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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *HARIDRAKHANDA* IN THE MANAGEMENT OF ALLERGIC RHINITIS IN PAEDIATRIC AGE GROUP

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ABSTRACT

Increased levels of environmental pollution, especially air pollution due to industrialization, increased vehicles, re-suspended dust on roads due to vehicle movement and construction activities, open waste burning, combustion of various fuels and also seasonal influences from dust storms, forest fires, open field fires during harvest season, sea salt near coastal areas and decreased immunity due to factors like lifestyle modifications, food habits and climatic variations leads to innumerable health hazards. Among those one such condition is *Vataja Pratishyaya* with a similar clinical entity with that of allergic rhinitis. Allergy is a condition in which the immune system reacts abnormally to a foreign substance. 'Allergic rhinitis' is characterized by inflammatory changes in the nasal mucosa caused by exposure to inhaled allergens. This is highly prevalent and common disease to the extent that 30% of the total diseases and around 20-30% of the Indian population suffers from the same. Allergic rhinitis is associated with number of co morbid conditions such as asthma, sinusitis, otitis media, atopic dermatitis and nasal polyps. The condition shows immediate hypersensitivity reaction of Nasal mucosa to allergens like pollen, dust, strong perfumes, smoke and cold climate. *Pratishyaya* is well known for its re-occurrence and chronicity. In this study *Haridrakhanda* was given internally for the management of Allergic rhinitis in children of 6 to 14 years of age group. Milk was given as *anupana* by considering the properties of drugs in the formulation and palatability in children. Subjective and objective parameters [according to 'Total Nasal symptom score', North West ENT and Allergy] were assessed and the results obtained were statistically significant.

INTRODUCTION

'Allergy' is an individual's sensitivity towards harmless foreign substances in the environment. It is a condition in which the immune system reacts abnormally to a foreign substance. 'Allergy' is an age old concept. In Ayurveda, it can be considered as *Asatmya/Ama/Anurja* i.e., substances that are non-conducive to the body, metabolic waste and reduced immunity respectively. These are the factors responsible for development of this particular disease.

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The pathogenesis described in modern science, also centers around IgE mediated immune response[1]. 'Allergic rhinitis' is characterized by inflammatory changes in the nasal mucosa caused by exposure to inhaled allergens. Two clinical types have been recognized[2].

Seasonal: Symptoms appear in or around a particular season when the pollens of particular plant, to which the patient is sensitive, are present in the air.

Perennial: Symptoms are present throughout the year.

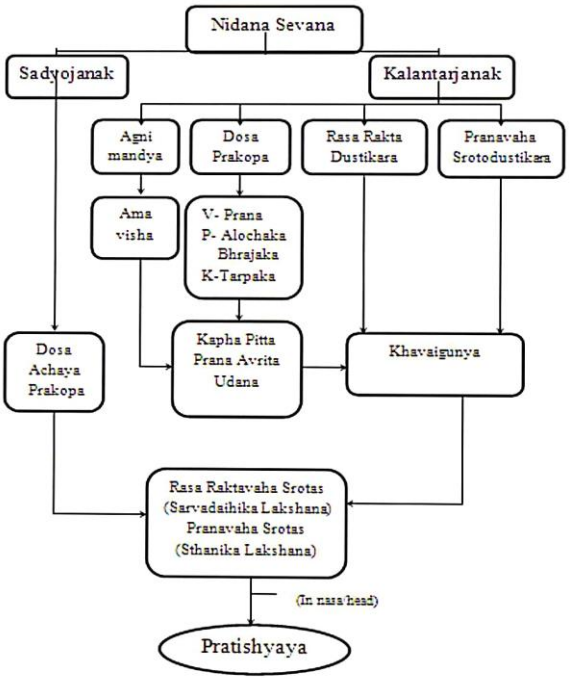
It causes significant disability and is often a poorly managed and a major chronic upper respiratory disease and has impact on quality of life, work and economy. It is quite difficult to treat and acts as forerunner of diseases like asthma, sinusitis, nasal polyposis[3] etc. According to AAAAI (American Academy of Allergy, Asthma and Immunology), allergic

rhinitis affects somewhere between 10 and 30% of the population worldwide. In India 20-30% of population suffers from this disease.[4] Allergic Rhinitis represents a common and serious health problem in pediatric age group. The chronic nature of disease and its association with other co morbid conditions like asthma; eczema etc. has shown significant negative impact on quality of life, school performance and cognitive functioning in children. The treatment modalities mentioned in modern science include avoidance of allergens, administration of antihistamines, nasal decongestants, corticosteroids etc. Though they relieve symptoms, their continuous use may lead to certain side effects like drowsiness, mucosal atrophy; rebound congestion and prolonged use of corticosteroids suppress the immune system. In spite of these treatments, recurrence is quite common putting the patients to a lot of agony. Effective management of Allergic Rhinitis should aim at minimizing the symptoms, optimizing the quality of life and reducing the risk of developing co-morbidities.

