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CLINICAL EVALUATION OF AN AYURVEDIC FORMULATION IN MANAGEMENT OF VATAJA PRATISHYAYA WITH SPECIAL REFERENCE TO ALLERGIC RHINITIS

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ABSTRACT

Ayurveda considers that the whole orchestra of treatment is governed by *'Chikitsachatushpada'* i.e. four basic pillars of treatment and also their required qualities lead to the fastest recovery of the disease. Among the four basic factors of treatment *Dravya* has been designated the second place quoting that it is a major tool in treating the diseases. In Ayurvedic classics there are a lot of single and compound drugs available which are mentioned in several contexts. Most of these are not retested according to the current research methodology. Unless the drug is tested through this methodology the drug will not get proper recognition in the scientific world. These drugs are used as single or in compound form where in their dosage and vehicle change the properties and thus widely applied in treatment. The route of administration of these drugs also vary; according to the disease e.g. locally, orally. So, that's why self formulated preparations *Pratishyaya Saarthak Nasya* with aqueous as a base and *Pratishyaya Saarthak Awleha* was selected. The results were very encouraging in 21 days and needs extensive study on large scale.

Keywords: *Pratishyaya Saarthak Nasya, Pratishyaya Saarthak Awleha, Vataj Pratishayaya.*

INTRODUCTION

The Sun, which diffuses dark to enlighten the sky, likewise the science of Ayurveda by virtue of its noble cause enlightens the obscuring dark of hidden and enigmatic subjects.[1]

While going through the Ayurvedic classics we observe a vivid description of the disease *Pratishyaya.* There is descriptive mention of this disease with regards to aetiopathogensis, classification, symptomatology, complication and management.[2] This reflects that ancient Ayurvedic galaxy was well versed with the concept of *Pratishyaya*. The importance of this disease is reflected by the fact that Aacharya Sushruta has mentioned a separate chapter for detail description of *Pratishyaya.*[3]

Aacharya Sushruta and Vagbhatta have mentioned five types of *Pratishyaya*.[4] These five different types of *Pratishyaya* reflect different type of rhinitis. After evaluating the symptomatology of different types of *Pratishyaya* it

seems prudent to accept that no individual type of *Pratishyaya* has got complete compatibility with symptoms of Allergic Rhinitis but *Vataja Pratishyaya*[5] seems to be in close proximity with Allergic origin of rhinitis[6]. A sincere endeavour has been made to annex and compile the compatible features of *Vataja Pratishyaya* and Allergic rhinitis subsequently.

Aims and objectives

1. Exploration of the Ayurvedic texts to define the equivalent terminology for Allergic Rhinitis.
2. To study the effectiveness of the drugs at both levels local and systemic.
3. To study and suggest an herbal formulation to combat nasal allergies with least side effect and prolonged efficacy.

DRUGS: -

For this present clinical study, the trial drug *Pratishyaya Saarthak Nasya* with aqueous as a base and *Pratishyaya Saarthak Awleha* was selected.

Though the formulation for the present clinical study are not mentioned in Ayurvedic texts, the fundamentals of Ayurvedic treatment i.e. *Dosha-Dushyavimarsha* etc. are deemed and respected in every sense.[7] Apart from this aspect an endeavor has been made to coalesce proven drugs having potency against pathogenesis of nasal allergic manifestation. Immunomodulators and proven mucous membrane decongestants drugs are also featuring in these formulations.

Ingridients of Pratishyaya Saarthak Nasya:-

Curcuma longa (*Haridra*)-2 parts, Albbizzia lebbeck (*Shirisha*)-2 parts, Clerodendrum serratum (*Bharangi*)-1part, Aegle marmelos (*Bilva* fruit pulp)-1 part, Solanum surattense (*Kantkaari*)-1part, Berberis aristata (*Daaru haridra*)-2 parts Tinospora cordifolia (*Guduchi*)-1 part, Glycyrrhiza glabra (*Yastimadhu*)-1part, Myristica fragrans (*Jaiphala*)-2 parts, Cannabis sativa (*Bhanga patra*)-2 parts, Sida cordifolia (*Balamoola*)-2 parts, Ephedra gerardiana (*Soma*)-2 parts and Cinnamomum camphora (*Karpoor*) 1/2gm./100ml.

METHOD OF PREPARATION: -

Decoction of coarse powder of the above said drugs except *karpoora* was prepared and ultra filtrated 3 times. Then *karpoora* was dissolved in this prepared decoction. A mixture of Methyl Paraban Sodium-2 gm. And Propyl Paraban Sodium was used as a preservative in these nasal drops. Prepared nasal drops were preserved in sterile small bottles with droppers.

