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CLINICAL EVALUATION OF THE EFFICACY OF MUSTADI YOG IN THE MANAGEMENT OF RESPIRATORY ALLERGIC DISORDERS (RADs) IN CHILDREN

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ABSTRACT

Aim of the study was to evaluate the efficacy of Mustadi Yog in the management of Respiratory allergic disorders (RADs) in children. 60 Children of the age group of 3 to 15 years were selected after evaluating them clinically for Respiratory allergic disorders RADs as per the inclusion criteria, from O.P.D. and I.P.D. of PG Department Kaumarabhritya, National Institute of Ayurveda Jaipur, divided into two groups, group A (Trial group) received Mustadi Yog I and Group B (Control group) received Mustadi Yog II as placebo; duration of study was three month. Assessment was done using four point severity scale of clinical symptoms and laboratory assessment through Peak flow expiratory rate (PEFR), Blood investigations (Hb%, TLC, DLC, TEC) and Serum IgE level. Statistical evaluation of overall morbidity features showed good result in group A patient, treated with Syrup Mustadi Yog I. In itching of nose and eyes, highly significant improvement was seen in group A. On the other hand, in group B all the outcomes were insignificant. Appreciative improvement was observed in TEC, Eosinophil count, IgE and TLC showed marked reduction in group A. The study drug Mustadi Yog I is effective in alleviating and reducing the morbidity score in Respiratory allergic disorders as compared to the previous morbidity history.

Keywords: Ayurveda, Respiratory Allergy, Morbidity, Mustadi Yog

INTRODUCTION

Allergy is a hypersensitivity disorder of the immune system of the human body. Allergic reactions occur when a person's immune system reacts abnormally to normally harmless substances, present in the environment.

Respiratory allergy is the commonest illness during childhood and often abating with age. On the other hand, if improperly managed, it may lead to severe consequences and troublesome life along with behavioral and developmental problems in the future. About 75% of asthmatics have associated allergic rhinitis, whereas 30-35% allergic rhinitis patients have associated hyper reactive airway disease.[1]

The therapy of Respiratory allergy usually employs H1-antihistamines, Bronchodilators, Leukotriene Inhibitor, corticosteroids and immunotherapy. The long-term use of these, however may not limit the disease progression and further all of these drugs have adverse effects and thus search for a novel drug continues.[2]

There is not any straight description in Ayurveda texts about the term of allergy. However, various etiological factors and symptoms of allergy are explained in many contexts. Several indirect and scattered ample references regarding allergens, allergic manifestation, respiratory system and respiratory disorders are available in Ayurveda classics, which have very much close resemblance with symptoms of allergic disorders e.g. Causative factor for Pratishyaya are dhooma (smoke), raja (dust particles), krodha (anger), change in weather, prajagarana (awakening in night), shitambu (cold water), bashpa (excessive humidity), asatmya (unfavorable conditions) and ama (undigested food particles).[3]

Thus, allergy can be described under headings Anurjata (hypersensitivity) towards immune system because of factors such as ahita[4] (substance by being of incongruent nature), viruddha[5] (incompatibility), apathya[6] (Use of unwholesome food and mode of life), anupashaya[7] (proved to be detrimental to health), asatmya[8] (thing which is not pleasurable to the body) etc.

Manasika bhava (psychological factors) also play an important role in the etiopathogenesis of allergic disorders[9]. All allergic manifestations can be considered as due to rasa dhatu dushti (Imbalance in Rasa Dhatu) resulting in production of ama[10].

If the Ayurveda medicines that can improve immunity and Agni (digestive capacity) are combined with each other, the combination might prove to be the most potent for the treatment of RADs and the side effects of the allopathic treatment can be reduced.

This produces a need to explore and utilize ancient wisdom of Ayurveda to find right solutions to the problem. Therefore, there is a need of a drug having low-cost, long lasting and permanent therapeutic effect required for management of RADs and should be affordable for all socio-economic sectors within the population.

