CLINICAL STUDY TO EVALUATE THE EFFECT OF ORAL ADMINISTRATION OF TULASI ARKA ON PRATISHYAYA (RHINITIS) IN CHILDREN

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Abstract- ***Pratishyaya*** **is one of the most common disorders of children known for its recurrence and chronicity. It could lead to complications such as** ***Kasa, Shwasa,Kshaya*** **if not managed in time. The recurrence of this disease can be attributed to lower level of immunity in children due to** ***Asampurna Bala. Tulasi*** **had been selected in the present study on the basis of its indication in** ***Pratishyaya*** **as mentioned** ***Astanga Hridaya*** **in** ***Sursadi Gana*****. Considering the aspect of palatability and acceptability of the medicine in children, the medicine was planned to be administered orally in** ***Arka*** **form.** ***Tulasi*** **is having** ***Katu-Tikta Rasa, Katu Vipaka*****,** ***Ushna Virya*** **and** ***Laghu-Ruksha Guna*****. Hence pacifies the** ***Vata*** **and** ***Kaphadosha*** **which are the predominant** ***dosha*** **in** ***Pratishyaya*****. The oral administration of** ***Tulasi Arka*** **may causes** ***Vilayana*** **of** ***Kapha*** **due to the** ***Vyavayi and Vikasi Guna*** **of** ***Arka.***

To Evaluate the Effect of Oral Administration of ***Tulasi Arka*** **on** ***Pratishyaya*** **(Rhinitis) in Children (2-6 years). 37 children between the age group of two to six years were taken for the study.** ***Tulasi Arka*** **was administered orally 3 ml (2-4 years), 5 ml (4-6 years) thrice a day for 7 days. Response of Drug compound were assessed on 0th, 4th and 8th day. Follow-up assessment was done on 14th day. Statistically significant results were seen in subjective parameters such as** ***Nasa srava, Kshavathu, Ghranavarodha, Nasagrapaaka, Aruchi.*** **During follow up period even though few children had some symptoms, but intensity was reduced compared to that of before treatment.** ***Tulasi Arka*** **given orally for continuous seven days found to beeffective on** ***Pratishyaya*** **and its recurrence.**

Index Terms- ***Tulasi Arka; Pratishyaya;*** **Children; Rhinitis.**

I. INTRODUCTION

Good health is considered to be the root of the objects of human life. Healthy transformation of a child into an adult is governed by the factors such as nutritious food, age, genetic makeup and non-affliction by diseases[1]. Rhinitis is a very common contagious disease seen in all over the world causing much distress and discomfort to the people. Rhinitis affects people of all the ages. The incidence of the rhinitis varies by age with highest prevalence in children below 5 years. Around 20- 40% of children suffer from rhinitis[2]. Rhinitis is one of the most common chronic conditions for which medical care is sought. The constant nasal discharge, foul smell of the nose and recurrent occurrence of the condition drags the individual far from the normal life.

Pratishyaya is one of the Urdvajatrugatavikara, Vata and Kapha are said to be the predominant doshas[3]. The symptom of Rhinitis shows resemblance with the lakshanas of Pratishyaya explained in Ayurveda classics. Pratishyaya is one of the diseases in which the inflammation of mucous membrane of the nose is observed. it is characterised by Nasasrava, Nasavarodha, Kshavathu, Shirashoola, Swasavarodha, Gandhaajnana etc. If the disease is not treated properly or neglected, it may lead to complication like Kasa and Kshaya[4].

Tulasi has been selected in the present study on the basis of its indication in Pratishyaya as mentioned Astanga Hridaya in Sursadi gana[5]. While administering medicines to children, palatability is very important. The problem arises when we prescribe the ayurvedic formulations such as Swarasa, Choorna, Vati, Kashaya etc. which are bitter in taste and the child fails to take the medicine. Considering the aspect of palatability and acceptability of the medicine in children, the medicine is planned to be administered orally in Arka form. Tulasi is having Katu-Tikta Rasa, Katu Vipaka, Ushna Virya and Laghu-Ruksha Guna. Hence pacifies the Vata and Kaphadosha which are the predominant dosha in Pratishyaya. The oral administration of Tulasi Arka may causes Vilayana of Kapha due to the Vyavayi and Vikasi Guna of Arka. Therefore, the present research work has been undertaken entitled *"Clinical Study to Evaluate the Effect of Oral Administration of Tulasi Arka on Pratishyaya* (Rhinitis) *in Children"*

II. REVIEW OF LITERATURE

Rhinitis is the inflammation of the nasal mucosa membrane. Rhinitis is the irritation and inflammation of some internal areas of the nose. The inflammation results in the generation of excessive amount of mucous, commonly producing the runny nose as well as nasal congestion and post nasal drip. Rhinitis is caused by chronic and acute inflammation of mucous membrane of the nose due to viruses, bacteria, allergens. Rhinitis describes a group of symptoms including rhinorrhea, itching and sneezing that are caused by irritation and congestion in the nose.