Ingredients of *Pratishyaya Saarthak Awleha:*

Curcuma longa(*Haridra*)-2 parts, Albbizzia lebbeck (*Shirisha*)-2 parts, Trachyspermum ammi (*Yawaani*)-1part, Clerodendrum serratum (*Bharangi*)-1part, Pistacia integerrima (*Karkatshringi*)-1 part, Glycyrrhiza glabra (*Yastimadhu*)-1 part, Solanum surattense (*Kantkaari*)-1part, Aegle marmelos (*Bilva* fruit pulp)-4 part, Tinospora cordifolia (*Guduchi*)-1 part, Cassia fistula (Amaltas fruit pulp)-4 parts, Berberis aristata (*Daaruharidra*)-

1part, Adhatoda vasica (*Vasapatra*)-1 part, Vitex negundo (*Nirgundi*)-1 part, Guda-32 parts and Butyrum depuratu (*Ghrita*)-1/2 part. Zingiber officinale (*Shunthi*), Piper nigrum (Marich), Piper lonum (*Pippali*) - Each 20 Gms. per kg. of Awleha Honey-1/2 part and Abhraka bhasma-5gm. /kg. of awleha as *prakshepa* drugs.

Method of Preparation:

Coarse powder of *Haridra, Shirisha,Yawaani, Bharangi, Karktashringi, Yastimadhu, Kantkaari, Guduchi, Daaruharidra, Vasapatra and Nirgundi* was made. Decoction of the up stated drugs was made as per classical texts and filtered. Pulp material of *Bilva* fruit and *Amaltas* was extracted and made into a paste. The paste of *Bilva* fruit and *Amaltas* pulp was fried in *Ghrita* as per direction of *Awleha* preparation methods. *Purana Guda* was dissolved into the filtered decoction of drugs in adequate amount and with the help of low intensity heat, converted into a semisolid *Awleha* subsequently. Already fried pulp and the semisolid resultant *Awleha* were mixed in an adequate size container. The fine powder of *prekshepa* drugs were admixed in the *Awleha* after its cooling down. The *Awleha* was ultimately preserved in sterile containers.

Nasya:-

Pooravkarma

Before *Nasya karm, Abhyantar snehpan* is not indicated. Asked to patient to free their morning routine[8]. Asked to sit or lie down on *Nasya peeth* or bed[9]. Medicated oil is to be applied on above the neck. Then Medicated *Mirdu* Fomentation should be done with *Nadi Sweda*. Gentle massage on the neck, checks, frontal part of head etc[10]. Then *Nasya* is to be given.

Pradhan Karma-

Lie down on a *Nasyapeeth* with his head bent a little backward. Vessel containing the *Nasya* medicine is put into hot water so that it becomes little warm. After closing one nostril the *Nasya* medicine is put into the other nostril and vice versa[11], His feet, shoulders, hands and ears should be massaged well at that time[12]. Head should be not bended too much. Patient should lie for one minute after giving *Nasya* medicine at about 100 matra[13]. Then asked to patient to sit and expel out the *kapha* again and again. Then *Gandoosh* should be done with lukewarm salt water again & again. *Dhoompan* & *dhoom Nasya* should be given with *Ghrit bharjit Erandnal* or *Yava* and asked to expel the aggravated *Kapha*.

Paschat Karma-

Always lukewarm water should be used for every purpose. Light diet should be taken.

Rajodhoom, Shok etc. are Contra indicated. Patient should kept in a room where no direct air should reached to him[14]. He should be kept awaken on daytime.

Clinical Study

Clinical study has been carried out in 3 trial groups TG- I, TG- II and T.G.-III. Twenty six patients were registered i.e. ten each in TGI and TGIII and 6 patients in TG II from E.N.T., O.P.D., **R.G.G.P.G.A. Hospital** and all have completed the trial. Complete description regarding the details of each research case was recorded in a predesigned proforma.

Criteria of Selection of Patient:

i. Inclusion criteria:

Patients of more than 16 years and less than 60 years of different age groups having features described in ***VatajaPratishyaya (Nasavarodha, Nasa pihita, Tanusravapravartana, gala,talu Aushtha shosha, Shankhatoda And Swarabheda)*** and Allergic rhinitis were selected and randomly divided into 3 groups irrespective of sex, caste etc.

ii. Exclusion criteria:

a. Severe obstruction of nasal cavity i.e. severe DNS, Adhesions in the nasal cavity presenting hindrance for nasal drops instillation in TG I and TGIII.
b. Established diabetics (for TG II and TG III)

Method of Study:

After taking consent of patients, they were divided randomly into following groups.

Trial Group I:

In this group *Pratishyaya Saarthak* Shamak *Nasya* 3 drops in each nostril twice a day was taken and 10 patients were given this drug for local use.

Trial Group II:

In this group *Pratishyaya Saarthak Awleha* 10 gm. twice daily with milk was taken as trial drug and 6 patients were treated with this drug.

