significant reduction in *Shirahshoola* for Group B. Distribution of "reduction in *Shirahshoola*" for group A and group B isn't significantly different. (p –value = 0.198) Thus trial drug and control drug can be considered as equally effective in reducing *Shirahshoola* at 5% level of significance. (Graph No. 3)
8. ***Bhutwa Bhutwa***: For group A, the median reduction in *Bhutwa Bhutwa* after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. we can say that there is significant reduction in *Bhutwa Bhutwa* for Group A. For group B, the median reduction in *Bhutwa Bhutwa* after treatment is

significant (P-value < 0.001) at 5% level of significance. i.e. we can say that there is significant reduction in *Bhutwa Bhutwa* for Group B. Distribution of "reduction in *Bhutwa Bhutwa*" for group A and group B isn't significantly different. (p –value = 0.298) Thus trial drug and control drug can be considered as equally effective in reducing *Bhutwa Bhutwa* at 5% level of significance.(Graph No. 3)

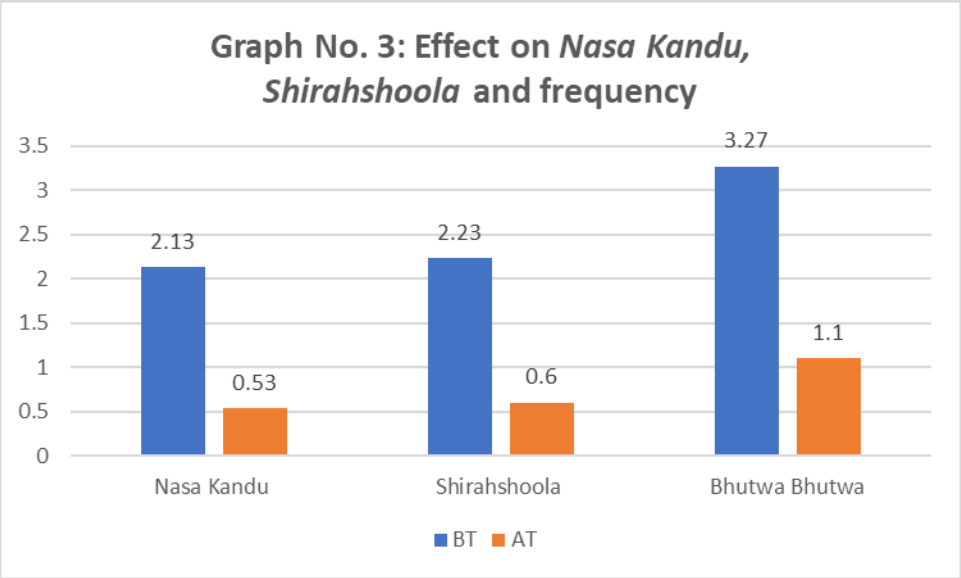
9. Overall Effect Of Therapy: Out of 30 patients of group A, 26 patients got relief while 4 didn't get relief and 23 patients out of 30 patients of group B got relief while 7 patients were not relieved. Chi-square test at 5% level of significance indicates that the relief rate group A and group B are not significantly different (P-value = 0.05). (Graph No. 4)



