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RANDOMIZED CONTROLLED TRIAL ON THE EFFECT OF VRISHA GHRTA IN CHILDHOOD ASTHMA MANAGEMENT

Kulkarni Reena^{1*} and Ramachandran SK²

¹Associate professor, Department of Post graduate studies in Kaumarabhritya, SDM College of Ayurveda and Hospital, Tanniruhalla, BM Road, Hassan, India

²Former professor and Head, Department of Kaumarabhritya, Government Ayurveda College, Consultant 'Sneha Ayurvedic Child development Centre' Poojappura Thiruvananthapuram-12, Kerala, India

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*Corresponding author

E-mail: drreenakulkarni@gmail.com

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ABSTRACT

An interventional randomized controlled trial was conducted to evaluate the efficacy of Vrisha Ghrita on Tamaka Swasa (with special reference to bronchial Asthma) with plain Ghrita as control in children aged up to 12 years. Vrisha Ghrita was given internally in a divided dose of 5-15ml twice daily along with honey according to the age for a period of 3 months during attack free intervals. The idea behind trial was to improve the immunological compliance of the child and to conquer recurrent asthma. A total number of 26 children attending OPD (Out patient department) section of the hospital participated in the study. Analysis of the data was done using clinical parameters, routine hematology with AEC (Absolute Eosinophil Count), selected immunoglobulin assay, lung function tests, measures of morbidity and asthma and quality of life questionnaire. The assessment reported that effects of Vrisha Ghrita were significant in combating the clinical manifestations of Tamaka Swasa ($p < 0.01$), reducing morbidity episodes, school absenteeism, number of unscheduled visits to doctors (all $p < 0.01$). All these point suggests that the trial drug is highly effective in controlling recurrent episodes of asthma and respiratory tract infections. However, the results were statistically not significant with respect to haematology, immunoglobulin assay and pulmonary function tests. Risks of side effects were minimal in both the groups. The study was effective in curtailing the conventionally used bronchodilators and antibiotic therapies in children.

Keywords: Efficacy Trial, Asthma, Tamaka Swasa, Vrisha Ghrita, Ayurvedic medicine.

INTRODUCTION

Tamaka Swasa¹ is one of the well-known clinical conditions described in Ayurveda that is almost equivalent to asthma. Allergy is said to be one of the major causes of asthma, and when it becomes chronic, diminishes Vyadhi kshamatwa². Allergies and asthma³ are two fastest growing health problems among children and their complexity challenges both doctors and parents. Throughout the world, asthma is amongst the commonest chronic diseases of childhood for which a general practitioner's help is sought. Evidence is consistent in showing substantial increase in the burden of childhood asthma over past 30 years, a time when prevalence and morbidity associated with many other childhood illnesses have been decreasing. The steep rise in asthma incidences in past two to three decades gives it a shape of epidemics. The prevalence of asthma worldwide is 200 million with a mortality of 0.2 million per year. According to recently released guidelines on asthma diagnosis and management in US, asthma affects 14 million to 15 million people.⁴ This chronic disease affects an estimated 4.8 million children.⁵ People with asthma collectively have more than 100 million days of restricted activity and 4, 70,000 hospitalization. More than 5000 people die of asthma in a year. Though the prevalence is more in the developed countries, the developing countries have higher total burden of the disease due to difference in population. In India, the estimated burden of asthma is believed to be more than 30 million⁶ with a prevalence of 4-20% in school children in different geographic area.⁷ However,

only due to other health concerns like malnutrition, refractive errors and infective disorders etc asthma incidences are not projected.

Many of the childhood illnesses come and go with an end in sight but asthma and allergy worries never seem to end. This is very tiring for children, their parents and their siblings and even for physicians. Present therapies and researches in the field of asthma, even though have brought about considerable improvement in the asthma management but they pose upon constant use of glucocorticoids, bronchodilators, and leukotrine receptors antagonists either orally or as inhalers or both.⁸⁻⁹ At the same time they fail to provide a comprehensive betterment in the child's condition. There is excellent evidence that a comprehensive, optimal care of children with asthma can reduce morbidity from the disease.

Ayurvedic line of management prescribed for asthma can provide an improved key to the management of asthma. Recurrent attacks of asthma when become chronic lead to Dhatu Kshaya (reduced vitality of the tissues) and hence Bala Kshaya (reduced immunity) in the affected child. This is further aggravated by improper nourishment of dhatus owing to hampered digestive activity. Unless the disease is de-rooted completely and strength is restored, there is no possibility of optimum health.

