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ORIGINAL RESEARCH ARTICLE - CLINICAL STUDY

Clinical evaluation of *pushkaradi* compound in respiratory allergic disorders in children

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ABSTRACT

Allergic rhinitis is a global health problem affecting the large population & its prevalence is increasing.In the Modern medicine, its management includes antihistamines, bronchodilators, mast cell stabilizers and corticosteroids. But most of the time, these are associated with many adverse effects. This produces a need to explore and utilize ancient wisdom of Ayuveda to find right solutions to the problem. So there is a need of a drug having low-cost and long lasting required for RAD and should be affordable for all socio-economic sectors within the population. **Design:** randomized control trial **Participants:** Children aged between 2-16 years. **Methods:** 60 patients were selected from OPD and IPD of National Institute of Ayurveda, Jaipur. That were satisfied the inclusion and exclusion criteria. They were randomly divided in two groups. In Group A administered Pushkaradi compound and in group B Placebo drugfor 12 weeks of duration with follow up at every forth night. **Results:** Statistical evaluations of overall morbidity features showed excellent result in group A patient. In intergroup comparison highly significant gain was seen in group A over group B . **Conclusion:** The trial drug "Pushkaradi compound" is effective , safe and palatable in reduce incidence of the symptoms of allergic disorders.

Keywords : *Pushkaradi Yoga*, Respiratory disorders, Allergic disorders

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Introduction:

Allergic diseases are common illnesses that have increasing in prevalence in the developed and developing countries and posing a serious health problem and economic burden. Recognizing the problem in children is very essential since the spectrum of presentation is variable and multiple, for proper management.

Allergic rhinitis is a global health problem affecting at

least 10 to 25% of the population and its prevalence is increasing. In India prevalence of Respiratory allergic diseases in school going children has been reported between 5-20% in different geographic regions. Male to female ratio % is 64:36. Respiratoryallergic disorders come under Type I hypersensitivity (Anaphylactic) reaction. Typical complaints include intermittent nasal congestion, itching, sneezing, clear rhinorrhea, conjunctional irritation, loss of sense of smell andtaste, headache, wheezing, cough and dyspnoea..

Although direct description of allergy is not given in the classical texts of *Ayurveda*, but on keen observation, there are mounting contexts regarding allergens and allergic manifestations in ancient Ayurvedic texts. For e.g. causative factors described for the *Shvasa, Kasa* and *Hikka* are dust, smoke, cold place, cold water, wind, excessive physical exercise, *virrudha* and *rukshaahara* and wrong eating practices (Cha. Chi. 17/10-16), (A. H. U. 19/1-2). Here allergy can be described as *Anurjta* and *Apathya* (Cha. Soo. 25/30-32), *Asatmya* (Ka.S. Khila 5-12), *Ahita*(Cha. Soo 25/33-34), *Anupashaya*(A.S. Ni. 1/10), *Viruddha*(A.S. Soo. 9/7-8) etc. can be considered under *Anurjakabhava*. *Manasikabhavas* also play an important role in the etiopathogenesis of allergic disorders (Cha.Vi. 2/9), (Su. U. 1/26). All allergic manifestations are due to *rasadushti*, which are of ama , in nature at *pachakagni* and bhutagni level.

Allergies are the hypersensitive reactions of the body to a foreign substance (*Vijatiya dravya*) which has not undergone proper *agnipaka* (metabolized)after entering into the body thus resulting into ama. It can also be said as *Pragnaparadha* of the immune system where the dhi, dhriti and smriti of the immune mechanism get hampered.

In *Ayurveda*, the roga that can be included under RADs are mainly Sadyah Pratisyaya (Su. U. 24/3), Vatika Pratisyaya (Su. U. 24/6), (Ma. Ni. 58/16-17) , (A.H.U. 19/4), (Cha. Chi. 26/105), (Ka. Chi. 12/6) Dushta Pratisyaya (Cha. Chi. 26/107-109), (A.H.U. 19/9-11), (Su. U. 24/14-15) and *Tamakashvasa* (Su. U. 24/3), (Su.U. 51/8-10)

Ayurveda has unique concept of *Vyadhikshamatva* (Cha. Soo. 28/7) and various measures and recipes are described to achieve it. Considering these facts, a clinical study to evaluate the effect of an Ayurvedic compound, has been planned. The proposed multimodal drug, "PushkaradiCompound (Bhai. Rat. 71/75) " is having few potent herbal medicines possessing Rasayana, Aampachaka, antiallergic, anti-inflammatory and mucolytic and adaptogenic effect.

