

Clinical Study

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An Open Clinical Trial on Hingwadichoorna in the Management of Tamakaswasa W.S.R to Bronchial Asthma in Children

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ABSTRACT

An open clinical trial was conducted to evaluate the efficacy of Hingwadichoorna on acute attack of Bronchial Asthma in children at SDM College of Ayurveda & Hospital, Kuthpady, Udupi. The trial was conducted on 34 patients, Hingwadichoorna was given in children of age group of 5years to 9yrs 11 months. The medicine was given 6th hourly in a 4 divided dose per day for 7 days and with a follow up of 14 days. The response was assessed using various clinical, quantitative parameters and analyzed statistically using paired't' test and Wilcoxon Signed Rank Test. Statistically significant results obtained in subjective parameter and peak expiratory flow rate and hemoglobin, AEC. Study showed Hingwadichoorna is effective in combating the signs and symptoms of Tamakaswasa.

Keywords: Tamakaswasa, Hingwadichoorna, Children, Bronchial Asthma, Shamanaushadhi.

INTRODUCTION

Kaumarabhritya is one among Ashtanga Ayurveda which deals with children where it has been given importance like Agnidevata ^[1]. Balyavastha is stage where predominance of Kaphadosha, Aparipakwadhatu and Asampurnabala ^[2] which makes children more prone to diseases.

Respiratory system is continuously in contact with the external environment since birth. It is most vulnerable to infections and considered as prime victim of hyper sensitization in most of the circumstance. 14% of world's children experience Asthma symptoms [3]. The peak incidence of Bronchial Asthma is seen in 5-10yrs of age group [4]. It is responsible for significant social, economic and psychological impact on family. Acute Asthma leads to disturbed sleep, restricted day to day activities and school absenteeism [5].

Pathological stipulation of Pranavahasrotas leads to manifestation of the disease named Swasaroga. Tamakaswasa is having its own etiology, pathology, management and is said to be sadhya ^[6]. The predominant morbidity of Vata and Kaphadosha, stemming out from Pittasthana affecting Rasadhatu, disturbing the functions of Pranavahasrotas, these pathological events collectively leads to occurrences of Tamakaswasa. In Ayurvedic classics mentioned about many ShamanaAuoshadi as it normalizes the aggravated Doshas ^[7]. Oral administration of Shamana drugs in the form of Choorna is of utmost importance to combating the signs and symptoms of Tamakaswasa in acute condition. Hence, Hingwadichoorna ^[8] is one of the formulation mentioned in the classics to control the Tamakaswasa and was taken as trial drug.

MATERIALS AND METHODS

Selection of cases: Patients having signs and symptoms of Tamakaswasa were selected from the Kaumarabhritya OPD and IPD of SDM Ayurveda College and Hospital, Kuthpady, Udupi, after detailed history taking on the basis of specially prepared proforma.

Inclusion criteria

- Patients of either sex.
- Patients between the age group of 05 to 9yrs 11month.
- Patients with Ghurghurka(wheeze) and any two or more symptoms described in the context of Tamakaswasawereselected.

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Exclusion criteria

- Patients with severe exacerbation and status asthmatic who require immediate intervention were excluded.
- Patients of Tamakaswasa associated with other systemic disorders.
- Tamakaswasa as Anubandhalakshana(associated feature) and Tamakaswasa as Upadrava in other diseases like Rajayakshama, Udara, Hridroga etc.
- Patients with history of congenital anatomical abnormalities of chest and respiratory system.

Method of study

- Study design: An Open label Clinical Trial
- Group: Single group of 30 patients received the trial drug Hingwadichoorna

Plan of intervention

- Dosage form: Choorna
- Dosage: Fixed as per Acharya Yogaratnakara- 5yr-6yrs = 5 Masha (5gm), 6yrs-7yrs = 6 Masha (6gm), 7yrs-8yrs = 7 Masha (7gm) 8yrs-9yrs = 8 Masha (8gm), 9yrs-9yrs11month = 9 Masha (9gm).
- Time of administration: In four divided dosage (6thhourly) after food, given with Madhu as Anupana
- Duration of treatment: 7days
- Follow up: 14 days
- Total duration of the study: 21 days

Table 1: Showing the ingredients of Hingwadichoorna

SI. No	DRUG	PART USED	QUANTITY
1.	Hingu (Ferula asfoetida Linn.)	Latex	½ Part
2.	Sauvarchalavana(Unaqua sodium chloride)	Crystal	1 Part
3.	Samanga (Rubiacardifolia Linn.)	Root	1 Part
4.	Pippali (Piper longum Linn.)	Fruit	1 Part
5.	Bala (Sidacardifolia Linn.)	Root	1 Part
6.	Kola(Zizyphusjujuba Mill.)	Fruit	1 Part

Preparation of Hingwadichoorna

Hingwadichoorna prepared ^[9] and standardized ^[10] at SDM Ayurveda Pharmacy and SDM Centre for Research in Ayurveda and Allied Sciences, Kuthpady, Udupi, Karnataka respectively.