AIMS AND OBJECTIVES OF THE STUDY

A clinical study of "Mustadi Yog" in the management of respiratory allergic disorders in children with the following aims and objectives:

- To assess the effect of trial drug regimen on Respiratory allergic disorders.
- To provide the relief or improve previous symptoms.
- To improve the quality of life by providing an effective, safe and economical remedy for prevention of RADs.
- To restore normal airway function and to promote of healthy life style.

MATERIAL AND METHODS

The study was done as double blind randomized placebo controlled. In the present study children belonging to the age group of 3-15 years of either sex were selected with the help of a pre-assessment questionnaire from the OPD/IPD of Kaumarabhritya Department of National Institute of Ayurveda, Jaipur. (DRC Letter Number, SR. No. F/5(1) education/Research/2012-13/15301 Dated 25-03-2013) Screened children or cases registered for the study were randomly divided into two groups as below.

Table 1: Division of the patients into Groups

Group	Drug	Number of patients		
		Completed	Discontinued	Total Registered
A	Trial drug	30	01	31
B	Placebo	30	06	36
Total	----------	60	07	67

Total 67 cases were registered. Group A was given the study drug, Mustadi Yog I and the children under group B were given placebo syrup, Mustadi Yog II.

Drug & Placebo - The trial drug (Mustadi Yog I) 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. The placebo for the study was also in the form of syrup (Mustadi Yog II) composed of sugar with similar appearance and presentation as that of trial drug.

Dose - The trial drug and placebo were prescribed in doses according to body weight of children (1ml/kg/day) in 2 or 3 divided doses.

Duration- The trial drug and placebo were administered for 12 weeks.

Follow up - Every fortnightly. Any discomfort or untoward side effects were noted.

Criteria Adopted

Pre-assessment Criteria

Children from O.P.D. and I.P.D. of P.G Department of Kaumarabhritya, of N.I.A. were screened out by the symptom checklist in the form of pre-assessment questionnaire constituting 14 questions. Parents of the concerned child were asked to fill up the questionnaire (Source-AAAI, 2004; 93:36-48).

Child scoring 7 out of the first 10 questions is considered as asthmatic (allergic) and, one out of next three is considered to have nasal allergy. The next four questions are related to the severity of the previous episodes and treatment taken.

Inclusion Criteria

- Age group 3 to 15 years of either sex.
- Cardinal features of respiratory allergy.
- History of at least 3 episodes in last one year.

Exclusion Criteria

- Severe and Complicated respiratory allergic disorders
- Patients suffering from systemic illness like Pneumonia, Tuberculosis,
- Plural effusion
- Emphysema
- Lung abscess
- Bronchiectasis
- Pleurisy
- Nasal polyposis.
- Congenital anomalies
- Chronic debilitating diseases.

Discontinuation criteria

- Parents/guardian not willing to continue treatment.
- Patient develops life threatening complication during treatment.
- Any other acute illness
- Appearance of features of respiratory infections.

Assessment criteria

Assessment of clinical symptoms – Nasal discharge, loss of smell, sneezing, nasal obstruction, headache, hoarseness of voice, fever, dyspnea, itching (nasal/eye), wheezing, cough and throat inflammation, was done depending on the severity with the help of four-point scale.

Laboratory Assessment

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

Side-effects Evaluation criteria – To rule out possible side effects of the study drug, clinical criteria was adopted. It included the 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.

Methods

Children lying under the inclusion criteria were thoroughly examined by general physical examination, complete history was taken and the children with problems/ factors in exclusion criteria were excluded.

Detailed information about the diagnosed children was recorded in a proforma prepared on the basis of Ayurveda as well as modern parameters. Information included history of any infections disease in the past, perinatal history, family history, history of other allergic diseases, history regarding risk factors for respiratory allergy, history of previous episodes, social, cultural and economic status, behavioral disturbances, satva, sara, satmya, samhanana and other Ayurvedic parameters.

Peak expiratory flow rate was measured on every follow up i.e. in every 15 days. For standard values, the study by H.Paramesh (2003) has been referred.

The blood investigations were done before the starting and after the completion of the trial i.e. after 3 months. Serum total IgE was quantified with an ELISA protocol according to the manufacturer's instructions.