Trial Group III:

In this group *Pratishyaya Saarthak Shamak Nasya* 3 drops in each nostril twice a day locally and group *Pratishyaya Saarthak Awleha* 10 gm. twice daily with milk orally were given to 10 patients as a trial drugs combination.

DURATION OF TIME: - 21 days for all groups.

FOLLOW UP: - After completion of trial every week for 2 months

Criteria of Assessment of Results:

In Subjective criteria scoring system was adopted.

In Objective Hematological (Total eosinophilic count, Hb%, TLC, DLC, ESR) and Radiological parameter Xray's PNS Water's view with open mouth was adopted.

OBSERVATION AND RESULTS:-

Effect of *Pratishyaya Saarthak Nasya* in 10 Patients in Group I

The effect of ***Pratishyaya Saarthak Nasya*** was observed in the clinical features kept under criteria for assessment. In nasal itching there was 62.92 % of relief percentage which is statistically significant at the level of $p < 0.001$ ($t = 8.01$), excessive sneezing was relieved by 60 % which is statistically significant at the level of $p< 0.001$ ($t= 9.11$). Thin and watery discharge from nose was relieved by 67.85 % which is statistically significant ($p< 0.001$, $t =10.72$). Nasal obstruction was relieved by 63.63 % which is statistically significant ($p<0.001$, $t = 8.70$). Itching in palate and pharynx was relieved by 75.18 % which is statistically significant ($p< 0.05$, $t = 4.28$). Watering from eyes was relieved by 93.75% which is statistically significant ($p< 0.001$, $t= 6.77$). Mucosal oedema was relieved by 55 % which is statistically significant ($p < 0.001$, $t = 11.21$). Paleness/congestion was relieved by 77.27 % which is statistically significant ($p < 0.001$, $t = 8.01$). Post nasal drip was relieved

by 88.88 % which is statistically significant ($p < 0.05$, $t = 6.59$) and retracted tympanic membrane was relieved by 75 % which is statistically insignificant ($p > 0.05$, $t = 3$). No unwanted effects and ill-hazards were noticed after the treatment.

Effect of *Pratishyaya Saarthak Awleha* in 6 Patients Under Group II:

In this trial group after the treatment nasal itching was relieved by 46.29% which is statistically significant ($P < 0.05$, $t = 3.87$). Excessive sneezing was relieved by 35.62 % which is statistically insignificant ($p > 0.05$, $t = 2.04$). Thin and watery discharge from nose was relieved by 53.6 % which is statistically significant ($p < 0.05$, $t = 6.24$). Nasal obstruction was relieved by 30.55 % which is statistically significant ($p < 0.05$, $t = 3.15$). Itching in palate and pharynx was relieved by 75.18 % but statistically evaluation is not possible as 'S.D'. is O. Watering from eyes was relieved by 100 % which is statistically significant ($p < 0.001$, $t = 9.11$). Mucosal oedema was relieved by 45.35 % which is statistically significant ($p < 0.05$, $t = 4.93$). Congestion/ paleness of nasal mucosa was relieved by 50.21 % which is statistically significant ($p < 0.05$, $t = 6.58$). Post nasal drip was relieved by 100 % which is statistically significant ($p < 0.05$, $t=5.26$) and granulation on posterior pharyngeal wall was relieved by 42.85 % which is statistically insignificant ($p > 0.05$, $t = 3$).

Effect of Combined Therapy I.E. *Pratishyaya Saarthak Nasya* and *Pratishyaya Saarthak Awleha* in 10 Patients Under Group – III

In the present group, after the treatment nasal itching was relieved by 72.72 % which is statistically significant ($p < 0.001$, $t = 9.91$). Excessive sneezing was relieved by 63.15 % which is statistically significant ($p < 0.001$, $t = 9.02$). Thin and watery discharge from nose was relieved by 66.66 % which is statistically significant ($p < 0.001$, $t=7.29$). Nasal obstruction was relieved by 83.33 % which is statistically significant ($p < 0.001$, $t = 9.57$). Itching in palate and pharynx was relieved by 88.88 % which is statistically significant ($p < 0.05$, $t= 4.0$). Watering from eyes was relieved by 100 % which is statistically significant ($p<0.001$, $t = 7.62$). Nasal mucosal oedema was relieved by 68.75 % which is statistically significant ($p<0.05$, $t=4.76$). Paleness/congestion was relieved by 81.81 % which is statistically significant ($p < 0.001$, $t=9.02$). Discharge collection in middle meatus and retracted tympanic membrane was relieved by 100 % but the statistical analysis is not possible as 'S.D'. is 0. Post nasal drip was relieved by 100 % which is statistically insignificant ($p > 0.05$, $t = 3.02$) and granulation on posterior pharyngeal wall was relieved by 54.64 % which is statistically significant ($p < 0.05$, $t = 3.87$).