Methods

Aims and objectives

A. clinical study of Pushkaradi Compound in the management of respiratory allergic disorders in children with the following aims and objectives:

1. To give symptomatic relief.
2. To restore normal or best possible long-term air way function.
3. To reduce the risk of severe attacks.
4. To ensure normal growth and development in children
5. To improve the quality of life by providing an effective safe and economical remedy for prevention of RADs
6. Establishment of relation of prakriti with allergic disorders of children.
7. Evaluation of the side effects of the study drug.

Study type

A Double blind randomized and placebo controlled study.

Selection of Cases

- **Source** – Children for the present study were screened out from the O.P.D. and I.P.D. of P.G Department of Kaumarabhrithya, National Institute of Ayurveda, Jaipur.
- **Age Group** – Children between 2 years to 16 years were included for the study.
- **Number of Cases** – Total 66 cases was screened out of which 08 numbers of cases are discontinued.

Grouping of Patients

Screened cases registered for the study were randomly divided into two groups using random allocation software.

- **Group A -** This group of children were administrated the trail drug Pushkaradi Compound.(Pushkaradi Compound I)
- **Group B -** This group of children were administered placebo (Pushkaradi Compound II)

Pre-assessment Criteria

Children from O.P.D. and I.P.D. of N.I.A. were screened out by the symptom-checklist in the form of pre-assessment questionnaire constituting 14 questions.

Inclusion Criteria

- Age 2-16 Years
- Cardinal features of respiratory allergy
- History of at least 4 episodes in last one year.

Exclusion Criteria

Patients suffering from systemic illness like- Pneumonia, Tuberculosis, Pleural effusion, Emphysema, Lung Abscess, Bronchiectasis, Pleurisy, Nasal Polyposis, Chronic debilitating disease and Congenital anomalies.

Discontinuation criteria

- ✓ Appearance of features of respiratory infections.
- ✓ Uncontrolled severe asthmatic attacks
- ✓ Any other acute illness.
- ✓ Parents not willing to continue

Side-effects Evaluation criteria

To rule out possible side effects of the study drug documentation of information from the patient on every follow up, related to the features as tachycardia, tremor, headache, sedation, drowsiness, weight gain oral thrush, reflex coughing etc.

Clinical Assessment

Assessment of clinical symptoms – Rhinorrhea, smell obliteration, sneezing, nasal obstruction, headache, change in voice, fever, dyspnea, itching (nasal/eye), wheezing, cough and sore throat, depending on the severity was done on four-point scale.

Morbity Score= incidence x Severity

Laboratory Assessment

- Peak Expiratory Flow Rate (PEFR)
- Blood – Hb%, TLC, DLC, TEC, IgE

Drug

The studying drug "*Pushkaradi compound*" was selected from *Bhaishajya Ratnavali*. Trial drug compound had following ingredients.

Table no. I: Showing the ingredients of trial drug

S.N.	Name	Botanical Name	Parts Used	Ratio
1	*Pushkaramula*	Inula racemosa	Root	01 part
2	*Ativisha*	Aconitum heterophyllum	Root	01 part
3	*Sringi*	Pistacia intergrima	Gall	01 part
4	*Pippali*	Piper longum	Fruit	01 part
5	*Yavasa*	Alhagi camelorum	Whole Plant	01 part

The trial drug Pushkaradi compound was used in the form of syrup in order to enhance its palatability for easy administration to children. It was prepared by the Pharmacy of N.I.A. Jaipur.

Dose and duration

The proposed Ayurveda compound was prescribed in doses according to body weight of children for 12 weeks (2ml/kg/day). Follow up was done fortnightly.