Evaluation of clinical efficacy

For evaluation of clinical efficacy, morbidity score was calculated as:

Morbidity Score = Incidence* × Severity**

[* Incidence was calculated as number of episodes during last 3 months. ** Severity was calculated on the basis of grading of the presenting complaints.]

The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria. Initially the variation and significance of effect seen within all the patients, were calculated by using Paired't' test. (Wilcokson two tailed for subjective parameters and for the objective parameters Paired't' test two tailed) has been applied. Inter group Comparison done by using Unpaired t test. (Mann Whitney-U Test) More specifically quantify the percentage of improvement in each patient was also calculated using the formula BT-AT/BTx100.

Parents' Consent / Child Assent- A voluntary, signed witnessed informed consent / assent was obtained from the participant / parent's / Guardians prior to the start of clinical trial.

Trial Drug

The study drug "Mustadi Yog I" is selected from Yog Ratnakar-Bal Rogadhikar, Kasa Chikitsa (pg. no.442).

Table 2: Ingredients of trial drug (Mustadi Yog I)

S.N.	Name	Botanical Name	Parts Used	Ratio
1	Musta	*Cyperus rotundus*	Root	01 part
2	Ativisha	*Aconitum heterophyllum*	Root	01 part
3	Karkat Shrungi	*Pistacia intergrima*	Gall	01 part
4	Pippali	*Piper longum*	Fruit	01 part
5	Vasa	*Adhatoda vasica*	Whole Plant	01 part

The research drug has been found to have anti-inflammatory, anti-allergic, bronchodilator, anti-stress, anti-tussive, mucolytic, analgesic, expectorant and immune-modulatory effect. The Mustadi Yog I has been used in the form of syrup in order to enhance its palatability and easy administration in children, in the dose of 1 ml/Kg/day, in 2 or 3 divided doses.

OBSERVATION AND RESULT

Study showed that, 7-11 years age group was the most affected group. Males were more prone to RADs as compared to females. Maximum numbers of cases were belonging to urban area and middle socio-economic status. Maximum number of cases exhibited seasonal manifestation. Hereditary influence and atopy is evident in RADs. The provocation factors observed were dust, smoke, cold air, cold season, cold water, ice creams, seasonal changes, cloudy weather, spicy food, oily food, sour food items sunlight, physical stress, and mental stress. Associated complaints found are snoring, serous otitis media, tonsillitis and migraine. The characteristic behavior and appearance were observed in the form of allergic shiners, allergic salute, nasal crease, allergic gape and allergic cluck. Kapha Vata Prakriti patients were found to be more prone for RADs. Maximum number of patients of the trial were under Mandagni (Loss of appetite). IgE level was found to be elevated in 86.00% and 80.00% in group A and B respectively. TEC level was found to be elevated in 76.66% and 70.00% in group A and B respectively.

Statistical evaluations of overall morbidity features showed good result in group A patient, treated with Syrup Mustadi Yog I. In itching of nose and eyes, highly significant improvement was seen in group A. Where as in other features such as nasal discharge, loss of smell, sneezing, nasal obstruction, headache, hoarseness of voice, dyspnea, wheezing, cough, inflammation of throat, significant improvement was seen in group A. In case of fever insignificant result was found in trial as well as placebo group. On the other hand, in group B all the outcomes were insignificant. (Table 3)

In intergroup comparison highly significant gain was seen in group A over group B at the level of ($P<0.001$) for loss of smell, sneezing, hoarseness of voice, dyspnea, itching of nose and eye, wheezing, inflammation of throat. Whereas for nasal discharge and cough significant ($P<0.01$) advantage was observed in group A over group B. Insignificant ($P>0.05$) gain was found in group A over B, for nasal obstruction, headache and fever. (Table 4)

Appreciative improvement was observed in TEC, Eosinophil count, IgE and TLC show marked reduction in Group A. (Table 5)

Peak Expiratory Flow Rate (PEFR)

As observed from the Table 6, in the maximum patients, of group A, Peak Expiratory Flow Rate got raised by 51-60 L/min in 42.10% patients. Followed by 21.05% of patients got raised by 61-70. The increase was maximum up to 91-100 L/min. In group B, in the maximum patients PEFR got raised by 0-10 L/min. in 44.44%.