Pratishyaya means a condition with a continuous flow[6]. The condition in which Kapha, Pitta and Rakta move along with Vata in the same direction is termed as Pratishyaya. Acharya Charaka has explained Pratishyaya in the context of Rajayakshma[7]. He defined that Pratishyaya is a severe and general body debilitating condition, which manifests due to the migration of the vitiated Doshas Kapha, Pitta and Rakta from the root of the Nasa Pradesha and gets lodged in Shira Pradesha. Raja, dhuli,dhuma,atisheeta jala sevana etc are the nidanas produce vitiation of all the three Doshas. Prana (Vata), Bhrajaka, Alochaka (Pitta) and Tarpaka (Kapha) are chiefly involved; all of them or along with vitiated Rakta accumulate in the region of head and manifests the disease[8]. .Kashyapa has specifically mentioned two factors i.e. Agnimandya and Ahita Aharasevana as essential pre-requisites in the pathogenesis of Pratishyaya.

Tulasi is Katu-Tikta Rasa, Katu Vipaka, Ushna Virya and having Laghu- Ruksha Guna, it is Kaphaghna and Vataghna .Tulasi is included under Tulsyadi Varga, Sursadi Gana ,Swasghna Gana, Puspavarga[9]and Karviradi Varga. It is also Pratishyayaghna. Vata and Kapha dosha are pacified by the Usna Veerya of Tulasi. Tulasi is having Deepan,Pachana,Sugandhi and Ruchkar property. Tulasi has been selected in the present study on the basis of its indication in Pratishyaya as mentioned Astanga Hridaya in Sursadi Gana.

Arka (hydro-distillation) is a traditional method for extraction of bioactive compound, mainly essential oils from plants and water with the help of Arka yantra. Arka is first mentioned in Gad Nigraha by Acharya Shodhal in 12th centuary[10]. it is widely described by Ravana in his book Arka Prakash[11]. Arka can be preserved for longer time than other like Swarasa Kwatha etc. Arka are Laghupaki, Vyavayi and Vikasi and thus assimilates quickly in the body. Arka acquires highest position in obtaining the potentially active volatile oils as the condensation take place during the process of distillation. Arka is a suspension of the distillate in water having slight turbidity and colour according to the nature of the drug used and smell of the predominant drug.

Objectives

To evaluate effect of oral administration of *Tulasi Arka* on *Pratishyaya* (rhinitis) in children.

Methodology

CTRI and Ethical clearance was obtained from the institutional ethics committee. Informed consent was obtained from the parents before registering the child for the trial.

III. MATERIAL AND METHODS

Source and Authentication of Drug: Required raw drug Tulsi was collected from Herbal Garden of Ayurveda College and Hospital, and authentication done at Dravya Guna Department of Ayurveda College and Hospital.

Source and Method of Collection of Data

Subjects with *Pratishyaya* fulfilling the inclusion and diagnostic criteria attending the Kaumarbhritya OPD in Ayurveda Hospital, irrespective of gender, religion and socio-economic status.

Diagnostic Criteria:

On the basis of symptoms of *Pratishyaya - Nasa srava* (Nasal discharge), *Kshvathu* (Sneezing) Associated with or without symptoms like- *Nasagrapaka* (Redness of nose), *Nasapaka* (Nasal congestion), *Kasa* (Cough), *Aruchi* (Anorexia), *Swarabheda* (Hoarseness of voice), *Shirashoola* (Headache), *Netra srava* (Watering of eyes)

Inclusion Criteria:

Children between the age group of 2-6 years. Children with *Pratishyaya* of recent onset within one week. Children irrespective of gender, religion and socio-economic status fulfilling the diagnostic criteria. Children whose parents willing to participate them in the study by giving informed parent consent.