Placebo

The placebo for the study was also in the form of syrup (Pushkaradi Compound II) composed of sugar. Children were called for follow up every fortnightly. Any discomfort or untoward side effects were noted.

Common observations and results

Table no. II: Showing common observations of trial

Sr. No.	factors	Classification	Group A		Group B	
1.	Age (yrs)	2-6	20	66.66	17	56.66
		7-11	06	20	04	13.33
		12-16	04	13.33	09	30.00
2.	Sex	Male	16	53.33	18	60.00
		Female	14	46.66	12	40.00
3.	Religion	Hindu	22	73.33	20	66.66
		Muslim	06	20.00	08	26.66
4.		Sikh	02	06.66	02	06.66
	Habitat	Urban	28	93.33	25	83.33
		Rural	02	6.66	05	16.66
5.	Socioeconomic Status	Higher	04	13.33	05	16.66
		Middle	17	56.66	10	33.33
		Lower	09	30.00	15	50.00
6.	Agni Status	Mandagni	21	70	20	66.66
		Vishamagni	03	10	05	16.66
		Teekshnagni	03	10	03	10.00
		Samagni	03	10	02	06.66

7.	Koshtha	Mrudu	07	23.33	06	20.00
		Madhya	13	43.33	20	66.66
		Krura	10	33.33	04	13.33
8.	Incidences of A.A., A.R. and Mixed group	Allergic Asthma(AA)	09	30.00	06	20.00
		Allergic Rhinitis(AR)	11	36.66	14	46.66
		A.A.+A.R.	10	33.33	10	33.33
9.	Hereditary Influence	Present	22	73.33	23	76.66
		Absent	08	26.66	07	23.33
10.	Type of A.R.	Seasonal	05	16.66	06	20.00
		Perennial	13	43.33	15	50.00
		Mixed (perennial with seasonal exacer-bation)	12	40.00	09	30.00
11.	Associated Allergic Manifestation	Allergic Rhinitis	10	33.33	12	40.00
		Allergic Asthma	08	26.66	09	30.00
		Allergic Dermatitis	04	13.33	04	13.33
		Allergic Conjunctivi-tis	04	13.33	02	06.66
		Allergic Gastritis	02	06.66	02	06.66
		H/O Drug allergy	02	06.66	01	03.33

Chart No.-1 Showing Provocating factors / Allergen wise distribution (in percentage)

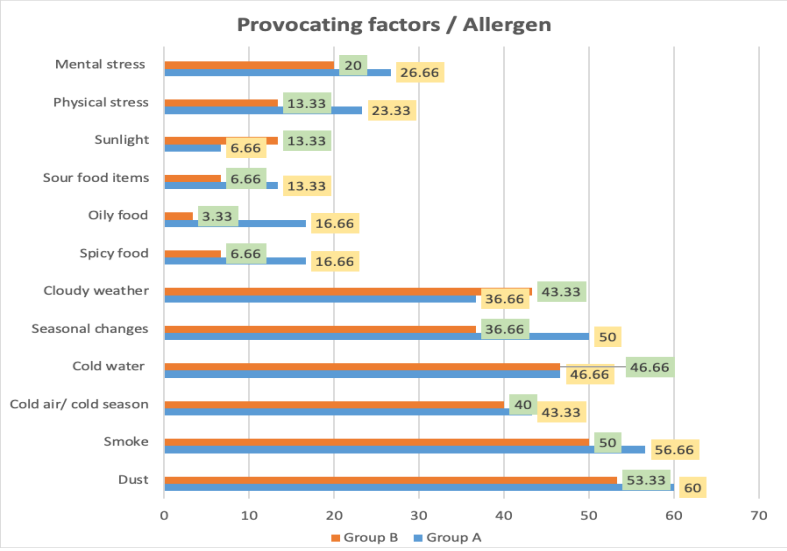

Chart No. 2 - Showing Risk factor wise distribution (in percentage)