Inter group comparison over criteria of assessment:

- In the inter group comparison over criteria of assessment:
- In nasal itching statistically G- I and G- II comparison is significant and Group III gives highest % relief.
- In excessive sneezing there is no significant statistical difference between any of

the group but G- III provides highest % relief.

- In thin and watery discharge from nose there is statistically significant difference between G- I and G- II and also between G-II and G-III while G- I gives highest % relief.
- In nasal obstruction there is significant statistical difference between G-I and G-II, G-I and G-III, G-II and G-III while G-III gives highest % relief -In itching in palate and pharynx there is no significant statistically difference between any of the groups but G-III gives highest % relief.
- In watering from eyes there is no statistically significant difference between any of the groups but G-II and G- III gives highest % relief.
- In nasal mucosal oedema is no statistically significant difference between any of the groups but G-III gives highest % relief.
- In paleness/congestion of nasal mucosa there is statistically significant difference between G-II and G- III while G- III gives highest % relief.
- In post nasal drip there is no statistically significant difference between any of the groups but G- II and G- III gives highest % relief.
- In retracted tympanic membrane there is no statistically significant difference between any of the groups but G-III gives highest % relief.
- In granulation on posterior pharyngeal wall there is statistically significant difference between G-I and G- II and between G- I and G-III while G- III gives highest % relief.

Effect on Laboratory Parameters:

a) Total eosinophilic count (TEC):-

The reduction in count is significant statistically in G- III at the level of $p<0.05$ ($t = 2.35$). The percentage change in this group is 19.39 %

b)* Hb *% -

The result was significant statistically in G- I at the level of $p < 0.05$ ($t = 3.01$). The percentage change in this group is 0.70 %.

c) TLC -

The result is not statistically significant in any of the three groups. In G- I % change is 1.5 %, in G- II % change is 7.68 % and in G- III % change is 0.79 %

d) ESR -

The result is not significant statistically in any of the three groups. In G- I % change is 15.66 %, in G - II % change is 17.31 % and in G- III % change after treatment is 14.68 %.

Effect on Radiological Parameters (water's view-PNS) -

- None of the trial group observed changes in mucosal thickening after the treatment which was found in total of 6 patients in the study.
- TG- III observed sinus clearance especially of maxillary sinuses after the treatment. Sinus haziness which may be attributed to associated sinusitis was observed in 2 patients of this group before the treatment.

The overall effect of the formulations in all the three groups suggested that:-

- Complete cure was not found in any of the three groups
- *In Group I* - Two patients were markedly improved, seven were moderately improved, and one patient was slightly improved.
- *In Group II* - In this group of six patients, four were moderately improved and two were slightly improved.
- *In Group III* -In this combined group of formulations, five patients were markedly improved and five patients were moderately improved.

DISCUSSION

Pratishyaya is *Vata-Kapha* Predominant *Tridoshaja* disease in which *Kaphadi Dosha* shows movement towards Nasa *Pradesh* under the influence of *Vata-Dosha*.

Pratishyaya Saarthak Nasya having predominance of *Tikta Rasa* (41.66%), *LaghuGuna* (37.93%), *UshnaVirya* (69.23%), *KatuVipaka* (76.93%) and *Vata-Kaphahara* properties (76.65%) whereas ***Pratishyaya Saarthak Awleha*** having Predominance of *Tikta Rasa* (44%), *Laghu* and *Ruksha Guna* (34.4% each), *UshnaVirya* (69.22%), *Katuvipaka* (76.92%) and *Vata-Kaphahara* properties (68.95 %) which can counteract the *Samprapti* of the disease *Pratishyaya*. According to different classical textual references the drug also possesses properties like *Vishaghana, Shirovirechna, Shothahara, Kandughana, Kasahara* and *Balya* which further varify the action of the trial drugs over the disease *VatajPratishayaya*. Apart from these facts the constituents of the combinations also have potentially proven Pharmacological actions like antihistaminic, vasoconstriction, Bronchodilator and anti-inflammatory activities in modern pharmacological context which will counteract various sequence of events responsible in pathogenesis of Allergic rhinitis.

CONCLUSION

If we see the symptomatology of *vattaja pratishyaya* in Ayurveda we find the same symptomatology of acute rhinitis. In modern's acute rhinitis and allergic rhinitis we found the same symptoms in the beginning of disease. It is very difficult for modern people also to differentiate these two diseases in beginning. The difference is only that all the symptoms are of recurrent type or remains in whole of the year. So, *VatajPratishyaya* can be correlated to Allergic Rhinitis if it is of recurrent type. The combined group observed good results in para nasal sinuses clearance. This study gave satisfactory results to the researchers and again strengthens the belief in the fundamentals of Ayurveda. No side effect was observed during the trial.

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