[* PEFR was done in above 07 yrs. of age patients only.]

Table 3: Statistical Presentation of overall improvement in various morbidity features after treatment in Group A and Group B

S. N.	Morbidity features	Group	Mean Score			Gain %	S.D.	S.E.	p	Interpretation
			B.T	A.T	Diff.					
1.	Nasal Discharge	A	6.48	3.51	2.96	45.75	4.85	0.90	0.0027	S
		B	6.28	6.00	0.28	4.54	5.04	0.95	0.7665	NS
2.	Loss of Smell	A	4.81	2.63	2.18	45.28	4.52	0.96	0.0343	S
		B	4.85	4.95	0.09	01.95	4.07	0.88	0.9157	NS
3.	Sneezing	A	7.15	3.53	3.61	50.53	3.84	0.75	0.0001	S
		B	7.00	6.29	0.70	10.12	3.56	0.72	0.3410	NS
4.	Nasal obstruction	A	5.81	3.68	2.13	36.71	4.42	0.94	0.0341	S
		B	5.90	5.33	0.57	09.66	4.95	1.08	0.6030	NS
5.	Headache	A	5.50	3.95	1.54	28.03	3.28	0.67	0.0308	S
		B	5.59	4.59	1.00	17.88	3.10	0.66	0.1454	NS
6.	Hoarseness of Voice	A	3.42	2.00	1.42	41.67	2.73	0.59	0.0264	S
		B	4.62	3.79	0.83	18.01	2.63	0.53	0.1345	NS
7.	Fever	A	3.68	4.12	0.43	11.86	2.55	0.63	0.5039	NS
		B	5.00	4.84	0.15	03.07	2.30	0.63	0.8138	NS
8.	Dyspnoea	A	4.08	2.56	1.52	37.24	3.23	0.67	0.0342	S
		B	4.85	4.66	0.19	03.91	3.75	0.81	0.8183	NS
9.	Itching(nasal/eye)	A	6.42	3.42	3.00	46.66	4.20	0.91	0.0039	VS
		B	6.20	5.58	0.62	10.06	3.72	0.76	0.4199	NS
10.	Wheezing	A	5.12	2.93	2.18	42.69	3.33	0.83	0.0191	S
		B	5.76	5.47	0.29	05.10	2.54	0.61	0.6400	NS
11.	Cough	A	5.57	3.96	1.60	28.84	4.03	0.76	0.0443	S
		B	5.57	5.30	0.26	46.59	3.53	0.69	0.7014	NS
12.	Throat inflammation	A	4.45	2.70	1.75	39.32	3.11	0.69	0.0210	S
		B	5.05	4.55	0.50	09.88	3.43	0.80	0.5450	NS

Table 4: Statistical presentation of Inter group Comparison after treatment

S. N	Morbidity features	Group [A.T.]	Mean	S.D.	S.E.	Mann Whitney U	P	Interpretation
1.	Nasal Discharge	A	3.517	2.627	0.4878	254.50	0.0141	S
		B	6.000	3.692	0.6977			
2.	Loss of Smell	A	2.636	2.279	0.4859	119.50	0.0064	VS
		B	4.952	2.941	0.6417			
3.	Sneezing	A	3.538	2.453	0.4811	140.00	0.0008	ES
		B	6.292	2.645	0.5400			
4.	Nasal obstruction	A	3.682	2.589	0.5520	172.50	0.1533	NS
		B	5.333	3.352	0.7314			
5.	Headache	A	3.958	2.095	0.4277	199.50	0.1474	NS
		B	4.591	1.869	0.3984			
6.	Hoarseness of Voice	A	2.000	1.183	0.2582	121.50	0.0021	VS
		B	3.792	2.206	0.4504			
7.	Fever	A	4.125	1.586	0.3966	80.000	0.2774	NS
		B	4.846	1.819	0.5044			
8.	Dyspnoea	A	2.565	2.063	0.4302	125.00	0.0046	VS
		B	4.667	2.852	0.6223			
9.	Itching(nasal/eye)	A	3.429	2.158	0.4709	139.00	0.0094	VS
		B	5.583	2.569	0.5245			
10.	Wheezing	A	2.938	1.843	0.4607	47.000	0.0011	VS
		B	5.765	2.463	0.5974			
11.	Cough	A	3.964	2.349	0.4439	218.50	0.0100	S
		B	5.577	2.212	0.4338			
12.	Throat inflammation	A	2.400	2.010	0.4496	77.500	0.0026	VS
		B	5.056	2.485	0.5856			

