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 seems to be in close proximity with allergic origin of rhinitis. A sincere endeavor 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. 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.

Ingredients of Pratishyaya Saarthak Nasya:-
Curcuma longa (Haridra)-2 parts, Albizzia lebbeck (Shirisha)-2 parts, Clerodendrum serratum (Bharangi)-1 part, Aegle marmelos (Bilva fruit pulp)-1 part, Solanum surattense (Kantkaari)-1 part, Berberis aristata (Daaru haridra)-2 parts, Tinospora cordifolia (Guduchi)-1 part, Glycyrrhiza glabra (Yastimadhu)-1 part, Myristica fragrans (Jaiphala)-2 parts, Cannabis sativa (Bhangat patra)-2 parts, Sida cordifolia (Balamoola)-2 parts, Ephedra gerardiana (Soma)-2 parts and Cinnamomum camphora (Karpoor) 1/2 gm./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 dropers.

Ingredients of Pratishyaya Saarthak Awleha:
Curcuma longa (Haridra)-2 parts, Albizzia lebbeck (Shirisha)-2 parts, Trachyspermum ammi (Yawaani)-1 part, Clerodendrum serratum (Bharangi)-1 part, Pistacia integerrima (Karkatshringi)-1 part, Glycyrrhiza glabra (Yastimadhu)-1 part, Solanum surattense (Kantkaari)-1 part, Aegle marmelos (Bilva fruit pulp)-4 part, Tinospora cordifolia (Guduchi)-1 part, Cassia fistula (Amaltas fruit pulp)-4 parts, Berberis aristata (Daaru haridra)-
Ipart, 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 Abhra 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 bed9. Medicated oil is to be applied on above the neck. Then Medicated Mirda Fomentation should be done with Nadi Sweda. Gentle massage on the neck, checks, frontal part of head etc. 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 versa11. His feet, shoulders, hands and ears should be massaged well at that time. Head should be not bended too much. Patient should lie for one minute after giving Nasya medicine at about 100 matra13. 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 him14. 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 Vataja Pratishyaya (Nasavrodha, 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 TG III.
- 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 =10.72). 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).

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 < 0.001, t=4.76). Watering from eyes was relieved by 100 % which is statistically significant (p<0.001, t=4.0). 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 Auleha** 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, Kundughana, Kasahara and Balya which further varify the action of the trial drugs over the disease VatajPratishyaya. 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.

**REFERENCES**


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