In Ayurveda, *Vataja Pratishyaya* can be co-related to Allergic Rhinitis. *Pratishyaya* is a *Vata-Kapha pradhana vyadhi*. *Samanya nidana*[5] of *Pratishyaya* include *Aharaja nidana* like *Ajeerna* (indigestion), *Ati sheetambu pana* (drinking cold water in excess), *Vishamashana* (improper and untimely food habits), *Ati jalapana* (excessive drinking of water) after meals and *Viharaja nidana* like *Vegasandharana* (controlling the natural urges), *Rajodhumra sevana* (exposure to dust and other suspended particles), *Shiro abhitapa* (injury), *Divaswapna* (excessive day sleep) etc which are also accepted as causative factors of Rhinitis by contemporary science. *Rituvaishamya* (seasonal variations) also plays a major role as causative factor.

Samprapti of *Pratishyaya* is as follows[6]:

Figure 1- *Samprapti* of *Pratishyaya*



Vatja pratishyaya follows the same *Nidana* and *Samprapti* as explained in *Pratishyaya samanya nidana* and *Samprapti*. *Lakshna* of *Vataja pratishyaya* are:

Table 1: *Lakshana* of *Vataja Pratishyaya*

Lakshanas	**Charaka[7]**	**Sushruta[8]**	**Vagbhata[9]**
Tanu Nasa Srava	+	+	-
Nasaavarodha	+	+	+
Nasatoda	+	-	-
Nasavedana	+	-	-
Pihitanasa	-	+	-
Chiratpaki	-	-	+
Shirashoola	+	-	+
Shankha Pradesha Vedana	-	+	+
Kshawathu	+	-	+
Oshtashosha	-	+	-
Mukhashosha	-	-	+
Gala – talu Shosha	-	+	-
Swaropaghata	+	+	-
Swarabheda	-	-	+

Ayurveda line of management includes *Nidana parivarjana, Shodhana* and *Shamanoushada* that contain drugs which possess the properties of antihistaminic and immunomodulating actions serve the mainstay of treatment. *Vishesha chikitsa* of *Vataja Pratishyaya* is explained by Sushruta[10] and Vagbhata[11] in which *Sarpi pana* along with *Panchalavana* or *Patupanchaka*, drugs belonging to *Vidaryadi gana* and *Nasya* are said to be the mainstay of treatment in *Vataja pratishyaya*. In this study *Haridrakhanda*[12] has been taken up in the management of Allergic Rhinitis.

AIMS AND OBJECTIVES

1) To study the disease *Vataja Pratishyaya* and Allergic rhinitis from both Ayurvedic and modern perspective.

2) To evaluate the efficacy of *Haridrakhanda* internally in the management of Allergic rhinitis in children of age group 6 to 14 years.

MATERIALS AND METHODS

Source of data/sample: Patients registered from the OPD and IPD of Government Ayurveda Hospital Bengaluru

Sample size: 30 patients

Sampling technique: Simple Random Sampling method.

Inclusion criteria

1. Cases with classical features of Allergic Rhinitis namely watery nasal discharge, nasal obstruction, sneezing, itching in nose, pharynx and eyes.

2. Subjects within the age group of 6 to 14 years.

3. Subjects were selected irrespective of gender, religion, and socio-economic status.

Exclusion criteria: Children suffering from acute or chronic illness like asthma and other systemic illness.

Investigation

- Absolute Eosinophil Count (AEC)
- Erythrocyte Sedimentation Rate (ESR)

Duration

Duration of treatment was 15 days.

Clinical findings, symptoms before, during and after treatment (two follow ups) were observed and the same were recorded in the specially designed pro-forma.