Assessment criteria

Subjective criteria

 Ghurghurka (wheeze), Kasa, Peenasa, Aaseenolabhatesaukyam (Comfortable in sitting position), Vishushkasyata (Dryness of lips and throat).

Objective criteria

Forced peak expiratory volume (F.P.E.V)

Lab Investigations

- Hemoglobin percentage
- Total Leukocyte Count
- Erythrocyte Sedimentation Rate
- Absolute Eosinophil Count

Statistical Evaluation

Statistical analysis was carried out using the software SPSS 20.0.The frequency calculations along with parametric and non-parametric test procedure had been performed. Parametric data within the group (Excomparison between BT, AT and FU) were tested with paired't'test, regard to significance. Wilcoxon Signed Rank test (non-parametric) was used for subjective criteria, with P value <0.05 was considered as statistically significant, P value 0.000 or 0.001 were considered as highly significant and P value > 0.05 was not significant.

Ethical clearance

This trial has been cleared by Institutional Ethical Comities, Reference Number. SDMCAU/ACA-49/ECA26/15-16

OBSERVATION AND RESULTS

Table 2: Showing an observation of 34 patients related to Demographic data and Disease

Observation	Maximum incidence	Percentage		
Age	7-9 yrs	26.5%		
Gender	Male	55.9%		
Religion	Hindu	88.2%		
Informant	Mother	67.6%		
Schooling	3 rd and 5 th standard	23.5%		
Kuppuswamy socio-economic scale	Upper-middle	55.9%		
Residential area	Rural	44.1%		
Immunization	Followed	97.1%		
SharireekaPrakruti	Pitta-Kapha	58.8%		
ManasikaPrakruti	Raja	50.0%		
Vikruti	Vata-Kapha	100%		
Sara	Madhyama	70.6%		
Samhanana	Madhyama	79.9%		
Pramana	Madhyama	88.2%		
Satmya	Sarvarasa	50.0%		
Satwa	Madhyama	85.3%		
Aharashakti	Madhyama	61.8%		
Vyayamashakti	Madhyama	76.5%		
Mode of onset	Episodic	53.3%		
Time of occurrence	Night	40%		
Proceeding factor	Wheeze	60%		
Reliving factor	Nebulization	50%		
Aggravating factor	Dietary habits	30%		
History of past illness	RRTI	85.3%		
Family history	Asthma	47.1%		
Appetite	Moderate	88.2%		
Bowel	Kroorakostha	100%		
Micturition	Normal	100%		
Sleep	Disturbed	91.2%		
Habits	Freeze food	85.3%		
Pets at home	Dogs	55.9%		
Mode of delivery	Normal vaginal delivery	50.0%		
Birth weight	>2.500gms	76.5%		

RESULTS

 Table 3: Showing the statistical analysis of subjective parameters (Wilcoxon Signed Rank Test)

Parameter	Z value		P value		Inference	
	AT-BT	FU-BT	AT-BT	FU-BT	AT-BT	FU-BT
Swasakricharata	4.583	4.636	0.000	0.000	HS	HS
Ghurghuraka	3.382	3.999	0.001	0.000	HS	HS
Muhuswasa	3.900	4.320	0.000	0.000	HS	HS
Duration of symptoms	5.303	4.835	0.000	0.000	HS	HS
Tasyevavimokshantemuhurthamlabhatesukham	2.814	4.093	0.005	0.000	Significant	HS
Pramoha	1.732	1.732	0.830	0.830	NS	NS
Peenasa	3.272	3.888	0.001	0.000	HS	HS
Kasa	3.442	4.580	0.001	0.000	HS	HS
Jwara	3.015	3.500	0.002	0.000	Significant	HS
Vishushakaasyata	2.183	3.345	0.029	0.001	Significant	HS
Kanthodhwamsa	0.905	3.216	0.366	0.001	NS	HS
Pranaprapeedana	2.000	3.546	0.460	0.000	NS	HS
Assenolabhatesukyam	1.728	3.743	0.840	0.000	NS	HS
Na cha apinidralabhateshayanaha	2.995	4.395	0.003	0.000	Significant	HS
Uraparshwashoola	3.357	3.906	0.001	0.000	HS	HS

Table 4: Showing the statistical analysis of objective parameters (Paired't' test)