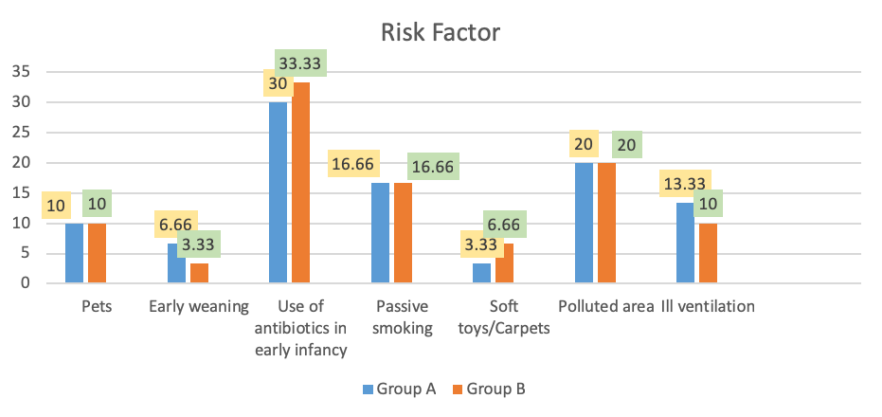

Chart No. 3- Showing incidences of all the morbidity features in last three months(in percentage)

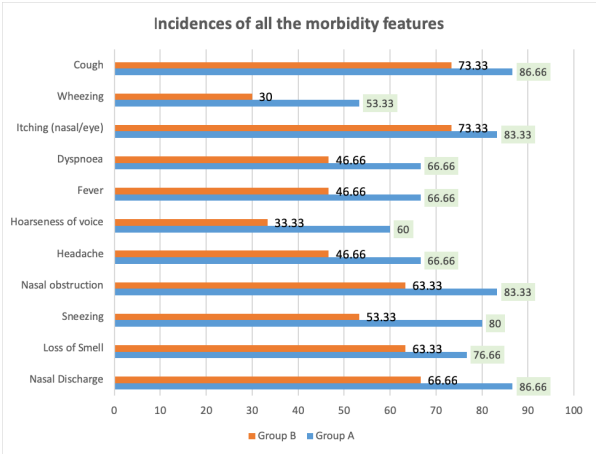

Table No. 3: Showing Statistical Presentation of Laboratory investigations

	Group	Mean Score			Gain %	S.D.	S.E.	t	p	Interpretation
		B.T.	A.T.	Diff.						
Hb%	A	10.9233	11.9166	0.99333	9.09368	0.66846	0.122045	8.139	< 0.0001	yes(****)
	B	11.1766	12.4059	0.0984	0.8804	0.6914	0.126232	1.221	0.2320	NS
TLC	A	9456.66	5716.667	3740	39.5488	1354.329	247.2655	15.13	< 0.0001	Yes (****)
	B	8874.091	12136.91	464.4497	5.23377	377.5907	68.93831	0.8875	0.3821	NS
Neutrophils	A	51.7333	56.0667	-4.3333	-8.3762	7.75634	1.416109	3.060	0.0047	Yes(**)
	B	48.5713	50.3089	-0.39512	-0.8134	12.6286	2.305657	0.6887	0.4965	NS
Lymphocyte	A	43.8333	37.5	5.1	11.6349	3.51695	0.642105	3.514	0.0015	Yes (**)
	B	43.5463	39.8083	2.2995	5.28063	13.1413	2.399274	1.949	0.0610	NS

Eosinophil Count	A	3.53333	2.5	1.0333	29.2452	1.7711	0.323356	3.196	0.0034	Yes(**)
	B	4.8950	3.56192	0.17246	3.523333	2.9819	0.544425	1.743	0.0920	NS
TEC	A	306.733	157.0333	149.7	48.80461	198.9504	36.3232	4.121	0.0003	Yes(***)
	B	365.2232	357.0584	-67.3611	-18.4438	364.9102	66.62319	0.9988	0.3262	NS
Ig E Level	A	546.5167	178.9333	368.5833	67.44229	243.2242	44.40646	8.307	< 0.0001	Yes (****)
	B	449.5001	426.1198	88.8158	19.7588	395.6748	72.24	1.580	0.1249	NS

/** -Significant ,-Highly significant ,****-Extremely significant , NS-Not significant**