Assessment Parameters[13]

Subjective Parameters

According to 'Total Nasal symptom score' (North West ENT and Allergy)

Kshavathu (sneezing), *Nasasrava* (nasal discharge), *Nasa Avarodha* (nasal block), *Kandu* (itching in nose, eyes and pharynx)

0 - None

1 - Mild (symptom clearly present but easily tolerated)

2 - Moderate (symptom bothersome but tolerable)

3 - Severe (symptom difficult to tolerate- interferes with activities)

Objective Parameters

AEC (Absolute Eosinophil count)

0 Normal count (40 – 440 cells/cmm)

1 Mild elevation in the count (441 – 600 cells/cmm)

2 Moderate elevation in the count (601 – 800 cells/cmm)

3 Severe elevation in the count (>800)

ESR (Westergren method)

0 Normal count (0-15 (males) & 0-20 (females) mm/hr)

1 16-30 (males) & 21-30 (females) mm/hr

2 31-40mm/hr

3 >40mm/hr

Assessment of Results

Criteria for Assessment of Response

Results obtained after clinical trial were classified as good response, moderate response, mild response and poor response based on the following criteria.

Good response – Above 75% relief in over all features.

Moderate response – Above 50% and below 75% relief in overall symptoms.

Mild relief – Above 25% and below 50% relief in overall symptoms.

Poor response – Below 25% relief in overall symptoms.

Table 2: Overall effect of treatment

Overall Effect Of Treatment		
Grading	**Relief in Percentage**	**Relief in Patients**
No Improvement	0%	3
Mild Improvement	1-30 %	12
Moderate Improvement	31 – 60%	15
Marked Improvement	61 – 99 %	0
Complete Remission	100%	0

Table 3: Showing effect on Sneezing

Symptom	Measures				%	S.D (+.)	S.E (+.)	t value	p value
	BT								
Sneezing	1.60	16th Day AT	0.93	0.67	41.67	0.547	0.102	4.36	<0.05
		FU1	1.17	0.43	27.08	0.568	0.106	3.07	<0.05
		FU2	1.17	0.43	27.08	0.568	0.106	2.90	<0.05

Table 4: Showing effect of treatment on Nasal Discharge

Symptom	Measures				%	S.D (+-)	S.E (+-)	t value	p value
	BT								
Nasal Discharge	1.60	16th Day AT	0.93	0.60	39.13	0.563	0.105	4.02	<0.05
		FU1	1.07	0.47	30.43	0.571	0.106	3.13	<0.05
		FU2	1.13	0.40	26.09	0.498	0.093	2.71	<0.05

Table 5: Showing the effect of treatment on Nasal Obstruction

Symptom	Mean score			%	S.D (±)	S.E (±)	T Value	p value
AEC	BT	AT	BT-AT					
	0.90	0.37	0.53	59.26	0.730	0.136	2.63	<0.05

Table 6: Showing the effect of treatment on Itching

Symptom	Measures				%	S.D (+-)	S.E (+-)	t value	p value
	BT								
Itching	1.50	16th Day AT	0.70	0.80	53.33	0.551	0.102	5.05	<0.05
		FU1	0.93	0.57	37.78	0.568	0.106	3.62	<0.05
		FU2	1.10	0.40	26.67	0.498	0.093	2.63	<0.05

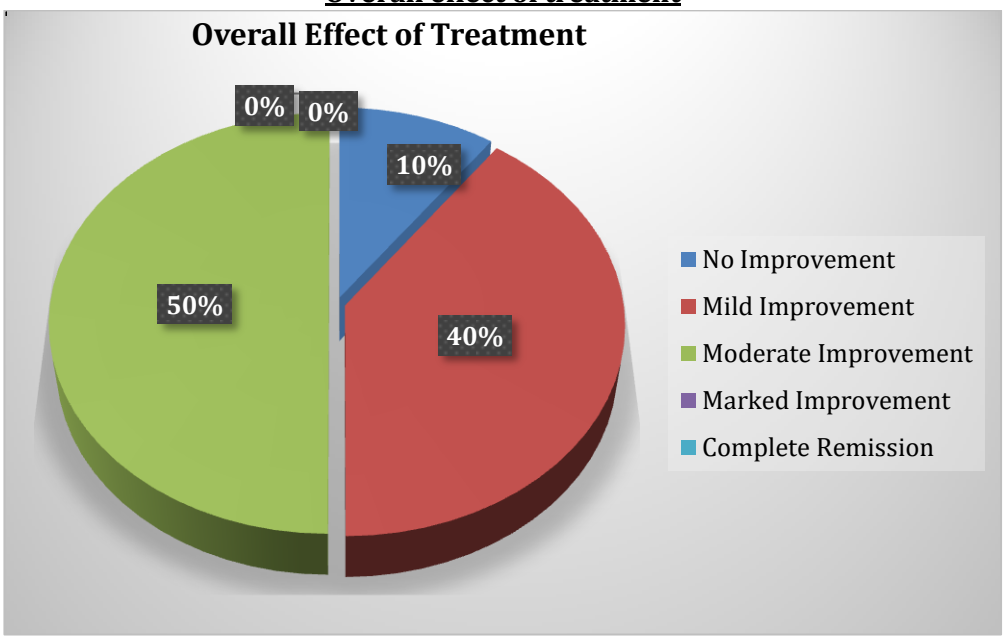
Table 7: Showing the effect of treatment on AEC

