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An Appraisement of Efficacy of *Shirish Twak Churna* in the Management of Childhood Bronchial Asthma – A Clinical Study

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ABSTRACT

Asthma is the most common chronic illness of the childhood. It is not different from that of adult but children face unique challenges. The condition is a leading cause of emergency department visit, hospitalization and missed school days. It can be difficult to tell whether a child's symptoms are caused by asthma. Periodic or long lasting wheezing is other asthma like symptoms that can be caused by infectious bronchitis or other respiratory problems. Unfortunately, childhood asthma can't be cured and symptoms can continue into adulthood but with right treatment symptoms can be kept under control and damages of growing lungs can be prevented. The modern medicine used for the management of chronic bronchial asthma may cause adverse effects, without complete cure but through Ayurveda, its treatment is possible without any adverse effect. In ayurveda chronic bronchial asthma can be considered as a type of *Shwas roga* i.e *Tamak Shwas*. The management of *Shwas roga* should comprise of drugs possessing *Ushna, Vatanulomak, Vata-kapha shamak, Amapachak, Srotoshodhak, Kapha nissarak* properties. By considering these fact the study shows the role of *Shirish twak churna* in the management of childhood bronchial asthma which have been performed clinically at 20 patients who included in trial on the basis of PEFR. The drugs were given in the dose of 120 mg/kg bd with honey for the duration of 45 days. According to subjective and objective criteria the study shows the statistical significant results.

KEYWORDS

Tamak Shwas, Chronic illness, Long lasting wheezes, PEFR

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INTRODUCTION

Asthma which is the most common chronic illness of the childhood is also the most frequent cause for visits to paediatricians. Around 74% of asthma episodes are experienced in children less than 5 years of age and 26% in less than one year of age. It causes negative effect on children during their critical periods of growth and development. It is also responsible for a significant loss of school days. Despite better knowledge of its patho-physiology childhood asthma continues to be under diagnosed and untreated. The prevalence of childhood asthma is still increasing. The increasing prevalence of asthma has been contributed by hygiene theory, dietary habits, western life style of living and air pollution[1-2].

"Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular element play role, the chronic inflammation is associated with air way hyper responsiveness that leads to recurrent episodes of wheezing breathlessness, chest tightness and coughing particularly at night or in the early morning. These episodes are usually associated with wide spread but variable air flow obstruction within the lung that is often reversible either spontaneously or with treatment[3-4].

According to the modern medicine, its management includes bronchodilators, mast cell stablizers, leukotriene modifying agents, antihistaminics and corticosteroids apart from avoidance of allergens but these medicines are mostly associated with many adverse effects like tremors, tachycardia, hypokalemia, restlessness, reflex coughing, sedation, weight gain, oral thrush, dysphonia, growth suppression etc. In spite of all these adverse effects these drugs are used but they are not capable of curing this notorious disease completely. Ayurveda has unique concept of managing diseases. Ayurvedic drugs do not cause such harmful effects but increases immunity of the body. On basis of clinical symptomatology bronchial asthma appears very close to *Tamak swasa* described in *Ayurveda litratures*[5-8].

The management of *Shwas roga* should comprise of drugs possessing *Ushna, Vatanulomak, Vata-kapha shamak, Amapachak, Srotoshodhak, Kapha nissarak* properties[9]. So considering these facts, a clinical study on the role of *Shirish twak churna* in the management of bronchial asthma in children has been planned.

AIMS AND OBJECTIVES OF THE RESEARCH WORK -

a. To study the efficacy of *Churna* of *Shirish (Albizzia lebbeck) twak* in the management of *Tamak swasa*.

b. To establish a safe and cost effective medicine for the treatment of *Tamak swasa*.

c. To study the other associated effects of the trial drugs if any.

MATERIALS AND METHODS

SELECTION OF CASES:

❖ ***Source of patients:*** Patients were selected from OPD and IPD, Department of *Kaumarabhritya*, R.G.G.P.G. Ayurvedic Hospital Paprola, Himachal Pradesh.

❖ ***Age group:*** Children between 3 to 10 years were included in the study.

❖ ***Number of cases:*** Total 22 cases were registered out of which 2 children discontinued the treatment during the course.

TRIAL DRUG:

Shirish twak churna was selected for the present study. Drug was given with *Madhu* in order to enhance its palatability in children.

DOSES AND DURATION:

Patients in a single group were managed with *Shirish (Albizzia lebbeck) twak churna* 120mg/kg BD with *Madhu* for duration of 45days.