Exclusion Criteria:

Congenital anomalies related to respiratory system. Lower respiratory tract infection. *Jwara* (>100^{o}F), *Dushtapratishyaya, Raktapratishyaya* and *Sannipatajapratishyaya.* Chronic rhinitis, Sinusitis, Asthma, Infectious diseases like T.B. and other systemic disorders which interfere during the course of treatment.

Grouping: Single Group Study with 32 samples

Plan of Study: Trial Drug T*ulasi Arka was administered orally in the dose of 3ml 3 times a day (*2-4 years) and 5ml 3 times a day (4-6 years) for the duration of 7 days. Response of drug compound assessed on 0, 4th & 8th day. Follow up assessment done on 14th day.

Assessment Criteria: Effect of the treatment assessed with the help of detailed proforma prepared for the purpose by grading the parameters mentioned below.

Subjective Parameter

Nasa srava (Nasal discharge), *Kshavathu* (Sneezing), *Ghranovarodha* (Nasal congestion), *Kasa* (Cough), *Jwara* (Fever), *Swarbheda* (Hoarseness of voice), *Ashrusrava* (Watering of eyes).

IV. OBSERVATIONS & RESULTS

Total 37 patients registered, fulfilling the diagnostic criteria were observed for prevalence according to Age, Gender, Religion, Socio-economic status, Diet, Diet habit, *Koshtha*, *Agni*, Sleepdisturbance, Recurrence, *Nasa srava, Kshavathu, Ghranavarodha, Kasa, Shirovedana, Aruchi.* 32 patients completed the study and there were 5 drop outs.

Among 37 children 54.05% were of 2-4 years, 45.95% were of 4-6 years. This is probably because of the increased incidence of upper respiratory tract infections during this period of age. The period of a child's development between the ages of 3 and 8 years is often described as catarrhal stage. The word catarrhal is derived from the Greek and means to "flow down". Among 37 Children, 62.16% were having sleep disturbances. ***Aaharaj Nidana*****:** 45.95% had freezed items/milk shakes, 24.32% had chocolates/bakery items, 21.62% had fruits and 8.11% had street food. ***Viharaj Nidana*****:** 51.35% had climate, 32.43% had Travelling History/Contact with Affected Person and 16.22% had allergens. **Recurrence:** 78.38% had Recurrence. These subjects were suffering from recurrent episodes of upper respiratory infections with a recurrence of at least six episodes in a year. This shows impact of lower levels of immunity leading to recurrence of *Pratishyaya*. If any person in the family/school gets infection, children may catch infection through droplet.54.05% did not have anyone in family with similar complaints whereas 45.95% had similar complaints.

On applying statistical test following results were obtained

Table-Results of Friedman's test on *Nasa srava*

Parameters	N	Mean Rank	X^2	P-Value	Remarks
Nasa srava BT	32	3.95	89.642	.005	S
Nasa srava DT	32	2.95			
Nasa srava AT	32	1.81			
Nasa srava FU	32	1.28			

Friedman test was applied to assess the effect of *Tulasi Arka on Nasa srava* (Running nose*). Nasa srava,* there was reduction seen in the mean rank (MR) from 3.95 (BT) to 1.28 (FU) with a X^2 value=89.642, p-value = 0.005. This shows that there is statistically significant improvement on the effect of *Tulasi Arka* on *Nasa srava* (Running nose). As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change.

Table- Results of Wilcoxon's sign rank test on *Nasa srava*

Parameters	Negative Ranks			Positive Ranks			Ties	Total	Z-Value	P-Value	Remarks
	N	MR	SR	N	MR	SR					
Nasa srava BT-DT	29	15.00	435.00	0	.00	.00	3	32	-5.166	.001	S
Nasa srava DT-AT	26	13.50	351.00	0	.00	.00	6	32	-4.604	.001	S
Nasa srava AT-FU	14	7.50	105.00	0	.00	.00	18	32	-3.742	.001	S
Nasa srava BT-AT	32	16.50	528.00	0	.00	.00	0	32	-5.013	.001	S

During BT-DT, it was found that 29 subjects had reduction in symptoms, whereas there was no further improvement in 3 subject which is evident with tie value at 3. This was statistically significant at z value= -5.166, p-value = 0.001. From DT-AT, 26 subjects had decrease in their symptoms, whereas there was no further improvement in 6 subject which is evident with tie value at 6. This was statistically significant at z value= -4.604,

p-value = 0.001. From AT-FU, it was found that 14 subjects had decrease in their symptoms, whereas there was no further improvement in 18 subject which is evident with tie value at 18. This was statistically significant at z value = -3.742, p-value =.001. By the end of the treatment (BT-AT), it was found that 32 subjects had reduction in symptoms, which was statistically significant with z value= -5.013, p-value = 0.001.