After an initial conquer of the acute symptoms, none other than the medicated ghee capable of restoring the integrity of Dhatus and proper functioning of Agni. It becomes more precise when disease specific drug processed ghee is selected. More over ghee also increases memory, lustre,

complexion, wisdom, proper functioning of sense organs and longevity that is in fact the indicators of the proper growth and development of children¹⁰. The trial drug Vrisha Ghrita mentioned in classical management of Raktapitta (hemorrhagic disorders) also finds its indication in Swasa (Asthma). Professional experience has shown that Vrisha Ghrita is excellent in the management of Tamaka Swasa and it can prevent recurrent respiratory tract infections by augmenting child's immunity.

MATERIALS AND METHODS

Formulation

Ingredients of the trial drug Vrisha Ghrita¹¹ are Panchanga of Vasa (whole plant of *Adhatoda beddomei*-GAVC/Herbarium/2005/187) and honey.

Method of Preparation of Vrisha Ghrita

Forty litres of standard ghee mixed with one hundred and sixty litres of Vrisha Panchanga Kashaya. Seven kilograms of Vrisha puspa paste was added to the above said mixture and heated over mild fire (Mandagni) till the classical features for proper preparation medicated ghee (Sneha Siddha Lakshanas) appeared. The procedure was completed in three days¹² as the liquid portion (Drava Dravyas) used in the preparation of Ghrita is Kashaya. While dispensing, two hundred grams of Vrisha Ghrita was added with hundred grams of honey of Khadi Graamodyog, Govt. of Kerala, India and given.

Research Design

It was an Interventional, single blinded, randomized controlled efficacy trial.

Research Setting

The Kaumarabhritya outpatient department of Govt. Ayurveda college Hospital for Women and Children, Poojappura, Thiruvananthapuram, Kerala, India was the research setting.

Research Population

The prevalence of childhood asthma is said to be 10% in Thiruvananthapuram, Kerala. The children affected with Tamaka Swasa aged up to 12 years attending the outpatient department of Kaumarabhritya, Govt. Ayurveda College Hospital, Poojappura, Thiruvananthapuram, India was the research population.

Sampling

Simple random sampling technique using random number tables

Sampling Element

Children up to 12 years affected with Tamaka Swasa of mild to moderate degree.

Sampling Unit

Sampling unit was decided as children affected with Tamaka Swasa in different age group (0-4, 4-8, 8-12 years). Such a grouping was done to facilitate the required and effective dosage of the trial drug and to limit some of the assessment criteria feasible to the respective groups like spirometry in 8-12yr group to minimize inaccurate results.

Ethical Clearance

Prior to the research study ethical clearance was obtained from the ethical committee, Govt. Ayurveda College Thiruvananthapuram, India. The parents of the children who participated in the trial were explained about the

study and informed consents were obtained from them before they were being recruited in to the study.

Inclusion Criteria

Children up to 12 years presenting with clinical manifestations of Tamaka Swasa of mild to moderate degree were included in the study. Patients having suffered a minimum of two attacks of dyspnoea before were selected. Patients who were on occasional corticosteroid therapy were first managed with Ayurvedic medication for acute condition, advised to stop the steroid therapy and then considered for the study.

Exclusion Criteria

Children suffering from severe Swasa requiring emergency intervention such as status asthmaticus, Pneumonia etc and those children receiving long term corticosteroid therapy were excluded from the study. Diagnosed cases of tuberculosis were also excluded.

Duration of the study

Study was started in July 2005 and completed by November 2006.

Assessment Criteria

Both subjective and objective parameters were considered for the assessment of response to the treatment on signs and symptoms of Tamaka Swasa, number of recurrent attacks, assessment of clinical parameters, and quality of life assessment¹³ were given importance. Laboratory assessment included hematology for Hb%, total white blood cell count, total red blood cell count, differential count, erythrocyte sedimentation rate and absolute eosinophil count. Serological assessment for IgA and IgE and lung function tests for PEF, FVC, EFV1 and FEV1/FVC.