Symptom	Mean score			%	S.D (±)	S.E (±)	T Value	p value
ESR	BT	AT	BT-AT					
	1.03	0.57	0.47	45.16	0.730	0.136	1.98	<0.05

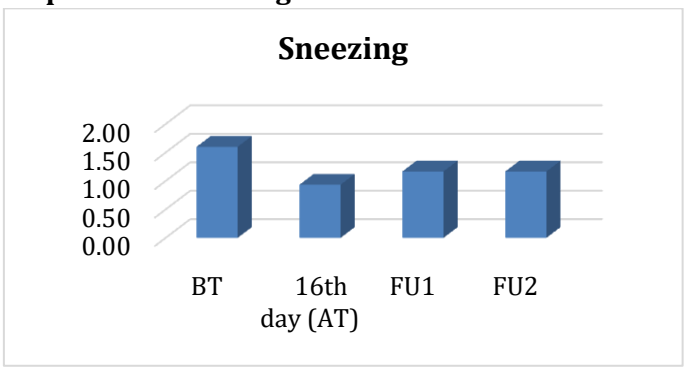
Table 8: Showing effect of treatment on ESR

Symptom	Measures				%	S.D (+-)	S.E (+-)	t value	p value
	BT								
Nasal Obstruction	1.07	16th Day AT	0.80	0.27	25.00	0.450	0.084	1.42	>0.05
		FU1	0.87	0.20	18.75	0.407	0.076	1.13	>0.05
		FU2	0.87	0.20	18.75	0.407	0.076	1.09	>0.05

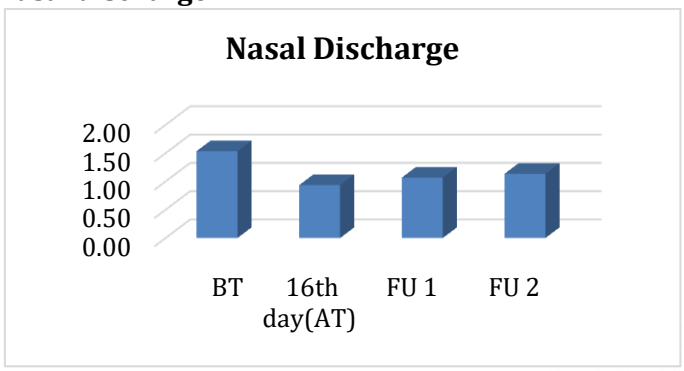
Overall effect of treatment



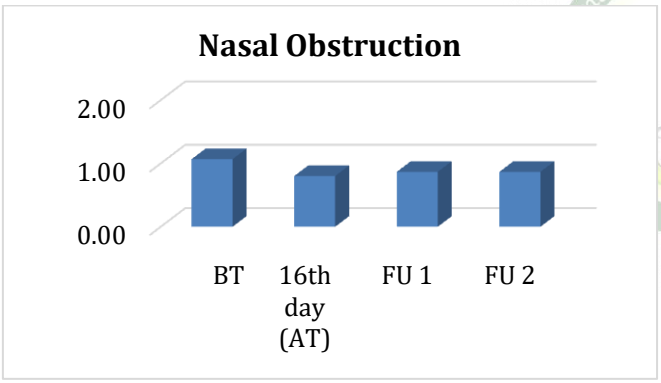
Graph no 01. Showing the effect of treatment on Seeezing