Table-Results of Friedman's test on *Kshvathu*					
Parameters	**N**	**Mean Rank**	**X^2**	**P-Value**	**Remarks**
Kshvathu BT	32	3.97	88.745	.005	S
Kshvathu DT	32	2.86			
Kshvathu AT	32	1.67			
Kshvathu FU	32	1.50			

Friedman test was applied to assess the effect of *Tulasi Arka on Kshvathu* (Sneezing*)*.

There was reduction seen in the mean rank (MR) from 3.97 (BT) to 1.50 (FU) with a X^2 value = 88.745, p-value = 0.005. This shows that there is statistically significant improvement on the effect of *Tulasi Arka* on *Kshvathu* (Sneezing*)*. As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change.

Table - Results of Wilcoxon's sign rank test on *Kshavathu*											
Parameters	**Negative Ranks**			**Positive Ranks**			**Ties**	**Total**	**Z-Value**	**P-Value**	**Remarks**
	N	**MR**	**SR**	**N**	**MR**	**SR**					
Kshavathu BT-DT	30	15.50	465.00	0	.00	.00	2	32	-5.203	.001	S
Kshavathu DT-AT	25	13.00	325.00	0	.00	.00	7	32	-4.838	.001	S
Kshavathu AT-FU	4	2.50	10.00	0	.00	.00	28	32	-2.000	.046	NS
Kshavathu BT-AT	32	16.50	528.00	0	.00	.00	0	32	-5.246	.001	S

During BT-DT, 30 subjects had reduction in symptoms, whereas there was no further improvement in 2 subject which is evident with tie value at 2. This was statistically significant at z value= -5.203, p-value = 0.001. From DT-AT, it was found that 25 subjects had decrease in their symptoms, whereas there was no further improvement in 7 subject which is evident with tie value at 7. This was statistically significant at z value= -4.838, p-value = 0.001. From AT-FU, it was found that 4 subjects had decrease in their symptoms, whereas there was no further improvement in 28 subject which is evident with tie value at 28. This was statistically significant at z value = -2.000, p-value =.046. By the end of the treatment (BT-AT), it was found that 32 subjects had reduction in symptoms, which was statistically significant with z value= -5.246, p-value = 0.001.

Similarly, the results were obtained for other parameters like *Ghranovarodha* (Nasal congestion), *Kasa* (Cough), *Jwara* (Fever), *Swarbheda* (Hoarseness of voice) & *Ashrusrava* (Watering of eyes) and statically significant values were observed.

V. DISCUSSION

Pratishyaya has been described in classics as a prodromal symptom, as an independent disease, a sequel and a complication. The major aspect of disease *Pratishyaya* is the chief cardinal symptom is continuous nasal discharge. *Vata Pradhana* disease. Recurrent and chronic in nature. Recurrence of the disease *Pratishyaya* mainly occurs due to *Doshas*, which are situated in the body in latent state and when favorable condition (aggravating factors) occurs then disease again and again reappear. As the children are with low immunity (which play the vital role in the prevention of a disease) and sukumara (Delicate) the disease may reoccurs frequently.

Bala, Agni, Ojas as well as improperly nourished *Dhatus* clearly highlight the decreased immune status of the children. When factors like genetic susceptibility, familial disposition, environmental conditions, specific foods and food habits etc. are present then it puts the child to an immune- compromised state and child become susceptible to repeated attacks from various pathogens and gives rise to diseases like *Pratishyaya* and its recurrence. In *Pratishyaya*, irrespective of the types, all the *Dosha* plays active role. If *Pratishyaya* is left untreated then it leads to immunodeficiency in child and can cause several diseases like *Tundikeri, Kasa, Shwasa and Kshaya*.