Technique of data collection

As per the inclusion criteria, the children suffering from Tamaka Swasa (asthma) were thoroughly interrogated, history and facts were noted in a specially designed clinical performa. It included perinatal history, family history, past illness, physical findings, clinical manifestations, treatment history and allergy history. To ensure sufficient accuracy, relevant data were collected by personal observation of salient features and relevant history that included environmental conditions of individuals, their characteristics such as age, sex, dietary habits, treatment or therapeutic procedures and responses of these individuals. The parents were asked to fill a quality of life questionnaire and to keep a daily assessment dairy so that the precision of data is fortified. Mechanical devices such as height, weight scale, measuring tape, and thermometer were used as aids in collection of data. Spirometry was carried out in the department itself by the investigator. The clinical qualitative parameters were graded and their variations were recorded by researcher only. Quantitative data relating to the routine haematology study and immunology in selected patients were collected from Advanced Clinical Research Laboratory, Medical College, Thiruvananthapuram, India. Owing high cost of the investigations, they were being carried out at a reduced charge, to ensure the maximum cooperation and participation of patients in the study. Very poor patients were investigated free of charges. Periodical assessment was done at an interval of one month. To check the

regularity of the patients and daily assessment record, children were dispensed medicine only for a period of two weeks and were asked to come with the records at the end of two weeks for a cross check and to obtain medication.

Treatment Schedule

As per the inclusion criteria, the selected 26 patients were then randomly allocated into study and control group by simple random sampling method. Vrisha Ghrita was given in study group while plain ghrita was used as control. Children were further divided in to 3 groups depending up on the age as 0-4 years, 4-8 years and 8-12 years age group. They received study or control drugs in a dose of

5ml, 10ml and 15ml respectively twice daily for a period of 3 months. Both groups were advised to follow some regulations strictly. The follow up period was 2 months.

Criteria for withdrawal

The children were allowed to have intervention for acute asthmatic attacks or withdraw from the study when the situation warranted.

Statistical Analysis

The observations made before and after treatment were considered for analysis. Statistical analysis was carried out using 'Z' test and paired 't' test.

Table 1: Effectiveness on Clinical Assessment under Different Treatment

	Group	BT			AT			Mean Diff.	Paired 't'	P
		Mean	SD	N	Mean	SD	N			
Breathlessness	Control	2.2	0.6	13	1	1.2	13	1.2	5.2	p<0.01
	Study	2	0.8	13	0.3	0.8	13	1.7	8.12	p<0.01
Audible wheezes	Control	2.3	0.5	13	1.2	1.3	13	1.1	3.74	p<0.01
	Study	1.9	0.8	13	0.4	0.8	13	1.5	8.4	p<0.01
Cough	Control	2.2	0.9	13	1.4	1.2	13	0.8	1.95	p>0.05
	Study	1.8	0.8	13	0.3	0.6	13	1.5	5.73	p<0.01
Discomfort	Control	1.8	1.2	13	1	1.2	13	0.8	2.67	p<0.05
	Study	1.8	1.1	13	0.3	0.9	13	1.5	5.28	p<0.01
Impact of activity	Control	1.3	1	13	0.8	0.9	13	0.5	2.52	p<0.05
	Study	1.6	1.2	13	0.5	1	13	1.2	2.56	p<0.05
Respiratory rate	Control	0.5	0.5	13	0.4	0.5	13	0.2	1.48	p>0.05
	Study	0.5	0.5	13	0.1	0.3	13	0.4	2.74	p<0.05
Chest expansion	Control	53.8	5.9	12	55.4	5.9	12	1.5	1.71	p>0.05
	Study	56.1	9	12	57.3	9	12	1.3	3.75	p<0.01
Total no of visit to doctor	Control	2.5	1.1	13	0.8	0.8	13	1.7	4.88	p<0.01
	Study	2.3	1.3	13	0.4	0.5	13	1.9	4.81	p<0.01

Table 2: Effectiveness on number of school absenteeism

	Group	BT			AT			Mean Diff.	Paired 't'	P
		Mean	SD	N	Mean	SD	N			
No. of school absenteeism	Control	24.2	12	10	14.7	11	10	9.5	3.9	p<0.01
	Study	17.7	8.5	10	6.7	8.7	10	11	7.49	p<0.01

Table 3: Effectiveness on immunoglobulin assessment under different treatment

Immuno globin	Group	BT			AT			Mean Diff.	Paired 't'	P
		Mean	SD	N	Mean	SD	N			
IGA	Control	175.6	137.6	8	145	84.1	8	30.6	0.79	p>0.05
	Study	126.8	69	10	132.7	60.2	10	5.9	0.36	p>0.05
IGE	Control	2085.4	1054	8	1811.3	926.3	8	274.1	1.55	p>0.05
	Study	1861.3	980.2	10	1802.1	1026	10	59.2	0.44	p>0.05

Table 4: Effectiveness on measures of morbidity assessment under different treatment