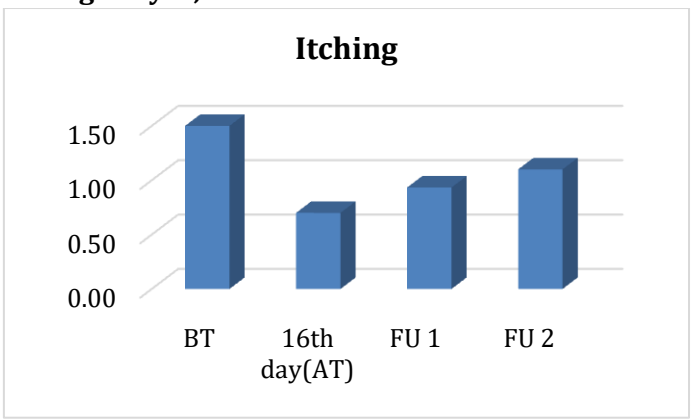
Graph no 02: Showing the effect of treatment on Nasal discharge



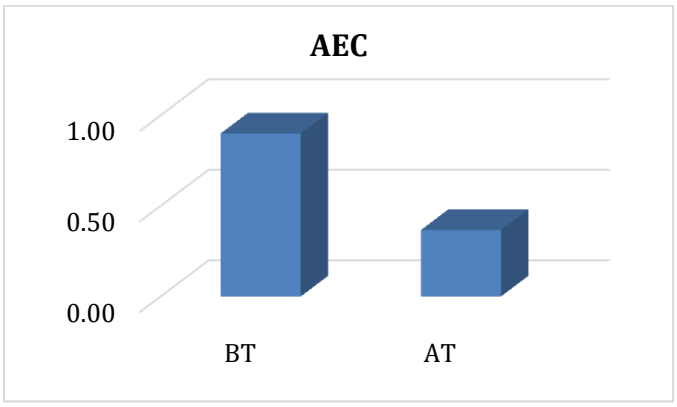
Graph no. 03: Showing the effect of treatment on Nasal obstruction



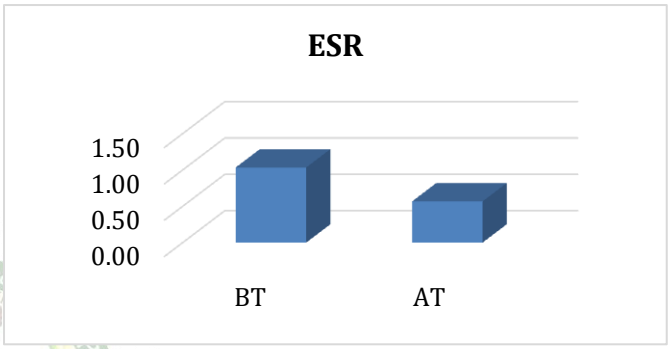
Graph no 04: Showing the effect of treatment on Itching of eyes, nose and throat



Graph no.05: Showing the effect of treatment on AEC



Graph no 16: Showing the effect of treatment on ESR



OBSERVATION AND RESULTS

Effect on Sneezing

This study consisting of 30 patients of Allergic rhinitis with sneezing revealed the result of it as shown in the table no 3.

Statistical analysis showed that the mean score which was 1.60 before treatment, was reduced to 0.93 after treatment and increased to 1.17 after follow up with 27.08% improvement, and there is a statistically significant change. (P<0.05)

Effect on Nasal Discharge

The result of treatment on Nasal Discharge is as shown in the table no 4.

Statistical analysis showed that the mean score which was 1.60 before treatment, was reduced to 0.93 after treatment and increased to 1.13 after follow up with 26.09% improvement, and there is a statistically significant change. (P<0.05)

Effect on Nasal Obstruction

The result of treatment on Nasal Obstruction is as shown in the table no 5.

Statistical analysis showed that the mean score which was 1.07 before treatment, was reduced to 0.80 after treatment and increased to 0.87 in after follow up with 18.75% improvement, and there is no statistically significant change. (P>0.05)

Effect on Itching

The effect of treatment on Itching of nose/eyes and throat revealed the result as shown in the table no 6.

Statistical analysis showed that the mean score which was 1.50 before treatment, was reduced to 0.70 after treatment and increased to 1.10 after follow up with 26.67% improvement, and there is a statistically significant change. (P<0.05)

Effect on AEC

Effect of treatment on Absolute Eosinophil Count is given in table no 5.