Table 5: Overall percentage gain in various laboratory parameters after treatment in Group A and Group B

Laboratory Parameters	Group A (Gain %)	Group B (Gain %)
Hb%	02.64	01.48
Total Leucocyte Count	11.96	02.33
Neutrophil Count	10.22	04.39
Lymphocyte Count	04.15	01.03
Eosinophil Count	19.63	05.30
Total Eosinophil Count	48.80	02.46
IgE	16.06	01.62

Table 6: Comparison of PEFR Before and After treatment

PEFR *(B.T.-A.T.) Increased	Group A (n=19)		Group B (n = 18)	
	Number	Percentage (%)	Number	Percentage (%)
00-10	00	00.00	08	44.44
11-20	00	00.00	05	27.77
21-30	00	00.00	03	16.66
31-40	00	00.00	02	11.11
41-50	03	15.78	00	00.00
51-60	08	42.10	00	00.00
61-70	04	21.05	00	00.00
71-80	01	05.26	00	00.00
81-90	02	10.52	00	00.00
91-100	01	05.26	00	00.00
Total	**19**	**100.00**	**18**	**100.00**

DISCUSSION

Regarding Mode of Action of Trial Drug

Respiratory allergic disorders or vitiation of pranavaha srotas (Respiratory System) mainly involves Pratishayaya and Shvasaroga. As described earlier the dosha involved are Vata and Kapha. Dushya involved is rasadhatu and srotas affected are pranavaha, annavaha, and rasavaha. Thus the drug selected should have the potency to act simultaneously on pranvaha, annavaha, and rasavaha srotas i.e., it should possess dipana, pachana, vatakapha shaman and srotoshodhaka properties. For this action, the drug should be laghu, sukshma, ushna, teekshna in guna.

The compound drug Mustadi Yog I is the combination of drugs having amapachaka (Pippali, Ativisha, Musta), rasayana (e.g. Pippali), vishaghna (e.g. Musta, Ativisha), sothahara (e.g. Pippali, Vasa) and shleshmahara (Vasa, Pippali, Ativisha, Musta, Karkatsringi) jwarahara (Vasa, Musta, Pippali) and, shulahara (Pippali, Ativisha, Vasa) properties.

The Study drug is having katu and tikta rasa, laghu, ushna and teekshna guna and katu vipaka, ushna virya and Kapha Vata shamaka properties. It shows srotoshodaka properties which may possibly assist to eliminate sluggish dosha in the srotas.

Katu and tikta rasa, Ushna virya and laghu, ushna, tikshna guna having the properties of kapha-vilayana, pachana, srotoshodaka. Due to this liquification of kaphadosha takes place resulting in clearing of respiratory tract on coughing. Most of the drugs have Vata Kapha shamaka properties. Mustadi Yog I having a potential properties of alleviating both vata and kapha dosha by virtue of tikta, katu rasa and ushna virya, laghu tikshna and ushna quality. Thus, kaphashamaka properties of drug help in breaking the srothorodha and digestion of ama, which leads to proper functioning of the Agni.

Some ingredients of the study drug having rasayana (immunomodulation) properties, which helps to improve dhatu both qualitatively and quantitatively. (e.g. Piper longum,). Pippali is very good rasayan for pranvaha srotas which is main site of manifestation of RAD.

