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CLINICAL STUDY ON THE EFFECT OF PARNAYAVANI ARKA ON BRONCHIAL ASTHMA IN INDIAN CHILDREN

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ABSTRACT

Objective: To evaluate the effectiveness of nebulization and oral administration of Parnayavani arka on acute episodes of Tamaka Swasa (bronchial asthma) in children (6-12) years. **Materials and Methods:** Present single group study was done on 30 subjects of 6 to 12 years suffering from Tamaka Swasa. All subjects were administered with of 3ml Parnayavani arka every 4th hourly for oral and nebulization for a duration of 3 days. Assessment was done based on the changes seen in the signs and symptoms of Tamaka Swasa recorded with a specially prepared scoring pattern and Becker asthma scoring. Subjects who are known case of other chronic respiratory conditions like tuberculosis, cystic fibrosis or other acute illness that would complicate current treatment and response for asthma were excluded from the trial. **Result:** Treated children showed marked improvement in the signs and symptoms of Tamaka Swasa in the assessment tool Lakshanas of Tamaka Swasa and Becker asthma score. The changes were found statistically significant at p value less than 0.05. **Conclusion:** Nebulization

of Parnayavani Arka showed good improvement in children with Tamaka Swasa of mild to moderate severity.

Keywords: Tamaka Swasa, Nebulization, Parnayavani arka, children

INTRODUCTION

The respiratory infections are one among the common childhood disorders [1]. More than 30% of children are diagnosed with allergies, which are a major cause of respiratory problems [2]. Among these, asthma is one of the leading forms of the disease in children [3]. In school-age children, it is one of the main causes of school attendance, play activities, school performance, daily activities and the child's development due to repeated attacks of bronchial inflammation and spasm [4]. According to World Health Organization, an estimated 235 million people are living with asthma [5].

Bronchial asthma in childhood can be successfully treated with Ayurvedic medicine [6]. Parnayavani (*Coleus aromaticus* Benth.) has katu tikta rasa, laghu rooksha and tikshna guna, and has ushna virya and kapha vata hara karma. The nebulization and oral administration of the drug may cause the vilayana of the kapha due to the vyavayi and vikasi guna of the arka, when it is directly controlled in the respiratory system, thus purifying pranavahasrotas and proving its effectiveness in the vegavastha of Tamaka Swasa. The present study is designed to

evaluate the effectiveness of nebulization and oral administration of Parnayavani arka on acute episodes of bronchial asthma in children.

METHODOLOGY

Source of data: Subjects were recruited from the out-patient and in-patient departments of Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan district, Karnataka state.

Ethical consideration: Ethical clearance was obtained from the institutional ethics committee of Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan district, Karnataka state (IEC-SDM/IEC/65/2020).

Method of collection of data: Data was collected from subjects using specially prepared case report form with all the points of history taking, physical signs and symptoms examination of Tamaka Swasa and investigations.

Diagnostic criteria: Diagnosis was made on the basis of Lakshanas of Tamaka Swasa and the subjects with the signs of acute exacerbation in bronchial asthma were included in this study like breathlessness, wheeze, chest tightness, cough and sputum production.

Table 1: showing diagnostic criteria based on Lakshanas of Tamaka Swasa [7]:

Cardinal features	Associated features	Aggravating/Relieving factors
Swasakrichrata	Kasa	Aseeno labhate saukhyam
Gurghuraka	Kantodhwamsa	Megha-Ambu-Sheetapragvata-Shleshmalaishca abhivardhate
Krichrabhashana	Peenasa	Shleshmanyamokshante bhrisham bhavati dukhita
	Nidranasha	Na nidram labhate shayanah - Aseeno labhate saukhyam
	Parshvagraha	Megha-Ambu-Sheetapragvata-Shleshmalaishca abhivardhate
Two cardinal features including Swasakrichrata, one associated feature and one aggravating/relieving factor will confirm the diagnosis of Tamaka Swasa.		

Inclusion Criteria:

1. Children with mild to moderate exacerbation of asthma.
2. Children of age group 6-12 years, irrespective of gender.
3. Parents who were consciously willing to participate their children in the study and ready to sign the informed assent form.

Exclusion criteria:

1. Children with life threatening asthma detected by presence of any of the following:
 - Cyanosis
 - SpO₂ < 90
2. High grade fever
3. Children who are known case of other chronic respiratory conditions like tuberculosis, cystic fibrosis or other acute illness that would complicate current treatment and response for asthma.

Study Design: Open labelled single arm clinical study

Intervention: Subjects with acute exacerbation were diagnosed and the clinical study was done for three days.