INCLUSION CRITERIA:-

1. Patients/Guardian willing to participate in the trial.
2. Age between 3-10yrs (school going children).
3. Only stable cases of Bronchial Asthma (as per WHO GINA guideline) for at least 6 weeks prior to study entry.
4. Positive test of reversibility

❖ Symptomatic patients–as improvement of 20% in PEFR, 10 minutes after inhalation with Salbutamol.

❖ Asymptomatic patients – 20% fall in PEFR by provocation with 5-10 minutes of physical exercise, followed by reversal upon inhalation with Salbutamol, when assessed after 10 minutes.

EXCLUSION CRITERIA:-

1. Patients unwilling to participate in the trial.
2. Patients presenting with systemic illness necessitating long term drug treatment (Tuberculosis etc.)
3. Children with congenital anomalies.
4. Patients with PEFR < 50%.
5. Patients on prolonged (>6 weeks) medication with corticosteroids, bronchodilators, mast cell stabilizers, anticholinergics etc.
6. H/o hypersensitivity to the trial drug.

ASSESSMENT CRITERIA

Assessment of effects of the therapy was done on the basis of various subjective and objective criteria. Patients were thoroughly assessed during the trial period after every fifteen days.

Objective Criteria of Assessment:

Patients were assessed biochemically and haematologically on parameters like Hb gm%, TLC, DLC, ESR, AEC, SGOT, SGPT, Blood Urea, Serum Creatinine, Serum bilirubin. Patients were also assessed on basis of PEFR.

Method of assessment:-

Prior to Selection (Screening)

a. Informed consent
b. Eligibility evaluation
c. Physical examination
d. Laboratory investigation
e. Measurement of PEFR

During Selection (Baseline)

a. General information (Personal identification and demographic profile)
b. Medical history, general physical and systemic examination.
c. Measurement of PEFR
d. Instruction to come after 15 days.

During treatment

a. Assessing drug compliance
b. Physical examination and clinical assessment.
c. Measurement of PEFR
d. Issue of drug
e. Instruction to come after 15 days.

After treatment

a. Assessing drug compliance.
b. Physical examination and clinical assessment.
c. Measurement of PEFR
d. Laboratory investigation
e. Instruction to come after 4 weeks.

Follow up

(After 1 month after complication of trial)

a. Clinical assessment
b. Measurement of PEFR

After completion of trial patients were followed up for the duration of two months at monthly interval to note the sustained effect or any untoward effect of the therapy.

Clinical (Subjective) Parameters-

Assessment of variables (Coughing, Wheezing, Dyspnoea, Rhinorrhoea, Use of accessory muscles, Decreased activity, Sleep disturbance and Restlessness) depending on the severity was done on four-point scale.

Nil=0, Mild=1, Moderate=2, Severe=3

Coughing

- No cough 0
- Occasional cough -1
- Continuous cough with moderate pain-2
- Continuous cough with severe pain-3

Wheezing

- No wheezing -0
- Mild wheezing -1
- Severe wheezing audible on auscultation-2

❖ Wheezing audible even without stethoscope - 3

Dyspnoea

❖ No dyspnoea at all in speaking-0

❖ Dyspnoeic but Speaks complete sentence-1

❖ Speaks in phrases or partial sentences-2

❖ Speaks only in single word or short phrases-3

Rhinorrhoea

❖ No nasal discharge -0

❖ Running nose without much visible fluid-1

❖ Rhinorrhoea with visible fluid-2

❖ Severe Rhinorrhoea with copious fluid-3

Use of Accessory muscle

❖ No use of accessory muscles-0

❖ No intercostal to mild retractions-1

❖ Moderate intercostal retractions with use of sternocleidomastoid muscle -2

❖ Moderate intercostal retractions with tracheosternal retractions and nasal flaring during inspiration-3

Physical Activity

❖ No breathless and able to do all type -0 of physical activities comfortably

❖ Breathless on moderate physical activity-1

❖ Breathless on mild physical activity-2

❖ Continuously breathless even without-3 any physical activity

Sleep Disturbance

❖ No interruption on sleep-0

❖ Little interruption-1

❖ During exacerbations-2

❖ Frequent sleep disturbance -3

Restlessness

❖ No restlessness-0

❖ Mild restlessness-1

❖ Moderate restlessness-2

❖ Severe restlessness -3

Statistical Analysis of the Results

The results obtained on different variables, were analyzed using the standard statistical methods. Student's paired and test was used. Its significance was estimated by means of 't' table on (n-1) degrees of freedom. 't' test was carried out at $p < 0.05$, $p < 0.01$, $p < 0.001$. The obtained results were interpreted as:

❖ Insignificant-$p > 0.05$

❖ Significant-$p < 0.05$ and $p < 0.01$

❖ Highly significant -$p < 0.001$

Assessment of Improvement:

Marked Relief

❖ More than 60% relief in sign and symptoms.