Parameter	Data	Mean %	M.D	Paired 't' test				Inference
	•			SD	SE	T value	P value	
Weight	BT-AT	0%	0.3800	1.87569	0.3424	1.110	0.276	
	BT-FU	4.21%	1.4300	4.85856	0.8870	1.612	0.118	NS
Chest expansion	BT-AT	34.5%	0.7666	0.5683	0.1037	7.389	0.000	
	BT-FU	36.3%	0.8000	0.6102	0.1114	7.180	0.000	HS
Peak expiratory flow rate	BT-AT	22.07%	.56667	0.5040	0.0920	6.158	0.000	
	BT-FU	48.06%	1.233	0.6789	0.1239	9.950	0.000	HS
Respiratory rate	BT-AT	28.11%	0.600	0.5632	0.1028	5.835	0.000	HS
	BT-FU	46.89%	1.000	0.6432	0.1174	8.515	0.000	

 Table 5: Showing the statistical analysis of Laboratory Investigation (Paired't' test)

Parameter	Data	Mean%	M.D	Paired 't' test				Inference
	•			SD	SE	T value	P value	
Hemoglobin	BT-AT	3.56%	43867	59821	10922	4.016	0.000	HS
Total leucocyte count	BT-AT	22.18%	2167	8.14648	4.2674	0.810	0.424	NS
Neutrophils	BT-AT	0.057%	0.0333	9.21574	1.68256	0.020	0.984	NS
Lymphocytes	BT-AT	2.70%	0.9666	8.31070	1.51732	.637	0.529	NS
Eosinophils count	BT-AT	11.69%	0.6666	1.98847	36304	1.836	0.077	NS
Monocytes	BT-AT	14.8%	0.1333	0.5713	0.1043	1.278	0.211	NS
ESR	BT-AT	9.74%	2.066	9.87485	1.80289	1.146	0.261	NS
AEC	BT-AT	13.4%	54.53	104.3801	¹⁹ .05713	2.862	0.008	Significant

DISCUSION

Discussion on Tamakaswasa (Bronchial Asthma)

Tamakaswasaaggravates during the unfavourable conditions and causes discomfort to the patients. The Doshas involved in the evolvement of Tamakaswasa are AvalambhakaKapha,Prana, Vyana, UdanaVata. It may be considered that the VataDosha present in Urdvashareera, Hridaya andUras are the functioning units of Pranavahasrotas. In the initial stage of Tamakaswasa, Sanga is seen and as the Kriyakala advances Vimarggamana develops. If the clinical features are considered, Atipravrutti is the major SrotodustiPrakara.

Chronic inflammatory disorder of lower airways characterized by recurrent episodes of variable, reversible airflow obstruction and airway hyper-responsiveness manifested as a recurrent wheeze and cough [11]. Intrauterine exposure, viral infection, diet, air pollution, genetics, endocrine factors are contributing for to cause the Asthma [12].

Discussion on observation related to disease

In the study, it was found 53.3% patients had episodic onset, which shows the nature of the disease. In 40% patients, time of occurrence was at night, because of pooling of mucous into the respiratory tract nature of disease which aggravate during night hours initial pathology attributed to the bronchospasm making the airflow obstruction.In Ayurveda, night is considered as Tamas predominant and Kapha Kala, hence attack of Tamakaswasa is seen more during the night hours. 60% patients, wheeze was a preceding factor, wheeze is cardinal sign of Asthma [13]. 50% patients reported nebulization as relieving factor it suggests that nebulization with improvement (12-15%) is highly suggestive of reversible airway obstruction in asthma [14]. 85.3% patients had a history of RRTI, research study showed upper respiratory tract infection triggers Bronchial asthma [15], 47.1% patients had familial allergy and genetic factor was responsible, the positive family history suggests genetic influence present in the parents which is responsible for producing abnormal amounts of IgE in response to exposure to environmental allergens [16]. 100% patients were of Kroorakostha, this might be due to the pratilomagati of Vata. 55.9% patients had dogs as a pet at home, research studies have shown increased incidence of bronchial asthma with patients having dogs as their pet [17].