Nebulization with Parnayavani arka was administered to the included subjects. The signs and symptoms were assessed with Becker Asthma score before and after each oral and nebulization, every 1st hourly till first 4 hours, 4th hourly till 8 hours and later every 8th hourly for a total of 13 times by PEFr readings before the initial and after the final nebulization. After the study period, on the third day, subjects were administered with suitable medications depending on the improvement which will not be considered for the study.

Sampling Method: Convenience sampling method.

Collection of raw drugs and authentication: The raw drugs were collected from the herbal garden of Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan district, Karnataka state and validated at the Department of Dravyaguna, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan district, Karnataka state.

Preparation of medicine

The medicine was prepared at teaching

pharmacy of Department of Rasa shastra and Bhaishajyakalpana, Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan district, Karnataka state. The preparation of Arka was done based on the method of Arka preparation as explained in Arka Prakasha. To one part of well pound leaves of Parnayavani, three parts of water was added and was continuously heated in Arka Yantra (distillation apparatus) till 60% of distillate was collected. After cooling, the collected Arka (distillate) was filtered and preserved in an air container.

Dose: 3ml of the Arka for nebulization and oral every 4th hourly.

Route of administration: Nebulization (Oro-nasal) and Oral

Study duration: 72 hours

Follow up: 7 Days (for relapse of acute exacerbation)

Assessment criteria:

Assessment of the effect of treatment will be done based on the changes observed in following subjective and objective parameters of Tamaka Swasa.

A. Lakshanas of Tamaka Swasa [8]:

Following parameters will be graded by using suitable scoring system.

1. Swasakrichrata
2. Gurghuraka
3. Krichrabhashana
4. Kasa
5. Nidranasha
6. Parshvagraha

7. Peenasa
8. Kantodhwamsa
9. Shushkasyata

Becker Asthma Score [9]: Changes seen in the Becker Asthma Score will be noted during each assessment points.

Score ≤ 4 – mild

Score >4 to <7 – moderate

Score ≥ 7 – severe

Objective parameters:

- Peak Expiratory Flow Rate

The assessment will be done for two times, i.e. before the initial nebulization on the first day and after the final nebulization on the third day.

OBSERVATIONS

Among the 33 participants recruited the trial, maximum numbers of participants i.e. 18 of them were of the 10 to 12 year category and 15 were of 6 to 9 year category. The study revealed that maximum numbers of participants were boys (n=22) and the rest 11 were girls. Majority of the participants recruited for the study were from the upper middle class (n=17) 2 from upper class, 6 from upper lower class, 3 were from lower middle class and 5 from lower class. 32 participants presented with wheezing, 32 with breathlessness in attack, 30 with cough, 29 with shortness of breath, 26 with tightness of chest, 4 with discomfort in lying down and 3 with sleep disturbances in lying down. In 27 participants, the symptoms got

aggravated by cold water, 25 by dust and smoke, 14 from winter, 17 from dietary habits, 11 from exercise and 8 from pollen. The relieving factors wise distribution showed that maximum number of participants got relief with hot water/fomentation (n=29), followed by rest (n=11), sitting posture (n=4), change of climate (n=14), nebulization (n=17), other medications (n=8). History of recurrent respiratory tract infections was present in 29 subjects. The majority of the participants i.e, 19 patients had a positive family history. 15 participants had sama agni, 8 had vishama agni and 10 had manda agni. 21 participants were having Madhyama Koshta, 4 participants and 8 participants were having Krura and Mrudu Koshta respectively.

RESULTS AND DISCUSSION

The result of friedman's test on effect of Parnayavani arka on Swasakrichrata, Gurghuraka, Krichrabhashana, Kasa, Nidranasha, Parshvagraha, Peenasa, Kantodhwamsa, Shushkasyata, respiratory rate, wheezing, I/E ratio, accessory muscle use are detailed in **Table 2**. The result of wilcoxon signed rank test on effect of Parnayavani arka on Swasakrichrata Gurghuraka, Krichrabhashana, Kasa, Nidranasha, Parshvagraha, Peenasa, Kantodhwamsa, Shushkasyata, respiratory rate, wheezing, I/E ratio, accessory muscle use are detailed in **Table 3**. The result of paired t test on effect of Parnayavani arka on PEFr is detailed in **Table 4**.