Table no. IV: Showing statistical Presentation of all the Morbidity features after Treatment in Group A

S.N.	Morbidity features	Mean Score			Gain %	S.D.	S.E.	t	p	Inter-pretation
		B.T.	A.T.	Diff.						
1.	Nasal Discharge	5.65	2.5	3.15	55.78	1.99	0.39	8.6	0.0001	ES
2.	Loss of Smell	3.2	2.5	0.76	23.33	1.19	0.25	3.96	0.0002	HS
3.	Sneezing	5.37	1.6	3.77	70.23	2.63	0.53	5.73	0.0001	ES
4.	Nasal obstruction	4.84	1.60	3.24	66.94	2.40	0.48	5.74	0.0004	HS
5.	Headache	3.75	1.25	2.55	68.00	2.012	0.45	4.55	0.001	HS
6.	Hoarseness of Voice	3.88	1.6	1.78	52.78	1.93	0.45	3.77	0.005	S
7.	Fever	3.25	2.2	1.01	32.30	1.44	0.32	3.39	0.0054	S
8.	Dyspnoea	3.75	1.8	1.95	52	1.53	0.34	5.6	0.0004	HS
9.	Itching(nasal/eye)	4.08	2.1	1.98	48.52	1.70	0.34	5.85	0.0001	ES
10.	Wheezing	3.625	0.9	2.72	75.17	1.52	0.38	5.89	0.004	HS
11.	Cough	3.76	1.9	1.86	49.59	1.77	0.49	0.34	0.004	HS
12.	Throat inflammation	3.75	1.0	2.75	73.33	1.57	0.32	1.54	0.0023	S

Table no. V: Showing statistical Presentation of all the Morbidity features after treatment in Group B

S. No.	Morbidity features	Mean Score			Gain %	S.D.	S.E.	T	p	Interpretation
		B.T.	A.T.	Diff.						
1.	Nasal Discharge	5.2	4.35	0.85	16.34	1.13	0.25	14.43	0.0119	S
2.	Loss of Smell	3.4	3.05	0.42	12.1	0.83	0.19	2.19	0.054	NS
3.	Sneezing	3.56	2.62	0.93	26.31	1.61	0.40	2.32	0.0545	NS
4.	Nasal obstruction	3.57	3.15	0.42	11.76	1.21	0.27	1.50	0.250	NS
5.	Headache	2.57	2.21	0.35	13.88	0.63	0.16	2.10	0.089	NS
6.	Hoarseness of Voice	2.4	2.3	0.1	4.1	0.87	0.27	0.36	0.850	NS
7.	Fever	2.4	2.0	0.4	17.64	0.75	0.20	2.12	0.094	NS
8.	Dyspnoea	2.14	2.28	0.14	6.66	0.53	0.14	-1	1.00	NS
9.	Itching(nasal/eye)	3.81	3.27	0.54	14.28	1.85	0.49	1.09	0.12	NS
10.	Wheezing	2.11	2.55	0.444	-21.05	0.88	0.29	-1.51	0.34	NS
11.	Cough	3.0	2.86	0.13	4.54	0.88	0.16	0.82	0.570	NS
12.	Throat inflammation	3.0	2.3	0.61	20.37	0.97	0.23	2.64	0.033	S

Discussion

The polyherbal compound drug "Pushkaradi Compound" is the combination of drugs having katu and tiktarasa, laghu, ushna and teekshnaguna and katuvipaka,ushna virya and Kapha Vata shamaka prabhava . It shows signs of srotoshodaka properties which may possibly assist to eliminate sluggish dosha in the srotas. Ushnavirya and laghuguna having the properties of vilayana, pachana , srotoshodaka. Due to this viscosity of kaphadosha is reduced ,mucolytic and expectoration of kapha ensures the respiratory tract on coughing.

Most of the drug has KaphaVatashamakaprabhava. Thus kaphashamaka properties of drug help in breaking the srothorodha and digestion of ama, which leads to proper functioning of the body.Some ingredients of the study drug having rasayana properties which supported to increase both qualitatively and quantitatively improvement in all dhathu of the body. Piperlongum, Inula racimosa, Aconitum heterophyllum contains rasayanaprabhava, immunomodulating activities and anti-inflammatory activities.