Group	BT			AT			Mean Diff.	Paired 't'	P
	Mean	SD	N	Mean	SD	N			
Control	8.5	4.2	13	5.6	5.6	13	2.9	4.53	p>0.01
Study	6.5	3.6	13	2.2	2.7	13	4.4	6.16	p>0.01

Table 5: Effectiveness on measures of quality of life assessment under different treatment

Group	BT			AT			Mean Diff.	Paired 't'	P
	Mean	SD	N	Mean	SD	N			
Control	25.2	6.9	13	18	5.6	13	7	3	p>0.05
Study	19.8	15.9	13	12	5.5	13	7.6	2.21	p>0.05

BT: Before Treatment, AT: After Treatment

Figure 1 :showing effectiveness on measures of morbidity assessment under different treatment

Figure 2 : showing effectiveness on measures of quality of life assessment under different treatment

RESULTS

The demographic data showed that majority the children participated in the study belonged to 4-8 year age group. A male preponderance was seen in the study (61.5%) as compared to females (38.5%). Increased incidence of asthma in children from urban area (76.9%) than from rural area (23.1%) is also consistent with the fact that the polluted environment and change in life style influence the increased incidence of asthma in children of urban area. Duration of illness revealed that a majority of children who attended the study (69.2%) had one year chronicity as compared to 30.8% of children with chronicity more than one year. In the present study precipitation of asthma and related symptoms were seen with different allergens. Dust in 76.9% of control and 69.2% of study group precipitated cold and sneezing while 69.2% and 61.55% in control and study group precipitated cough and dyspnoea. Exercise precipitated cough and dyspnoea in 61.5% of children in control group and dyspnoea 69.2% in study group. Incidentally there was precipitation of asthma related symptoms in 23.15% of children in control group and about 69.2% of children in study group. Among climates, Hemantha and Sisira ritu find highest incidence of asthma related symptoms (100%, 76.9% in study and 76.9%, 100% in control group respectively), Vasantha ritu (84.65% in control group and 61.5% in study group) while Pravrit had comparatively less incidence of asthma (46.2% in control and 38.5% in study group). This may be understood as hemantha, sisira and vasantha are the seasons when kapha undergoes chaya (accumulation) and prakopa (aggravation) which then obstruct the path of vata leading to manifestation of Swasa roga. In Ayurveda cold is considered as one of the precipitating factors for asthma. The high incidences of asthma related symptoms in cold seasons such as Hemantha and Sisira proves cold as a major precipitating factor while the Pravrit is considered as a relatively, healthy period when dosas maintain their homeostasis. Moreover autumn (Sharath) and winter (Sisira and Hemantha) are the seasons when viral infections trigger to cause patterns of autumn or winter asthma. While summer are generally free of symptoms.

Clinical assessments of a set of graded clinical symptoms that are frequently associated with asthma before and after treatment in study group are described in table 1.

Mean of number of school absenteeism was 24.2 ± 12.2 and 17.7 ± 8.5 in control and study group which after treatment changed to 14.7 ± 11.2 and 6.7 ± 8.7 respectively. The values were statistically significant ($p < 0.01$). The details of the data are given in the table 2.

In the present study substantial results could not be obtained with respect to pulmonary function tests.

Biochemical assessment showed marginal changes in parameters like Hb% (11.5 ± 0.9 to 11.7 ± 0.9), neutrophils (40 ± 8.7 to 40.8 ± 10.3), lymphocytes (50.8 ± 8.8 to 49.5 ± 9), Eosinophils (9.4 ± 3.4 to 8.6 ± 3) and absolute Eosinophils (868.2 ± 419.9 to 831.8 ± 295.6).

Marginal improvement noticed in Serology (immunoglobulin assay - IgA: 126 ± 69 to 132.7 ± 60.2 , IgE: 1861.3 ± 920 to 1802.1 ± 1026) indicate that the result was not statistically significant. (Table 3)

Measures of morbidity are considered good indicators of recurrent asthma exacerbations. They provide the total number of recurrent episodes and actual duration of sickness. Significant mean changes noted in both control and study group in number of attacks of recurrent respiratory symptoms 3 month before treatment and after treatment ($p < 0.01$), it indicates potential decrease in the recurrent episodes and the average sick period (Table 4; Figure 1)

Quality of life assessment showed significant results ($p < 0.05$) in both groups (Table 5; Figure 2)

DISCUSSION

Ayurveda gives much emphasis on maintenance of health. Hence Chikitsa (treatment) always includes Shamana (palliation) and Apunarbhava (prevention by rejuvenation) therapy. The idea behind Apunarbhava is to improve the resistance power to prevent the recurrence of the disease. Sneha (unctuous preparation) is considered to be superior in achieving this. It is more so applicable in children who are contraindicated for drastic treatment procedures. More over Sneha is the drug of choice for Oorjaskara Chikitsa (rejuvenation) in children. Asthma being commonest clinical concern in children known to have resulted in reduced resistance power. Hence Vrisha

Ghrita was selected as Swasa Hara drug which is also Apunarbhava Rasayana in its effect.