Table 2: showing friedman's test on effect of Parnayavani arka on parameters

Parameters	Mean Rank	N	CHI SQUARE	p value	Remarks
Swasakrichrata BT	8.83	30	225.957	0.001	S
Swasakrichrata AT	1.88				
Gurghuraka BT	8.85	30	236.614	0.001	S
Gurghuraka AT	1.83				
Krichrabhashana BT	8.65	30	214.048	0.001	S
Krichrabhashana AT	2.13				
Kasa BT	8.57	30	229.394	0.001	S
Kasa AT	2.28				
Parshvagraha BT	8.13	30	172.823	0.001	S
Parshvagraha AT	3.05				
Peenasa BT	5.58	30	9.000	0.001	S
Peenasa AT	5.42				
Kantodhwamsa BT	5.67	30	10.731	0.001	S
Kantodhwamsa AT	5.42				
Shushkasyata BT	5.75	30	21.304	0.001	S
Shushkasyata AT	5.17				
Respiratory rate BT	9.03	30	233.499	0.001	S
Respiratory rate AT	1.78				
Wheezing BT	8.47	30	197.631	0.001	S
Wheezing AT	2.47				
I/E ratio BT	8.75	30	192.959	0.001	S
I/E ratio AT	2.13				
AMU BT	8.85	30	192.959	0.001	S
AMU AT	2.13				

Table 3: showing wilcoxon signed rank test on effect of Parnayavani arka on parameters

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	Remark
	N	MR	SR	N	MR	SR					
Swasakrichrata BT and AT	0	0.00	0.00	30	15.50	465.00	0	30	-4.927	0.001	S
Gurghuraka BT and AT	0	0.00	0.00	30	15.50	465.00	0	30	-4.928	0.008	S
Krichrabhashan aBT and AT	0	0.00	0.00	29	15.00	435.00	1	30	-4.818	0.001	S
Kasa BT and AT	0	0.00	0.00	28	14.50	406.00	2	30	-4.770	0.000	S
Nidranasha BT and AT	0	0.00	0.00	5	3.00	15.00	25	30	-2.041	0.041	S
Parshvagraha BT and AT	0	0.00	0.00	23	12.00	276.00	7	30	-4.320	0.000	S
Peenasa BT and AT	0	0.00	0.00	1	1.00	1.00	29	30	-1.000	0.317	NS
Kantodhwamsa BT and AT	0	0.00	0.00	1	1.00	1.00	29	30	-1.000	0.317	NS
Shushkasyata BT and AT	0	0.00	0.00	3	2.00	6.00	27	30	-1.633	0.102	NS
Respiratory rate BT and AT	0	0.00	0.00	30	15.50	465.00	0	30	-4.920	0.001	S
Wheezing BT and AT	0	0.00	0.00	27	14.00	378.00	3	30	-4.638	0.001	S
I/E ratio BT and AT	0	0.00	0.00	29	15.00	435.00	1	30	-4.802	0.001	S
Accessory muscle use BT and AT	0	0.00	0.00	28	14.50	406.00	2	30	-4.744	0.001	S

Table 4: showing paired t test on effect of Parnayavani arka on PEFR

Parameter	Mean	Std devn	Std error	95% confidence interval of the differences		t	df	p value	Remark
				Lower	Upper				
PEFR BT and AT	-70.333	24.138	4.407	-79.347	-61.320	-15.960	29	.001	S

Mode of action of Parnayavani Arka on Tamaka Swasa

The two main components in Parnayavani are Thymoland Carvacrol [10]. Thymol is a naturally occurring monocyclic phenolic compound found in Parnayavani, which has many recorded antioxidant, antispasmodic and anti-inflammatory effects [11]. Carvacrol is a phenolic monoterpene known as tracheal smooth muscle relaxant. It has also been shown to selectively reduce the release of IL-4 (a cytokine that is a inflammatory mediator

released by Th2 helper cells), while stimulating the release of INF-gamma (interleukin which naturally counteracts the action of inflammatory mediators, produced by Th1 helper cells). Double-blind clinical study of Carvacrol in asthma patients has been shown to improve LFTs, and reduce subjective barriers to asthma such as dyspnoea and asthma, as well as objective parameters such as infiltration of inflammatory cells into the airways [12]. Therefore, when giving a liquid distillate of the drug through nebulization - directly

targeting the respiratory tract and lungs, rapid relief is seen due to its anti-inflammatory and bronchodilator action. In Tamaka Swasa, there is the Vata Avarana of Kapha [13]. So in this case, Vata is in Moodavastha. Parnayavani Arka causes Kapha Vilayana, because of the Teekshna, Ushna and Laghu Gunas, which removes the Avarana of Kapha. As Vata reaches its Prakrutavastha, and resumes its normal course at Pranavaha Srotas, the patient finds relief in Swasakrichata.

CONCLUSION

The study concludes that Parnayavani arka at a dose of 3ml every fourth hourly for nebulization and oral administration for 3 consecutive days was effective in Vegavastha of Tamaka Swasa.

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