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[11], or by inhibiting mast cell degranulation as for e.g. Piper longum depletes histamine from bronchial and lung tissues. Mast cell inhibitory activity is possessed by Piper longum.[12] On the other hand some are effective for late phase allergy owing to the inhibitory action on leukotriene systems as or by reducing the eosinophil count. e.g. Musta, Vasa and pippali.[13, 14]

The efficacy of trial drug in reducing the nasal discharge is because of the vata and kapha shamaka quality 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. (e.g., Musta).[14, 15.]

Cough in RADs is mainly due to post-nasal dripping causing throat irritation. Improvement in cough may be because of pacification of Vata and Kapha dosha and removal of obstructing Kapha from the Pranavaha srotas due to anti-tussive and mucolytic properties of the ingredients as Pippali and Vasa as potent expectorant liquefies the thick viscid sputum.[12, 16, 17] Expectorant action was also attributed to Vasa because of similar structure of vasicine as bromhexine.[17]

Relief from dyspnea and reduction in wheezing was because of relieving the obstruction in passage of prana vayu by sama kapha. The probable action of drug was because of its Kapha Vatahara effect and ushna teeksna guna. The relief might be the result of bronchodilator action of Pippali, Vasa and Ativisha. Spasmolytic action of Pippali acts by inhibiting the contractile action of histamine by glycoside saponin.[18]

Nasal obstruction, throat inflammation, loss of smell and hoarseness of voice are because of edematous and later on inflammatory changes in various target organs in the disease process. The study drug showed significant anti-inflammatory effect. (e.g. Vasa, Ativisha and pippali.[15] although as observed during the study that, very severe inflammation have shown lesser changes. Therefore, it may be suggested that the therapy may be continued further for the few more months.

Headache is mainly because of allergic sinusitis accompanying the RADs. Significant relief from headache after treatment was observed which might be due to anti-inflammatory properties of vasa and pippali.[15] In addition, vata dosha get pacified and becomes responsible for the relief. Vasa, Pippali and Karkatasringi also proved to possess analgesic property [19]

Mild inflammation due to allergic reaction showed marked relief. It may be because of proven anti-inflammatory activity of Vasa, Ativisha and pippali.[15, 20]

Improvement in the status of leucocyte count shows the anti-inflammatory activity of trial drug. It may be

attributed to immunomodulatory and its anti-inflammatory effect of various components such as Pippali, Ativisha and Karkatsringi.[21]

Eosinophils are key effector cells of inflammatory response in RADs. Reduction in eosinophil and IgE is suggestive of potent anti-allergic and anti-inflammatory activity of the study drug.

Increased PEFR is suggestive of the fact that, trial drug could have modified the existing airflow limitation caused due to obstruction. Thereby, the drug is helpful in restoring normal breathing. As pippali acts as rasayan on pranvaha srotas, it may have worked on quantitative and qualitative improvement of lung structure and function.

Apart from the relief of symptoms during the treatment, the study drug had provided sustained relief and improved the quality of life, as evident from the follow up study after 3 months of therapy. The insignificant change in the condition of patient after follow up with respect to after treatment position is suggestive of requirement of long-term therapy.

From this research work, it has been concluded that along with anti-allergic & bronchodilator effect, immunomodulatory regimen will play a key role in future therapies for allergic diseases. These treatment modalities may not only treat allergic disease, but also be beneficial in reducing the morbidity and mortality for which it is responsible.[22]

Psychological stress may be an additional environmental factor that worsens the oxidative toxicity[23] the ingredients like, Pippali by their anti-stress activity are responsible for regression of symptoms.[24]

Thus, overall improvement in the condition of the patient of the study group may be because of the multidimensional Properties of the drug. (Vata kaphahara, Deepana, Pachana, and Vatanulomana properties), which are essential for breaking down pathogenesis of RADs.

CONCLUSION

Concisely, it can be concluded that the study drug "Mustadi Yog I" is effective in alleviating and reducing the morbidity score in RADs, as compared to the previous morbidity history. Post treatment follow up study showed that trial drug provides the long-term sustained relief. No adverse effect, of the trial drug was observed during the study.

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