Statistical analysis showed that the mean score which was 0.90 before treatment was reduced to 0.37 after treatment with 59.26% improvement, and there is a statistically significant change. (P<0.05)

Effect on ESR

Effect of treatment on Erythrocyte Sedimentation Rate is given in table no 6.

Statistical analysis showed that the mean score which was 1.03 before treatment was reduced to 0.57 after treatment with 45.16% improvement, and there is a statistically significant change. (P<0.05)

Overall Effect of Treatment

Out of 30 patients in this study, 3 patients (10%) were finding no improvement, 12 patients (40%) were getting mild improvement and 15 patients (50%) were getting moderate improvement.

Overall effect of the treatment is 30.08%.

DISCUSSION

Pratishyaya is one among *the Nasagata rogas* which is explained in detail in classics. *Pratishyaya* is a *Vata-Kapha pradhana vyadhi*. *Vataja pratishyaya* can be co-related to Allergic Rhinitis considering the causative factors, signs and symptoms.

Probable mode of action of *Haridrakhanda*

Haridrakhanda is a well known formulation that is told in classics for all allergic conditions.

- The principal ingredient of the formulation *Haridrakhanda* is *Haridra* that is *Curcumin longa*. *Haridra* by its *Shothahara* property, helps in reducing the *Shotha* (inflammation) in nasal turbinates and respiratory tract.
- *Haridra* is a drug that alleviates *Vata-kapha dosha* by its *Katu-tikta rasa* and *Ushna guna*, thereby helps in management of *Pratishyaya* which is a *Vata-kapha pradhana vyadhi*.
- By its *Rasayana*, *Ojovardhana*, *Balya*, *Dhatu poshaka* properties, *Haridra* also improves *Vyadhikshamatva* (immunity).
- Curcuminoids present in turmeric are natural anti-oxidants which help in enhancing immunity and thereby prevents recurrence of the disease. They also have an ability to inhibit non specific and specific mast cell dependent allergic reactions.
- *Haridra* is also having anti-histaminic property, which helps in reducing the symptoms that are produced due to histamine that is released by inhalation of an allergen.
- The main ingredients of *Haridrakhanda* are of *Katu-tikta rasa*, *Ushna veerya*, *Katu vipaka*, *Laghu-ruksha guna*, which helps in pacifying both *Vata* and *Kapha dosha* and also helps in subsiding symptoms like *Nasa kandu* (itching in nose), *Srava* (nasal discharge). The *Teekshna guna* helps in penetration of the drug into *Sukshma srotas* and thereby clears *Srotovararodha*. The *Rooksha, Teekshna guna* helps in reducing the *srava*.
- The other ingredients of *Haridrakhanda* such as *Twak, Ela, Patra* are *Teekshna* helps as *Srotoshodaka*.
- *Pippali*, *Vidanga*, *Trivrt* are having *Teekshna*, *Krimighna* and *Kandughna* properties which help in reducing nasal itching and also helps in preventing secondary infections.
- Other ingredients like *Go-ghruta* (cow's ghee) and *Go-dugdha* (cow's milk) are having *Ojo-vardhaka, Rasayana* and *Balya* properties which also contributes in improving immunity.

CONCLUSION

1. *Pratishyaya* is a complex disease involving several symptoms and diversified pathogenesis.
2. Like many other diseases the immunological factors also play vital role in the development, recurrence as well as in the cure of *Pratishyaya*.
3. Signs and symptoms of Allergic rhinitis are similar to *Vataja pratishyaya* and therefore can be co-related to *Vataja pratishyaya.*
4. Proposed medicine *Haridrakhanda* has the remarkable results with the ingredients embedded in it.

Overall effect of the treatment is 30.08%.

5. *Haridrakhanda* was selected in this study as *nasya* and other procedures are not advisable in children. *Haridrakhanda*, given orally is safe and effective. It is also palatable for children as it is having *Madhura rasa* as pradhana rasa.
6. *Haridrakhanda* was given with milk as *anupana* by considering the properties of the drugs present in the formulation. *Ksheera* is *Aajanma satmya* and it is palatable and easy for children.
7. Increased duration of treatment with regular follow ups is likely to yield better results and the co-morbidities and complications of the disease can be avoided.

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