Nidanas of *Pratishyaya* are broadly classified under two headings i.e. *Sadyojanaka* and *Kalantarajanaka*. Majority of factor described under the heading of *Nidanas* act as triggering factors, which are responsible for an acute response. Most of these are applicable to pediatric patients. A good number of modern clinical conditions go hand in hand with the symptomology of disease *Pratishyaya*. But looking through the five aspects of a disease viz *Nidana*, *Purvarupa*, *Rupa*, *Upashaya*and *Samprapti* only few conditions fit with the disease *Pratishyaya*. Rhinitis is one of them. Rhinitis is well known for its recurrence and the most common infectious diseases among children who may have six to ten episodes of a common cold per year (and up to 12 common colds a year for school children). The pathogenesis of Rhinitis mainly points toward the inflammatory process of upper airways in response to infection by causative agents (bacteria's, viruses), which leads to the obstruction of upper airways and resultant hyper secretion of mucous leading to nasal discharge.

According to classics the condition described under the obstruction in the channel of *Udana Vayu* by Vitiated *Prana Vayu*, *Kapha* and *Pitta* leading to stage of *Marutapurna Siras* reveals the aspect of *Pratishyaya*. The symptoms of Rhinitis such as nasal discharge, nasal obstruction, fever, headache, dyspnoea, anorexia etc. are similar to the *Lakshanas* of *Pratishyaya* such as as *Nasasrava*, *Kshavathu*, *Ghranoparodha*, *Jwara*, *Shirovedana*, *Swasakastata*, *Aruchi* etc. Hence the disease entity Rhinitis can be compared to the *Vyadhi Pratishyaya*.

Tulasi has *Katu Rasa* and *Usna, Tikshna Guna* it liquifies *Kapha. Katu Rasa* has property of *Pachana* and *Shoshan* of *Kapha*. it was observed that children got relief in *Lakshana* of *Nasasrava*. *Ocimum sanctum* having antibacterial, anti-inflammatory and allergenic property due to the presence of components alpha-farnesene and eugenol which relives *Nasasrava* by its anti-inflammatory effect on *Pratishyaya*. *Kshvathu* occurs due to *Chala Guna* of *Vata* and *Sheet Guna* of *Kapha Dosha*. As drug *Tulasi* has *Vataghana* property. Symptoms *Kshvathu* was decreased by *Usna Virya* of drug. *Tulasi* which causes *Vatashamana* (bh.ni) as drug *Tulasi* being *Kapha Vataghana*. *Ocimum sanctum* gives relief in congestion due to the presence of phytoconstituents like camphene, cineole and eugenol and its essential oils.

Overall Result

Oral administration of *Tulasi Arka* has shown statistically significant results in reducing cardinal features of *Pratishyaya* such as *Nasasrava, Kshavathu, Ghranavarodha, Ghranapaka.* All the symptoms were seen to reduce effectively within the first week in mostof the children. But whoever persisted with those symptoms were completely reduced after intervention. During follow up, mild persist symptoms got reduced but symptoms intensity was reduced compared to that of before intervention.

Discussion on *Arka*:

Arka can be preserved for longer duration, easy to administer and one who has hesitated to take medicine like *Kwath, Vati* etc. *Arka* has good palatability. *Arka* is prepared by the combination of *Jala* and with the help of *Agni*; hence *Arka* are *Laghupaki, Vyavayi* and *Vikasi Guna* thus assimilates quickly in the body. *Arka Kalpana* acquires highest position in abstaining the potentially active volatile principle as the condensation takes place during the process of Distillation.

VI. CONCLUSION

The present study titled "Clinical study to evaluate the Effect of oral administration of *Tulasi Arka* on *Pratishyaya* (Rhinitis) in children" concludes that,

The *Pratyatma Linga* of *Pratishyaya* is *Nasa Srava*, *Kshvathu* in children. According to symptomology along with long term complication, the disease entity Rhinitis/Common cold goes almost hand in hand with the *Pratishyaya*. All the three *Doshas* played active role in the occurence of disease *Pratishyaya*, but dominance of *Vataja Lakshanas* was observed in the patients. Statistically significant improvement in all the cardinal symptoms such as *Nasa Srava, Ghranavarodha, Kshavathu, Gharanpaka, Gharanapitika, Aruchi, Kasa* and *Jwara* was seen at $p<0.001$ in all children. Statistically significant reduction seen in *Nasasrava, Kshvathu, Gharanavrodha, Gharanapka* in follow up period. During follow up study, patients showed reduction in all symptoms. *Tulasi Arka* helped in reducing symptoms of acute *Pratishyaya* by its properties like Anti-allergic, anti-inflammatory, anti-histaminic and immune-modulatory which proves its

action.

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