There was significant decrease noticed in the average duration of sickness, severity of each episodes and number of recurrent upper respiratory tract infections after the treatment with Vrisha Ghrita. These may be attributed to the specific Swasa Hara activity of the Vrisha Ghrita by reducing the inflammation in the bronchial tree and improving the Agni (Appetite).

In the present study substantial results could not be obtained with respect to pulmonary function tests. This could be either due to poor performance of the subjects in spirometry, instrumental error or even due to chronicity of the disease that requires a long term medication to get substantial difference. Biochemical assessment showed only marginal changes. This can be due to the reduced sample size and short period of study that could not bring up on complete cure of the disease. Moreover, hematological variation in asthma has to be considered as a part of the host defence consequence and hence much variation in these parameters cannot be expected before complete cure of the condition. The marginal variation obtained in the hematological parameters indicates that the Vrisha Ghrita has initiated the process of compensation.

In the present study significant results obtained in the measures of morbidity after treatment ($p < 0.01$). It indicates potential decrease in the recurrent episodes and the average sick period. There was significant decrease noticed in the average duration of sickness, severity of each episodes and number of recurrent upper respiratory tract infections after the treatment with Vrisha Ghrita. These may be attributed to the specific Swasa Hara activity of the Vrisha Ghrita by reducing the inflammation in the bronchial tree and improving the Agni.

Quality of life assessment showed significant results ($p < 0.05$) in both groups. This also gives an idea about the objective improvements in the day to day activities of the child and the degree of control of the disease in the view of the parents who are the immediate and close observers of the child suffering from asthma.

The major objective of the study was to assess whether Vrisha Ghrita can prevent the asthma exacerbations and recurrent respiratory infections. Statistically significant results in reduction in number of visits to the doctor ($p < 0.01$), school absenteeism ($p < 0.01$), night waking with cough ($p < 0.01$), day time and night time asthma ($p < 0.01$), loss of sleep ($p < 0.01$) and most importantly measures of morbidity ($p < 0.01$) indicated that Vrisha Ghrita is potentially effective in decreasing recurrent episodes of asthma and respiratory tract infections. The significant results related to clearing the vitiation of srotas in the study indicate the effectiveness of Vrisha Ghrita in resolving the pathogenesis (Srotorodham) of Tamaka Swasa in children. The significant changes noted in clinical symptoms such as breathlessness ($p < 0.01$), cough ($p < 0.01$), audible wheezes ($p < 0.01$) and related respiratory symptoms may be attributed to the Swasahara and Raktapithahara action of Vrisha Ghrita. This can be presumed as Vrisha Ghrita owing to its Raktapithahara action may cause vasoconstriction of the bronchial blood vessels (secretion of epinephrine and vasopressin

resulting in bronchial vasoconstriction) and hence brings about bronchio dilation due to stimulation of beta adrenergic function (Swasahara action) by reducing the excess pooling of secretions in the bronchial tree. This effect in turn leads to reduction in the inflammation of the bronchial smooth muscles. Thus this study proves that Vrisha Ghrita is effective in controlling Tamaka Swasa mainly because of its Swasa Hara (bronchodilator effect) and Raktapithahara (vasoconstrictor effect) properties rather than Vatahara (anticholinergic effect) and Rasayana (immunological effect) properties.

Control group also showed equally significant results which may be attributed to Rasayana effect of the Ghrita.

CONCLUSION

Preventing asthma exacerbations is one of the most important goals in asthma management. It represents a good indicator of the degree of overall disease control. The clinical trial proved the efficacy of Vrisha Ghrita in Tamaka Swasa by its presumed vasoconstrictive (Raktapithahara) and bronchio dilatory (Swasa Hara) effect. Pulmonary function tests and bio chemical assessment could not yield significant statistical results. The available data was not enough to prove the immunological activity of the Vrisha Ghrita. Risks of side effects were minimal in both the groups. To prove the significance of the Vrisha Ghrita over the control drug it may need a comparative trial in a large sample and to be documented.

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