The components of the study drug might have acted at various levels in breaking the pathogenesis of the allergic disorders.

Some hampers the immediate hypersensitivity reaction by inhibiting histamine release, or by inhibiting mast cell degranulation as for e.g. Piperlongum depletes histamine from bronchial and lung tissues . Mast cell inhibitory activity is possessed by Piperlongum and Inularacemosa. On the other hand some are effective for late phase allergy owing to the inhibitory action on leukotrine systems as or by reducing the eosinophil count.

The efficacy of trial drug in reducing the nasal discharge is because of the vata and kapha shamaka prabhava of the drug. The anti-allergic effect of various ingredients is responsible for the overall relief in the symptoms, including nasal discharge, sneezing, itching etc.

Conclusion

- Pushkaradi compound, a multimodal drug is an

effective recipe in reducing the morbidity pattern of RADs, as compared to the previous morbidity history.

- Statistical evaluations of overall morbidity features showed excellent result in group A patient, treated with Syrup Pushkaradi Compound. Some cardinal features such as nasal discharge, sneezing, and itching (Nasal/Eye) demonstrated extremely significant improvement while, loss of smell, nasal obstruction, wheezing, headache, dyspnoea, and cough had highly significant improvement. Fever, hoarseness of voice, inflammation of throat showed significant improvement. On the other hand, in group B statistically except nasal discharge and throat inflammation all the outcomes were insignificant.
- In intergroup comparison highly significant gain was seen in group A over group B at the level of ($P<0.001$) for inflammation of throat, whereas for nasal obstruction, loss of smell, sneezing, nasal obstruction, fever, wheezing, and cough, significant ($P<0.01$) advantage was observed in group A over group B.
- The follow up study depicts the sustained effect of the therapy.
- Appreciative improvement was observed in Hb%, TLC, PEFR, Eosinophil count. TEC and IgE show marked reduction.
- No untoward effect of the study drug was observed during the study.

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सारांश:

एलर्जिक राइनाइटिस एक वैश्विक स्वास्थ्य समस्या है जो बड़ी आबादी को प्रभावित कर रही है और इसकी व्यापकता बढ़ रही है। आधुनिक चिकित्सा में, इसके प्रबंधन में एंटीहिस्टामाइन, ब्रोंकोडाईलेटर्स, मास्टसेलस्टेबलाइजर्स और कॉर्टिकोस्टेरॉइड शामिल हैं। लेकिन अधिकांश समय, ये कई प्रतिकूल प्रभावों से जुड़े होते हैं। समस्या के सही समाधान खोजने के लिए आयुर्वेद के प्राचीन ज्ञान का पता लगाने और उसका उपयोग करने की आवश्यकता है। इसलिए आर.ए.डी. के लिए कम लागत वाली, लंबे समय तक चलने वाली एक दवा की आवश्यकता है।

डिजाइन: यादृच्छिक नियंत्रण परीक्षण प्रतिभागीरू 2-16 वर्ष की आयु के बच्चे।

विधि: राष्ट्रीय आयुर्वेद संस्थान, जयपुर के ओपीडी और आईपीडी से 60 मरीजों का चयन किया गया। यह समावेश और बहिष्करण मानदंडों के अनुसार थे। वेयादृच्छिक विधि से दो समूहों में विभाजित थे। समूह ए में पुष्करादि यौगिक और समूह बी प्लेसबोदवा 12 सप्ताह की अवधि के लिए दी गई।

परिणाम: समग्ररुग्णता के लक्षणों के सांख्यिकीय मूल्यांकन ने समूह ए रोगी में उत्कृष्ट परिणाम दिखाया। अंतर समूह तुलना में समूह बी में समूह ए में अत्यधिक महत्वपूर्ण लाभ देखा गया।

निष्कर्ष: एलर्जिक विकारों के लक्षणों को कम करने के लिए दवा "पुष्करादियौगिक" प्रभावी, सुरक्षित और सुस्वाद है।