Discussion on results

The clinical trial revealed the efficacy of Hingwadichoorna in controlling the symptoms of respiratory system by virtue of its Kaphara and Vatanulomana properties. Pippali being Kaphara and Kasa hara, it relieves bronchospasm and expels the mucous out of the respiratory system. Piperine in Pippali acts as bronchodilator, by which it dilates the constricted bronchioles and there by reduces Swasakrichrata, Muhurshwasa, Ghurgurata. It has been proven that Pippali andBadara acts as anti-inflammatory [18] by which it can be assumed that it reduces the inflammation in respiratory system and reduces the pooling of the mucous, which is evident in significant results in Kasa and Ghurghurata. Anti-spasmodic property of Pippali, Hingu and Bala helps in reducing the pain, therefore significant reduction in Pranaprapeedana andAssenolabhatesaukyam were observed. Vascine andvasicinone which is present in Bala [19] is known for its smooth muscle relaxing effect, thereby it reduces the bronchospasm and normalises the bronchioles for breathing, reduction in the inflammation of bronchial

smooth muscle; whichreduces the Duration of symptoms that facilities the easy ventilation in short time. Significant change in Tasyevavimokshantemuhurthamlabhatesukhamthis might be because LaghuGuna of Hingu, Souvarchalavana, Pippali and Matulunga does the Lekhanakarma and mucolytic action of Pippali and Sauvarchalalavana helps in reducing sticky sputum and expels its out, thereby reduces the mucous. There was relief from Peenasaas Choorna is having Ushna, TeekshnaGuna andKaphahara action along with madhu as anupana that results in releasing hyper secretion in nasal mucosa. Significant changes in Jwarashows the ability of the drug in reducing the inflammation andcontrolling the symptoms. Significant changes were found in Kanthodhwamsaas the trial drug is mucolytic and has soothing effect on throat. This might be because UshnaVirya, KatuVipaka of Samanga and Hingu. Significant changes in the Na cha apinidralabhateshayanaha shows the ability of the trial drug in relieving the symptoms of acute attack of bronchial asthma, thus making patient to sleep comfortably. This might be becauseUshnaViryaof Hingu, Souvarchalavana, Samanga, Matulunga are breakdown the obstructed Kapha and reduce the intensity of cough. Significant changes in Uraparshwashoola shows the efficacy of trial drug in relieving the bronchospasm there by reducing the respiratory rate and involvement of accessory muscle of respiration.

No significant result on parameter of Pramohamight be due to only 3 patients had complaints so, much difference was not noticed.

Significant results on Peak expiratory flow rate shows the ability of the drug in reducing the pathology by bronchodilation, smooth muscle relaxation and expectorant thus helping the patient to breath for maximum capacity. Changes in Chest expansion might be due to increased peak expiratory flow rate helps in the expiratory capacity of the lungs and allowing the lungs to inflate to its maximum limit.Respiratory ratethis might be because vasoconstriction and bronchodilator activity of Hingwadichoorna, which reduces excess pooling of mucous into the bronchial tree making the airflow easy.

No significant results were observed on parameter of Weight because of shorter duration of the study.

Significant improvement was on served in Haemoglobin which might be because of action of the drug but the sample size is not adequate to comment on this.Reduction in Absolute eosinophil count this might be because decreased in the magnitude of allergy shorter duration of treatment. No significant results on parameter of Total leucocyte count (Neutrophils, Lymphocytes, Eosinophils and Monocytes) this might be because Hingwadichoorna works in the early phase of Bronchial Asthma.No significant results on parameter of Erythrocyte sedimentation rate this might be very minimal action of Hingwadichoorna combating the infection in a shorter duration of treatment.

CONCLUSION

Tamakaswasa is related to Pranavaha, Annavahaand Udakavahasrotas. It is dominant of Prana Vayu with amalgamation of Kaphadosha and it is PittastanaUdabhava disease. Bronchial Asthma is a most common chronic inflammatory disorder of lower airway in children, with a variety of symptoms those are variable, intermittent, worse at night. In Tamakaswasa the aggravated Kapha and VataDosha plays a major role in causing Sthanasamshraya in the Pranavahasrotas, where in the VrudhaKapha gets accumulated and causes obstruction to the normal

movement of PranaVata, which ends up in Pratilomagati of Vata producing the Lakshanas of Tamakaswasa. After analyzing the Hingwadichoorna the clinical trial has proved that it gives symptomatic relief in Tamakaswasa. Due to Vata-Kaphahara, UshnaVirya, Vatanulomana, Bronchodilator, Smooth muscle relaxant, Anti-inflamatory, anti-allergic properties of Hingwadichoornadoesthe Sampraptivighatana. Also statistical datasupported that Hingwadichoorna gives a better relief in acute condition of bronchial asthma; which is also supported by Peak expiratory flow rate and minimal change in TC, ESR and AEC. Henceforth it is concluded from the clinical trial that Hingwadichoorna is effective in treating the disease Tamakaswasa of 5- 9yrs 11month of agegroup.

ABBREVATION

AEC- Absolute eosinophil count

ESR- Erythrocyte sedimentary rate

HS- Highly significant

NS- Non significant

M.D- Mean difference

S.D- Standard deviation

S.E- Standard error

TC- Total count

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