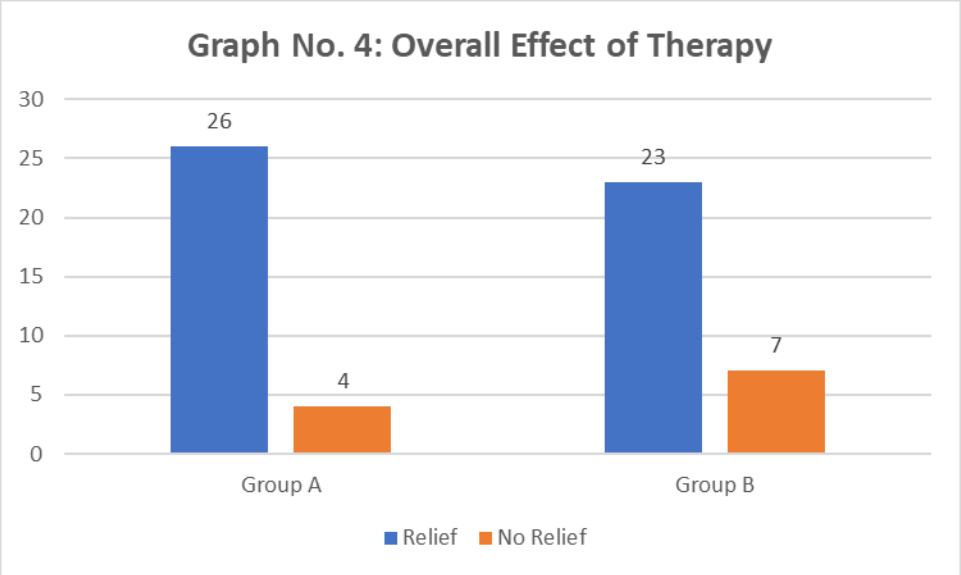
Graph 1: Effect of therapy on ESR and Absolute Eosinophil count



Graph2: Effect of therapy on *Kshavathuu, Nasasrava* and *Nasavarodha*



Graph 3: Effect of therapy on *Nasakadnu, Shirashoola,* and frequency



Graph 4: Overall effect of therapy

1.5 DISCUSSION

Among the various formulations prescribed for the treatment of *Kshavathu* by different Acharyas, *Kushthadi Taila* is mentioned in Sharangdhara Samhita. All its ingredients has *Vata Kapha Shamaka* effect. Moreover all the ingredients are known for its antibactrieal and anti-inflammatory activity.

Probable mode of action of *Kushthadi Taila Nasya*:

The medicine administered through *Nasya* easily spreads in Shira and gets absorbed. Acharya Vagbhata mentions Nasa as the gateway to *Shirah*, the drug administered through nostrils reaches *Shringataka*, A

Siramarma by *Nasa Srota* and spreads in the *Murdha* (brain), taking routes of *Netra, Shotra, Kantha* and stretches the morbid doshas in *Urdhwajatru* and expels them from *Uttamanga*.[v]

Due to the *Laghu* and *Vyavayi Guna, Kushthadi Taila* possesses a good spreading capacity through minute channels. *Avarana Bhedana* probably takes place due to *Tikshnata* & *Ushnata* of *Kushtadi Taila. Tikta Katu Rasa, Laghu Tikshna Guna, Ushna Veerya* and *Katu Vipaka* helps for *Srotoshodhakatwa* . By the above two properties, the *Nasya* drug removes the obstruction and facilitate the drainage of the discharge. *Balya, Brimhana, Rasayana* etc properties can increase general and local immunity. This immune-modulation will reduce the inflammatory process in nasal cavity and sinuses. Majority of ingredients possess anti-inflammatory activity, which also prevent the inflammatory process. Relieving of symptoms take place due to *Kapha-Vata Doshaghnata* of the *Taila*. Antibacterial, Antiviral etc properties of ingredients will arrest the secondary infection. *Taila* is the best drug for *Vata* dosha, here the chronicity of the disease indicates aggravation of *Vata* dosha, so oil preparation may be the best form for conditions like Allergic Rhinitis.[vi]

1.6 CONCLUSION

Description of Allergy & Allergic disorders can be seen in Brihattrayi under the heading of *Ritu Sandhi, Viruddha* & *Asatmya Ahara Vihara* & *Dushivisha*. All of them are the results of an *Asatmyaja Vyadhi*. On the basis of signs and symptomatology *Kshavathu* can be correlated with Allergic Rhinitis. This study has established that *Kushtadi Taila Nasya* showed better results in the clinical symptoms of *Kshavathu*- Allergic Rhinitis but still the results obtained in *Tila Taila Nasya* are also encouraging. In nutshell, *Kushtadi Taila Nasya* formulation is better choice of treatment in case of *Kshavathu* and *Tila Taila Nasya* formulation also can be adopted by considering the convenience of the patients.

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