Moderate Relief

❖ 30-59% relief in sign and symptoms.

Mild Relief

❖ Below 30% relief in sign and symptoms.

No relief

❖ No relief in sign and symptoms.

OBSERVATIONS AND RESULTS

In the present study, 22 patients were registered for the clinical trial, out of them 20 completed the trial while 2 patients failed to complete the trial.

OBSERVATION ON VARIABLES`S PROFILE

Table 1 Distribution of 20 patients according to the Variables

Variables	Total patients	Percentage
Cough	20	100
Wheeze	19	95.00
Dyspnoea	16	80.00
Rhinorrhoea	16	80.00
Use of accessory muscles	10	50.00
Physical Activity	19	95.00
Sleep disturbance	16	80.00
Restlessness	18	90.00

Table 1 - Profile of variables in registered patient's revels that Cough was present in all the patients followed by Wheeze and Activity in 95%, Restlessnes in 90%, Rhinorrhoea, Sleep disturbance & Dyspnoea in 80%, and use of Accessory muscle in 50%, respectively.

EFFECT OF THERAPY : Clinical observations are related to 20 patients who completed the treatment for entire duration.

Table2 Statistical Presentation of Coughing

Group	N	Mean		D	% Change	± SD	± SE	t	P
		BT	**AT**						
Group I	20	2.55	0.75	1.80	71.15	0.41	0.09	19.62	<0.001

Table2 - The mean score obtained before the trial was 2.55 and after trial the mean score was reduced to 0.75 and the percentage relief was 71.15 % which is statistically highly significant ($p<0.001$).

Table 3 Statistical Presentation of wheezing

Group	N	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	19	1.89	0.58	1.31	69.44	0.48	0.11	12.01	<0.001

Table3 - The mean score obtained before the trial was 1.89 and after trial was reduced to 0.58. The percentage relief was 69.44 % which is statistically highly significant ($p<0.001$).

Table 4 Statistical Presentation of dyspnoea

Group	N	Mean		D	% change	± SD	± SE	T	P
		BT	**AT**						
Gr I	16	1.88	0.75	1.13	60.00	0.34	0.09	13.18	<0.001

Table4 - The mean score obtained before the trial was 1.88 and after trial was reduced to 0.75. The percentage relief was 60 % which is statistically highly significant ($p<0.001$).

Table 5 Statistical Presentation of Rhinorrhoea-

Group	n	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	16	1.94	0.75	1.19	61.29	0.40	0.10	11.78	<0.001

Table5 - The mean score obtained before the trials was 1.94 and after the trial was reduced to 0.75. The percentage relief was 61.29 % which is statistically highly significant ($p <0.001$).

Table 6 Statistical Presentation of Use of Accessory Muscles

Group	N	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	12	1.83	0.75	1.08	57.14	0.29	0.08	13.00	<0.001

Table6 - The mean score obtained before the trial in was 1.83 and after trial the mean score was reduced to 0.75. The percentage relief was 57.14% which is statistically highly significant (p<0.001).

Table 7 Statistical Presentation of Physical Activity

Group	n	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	19	1.84	0.79	1.05	57.14	0.62	0.14	7.39	<0.001

Table7 - The mean score obtained before the trial was 1.84 and after trial was reduced to 0.79. The percentage relief was 57.14 % statistically which is highly significant (p<0.001).

Table 8 Statistical Presentation of Sleep Disturbance

Group	n	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	16	1.88	0.69	1.19	63.33	0.40	0.10	11.78	<0.001

Table8 - The mean score obtained before the trial was 1.88 and after trial was reduced to 0.69. The percentage relief was 63.33 % which is statistically highly significant (p<0.001).

Table 9 Statistical Presentation of Restlessness

Group	n	Mean		D	% change	± SD	± SE	t	P
		BT	**AT**						
Gr I	18	2.22	0.89	1.33	60.00	0.49	0.11	11.66	<0.001

Table9 - The mean score obtained before the trial was 2.22 and after trial was reduced to 0.89. The percentage relief was 60% which is statistically highly significant (p<0.001).

Table 10 Effect on PEFR

Group	**n**	**Mean Score**		**D**	**% change**	**SD ±**	**SE ±**	**'t'**	**P**
		BT	**AT**						
G- I	15	171.00	210.53	39.53	23.00	10.13	2.61	-15.12	<0.001

Table10 - The mean score obtained before the trial was 171.00 and after the trial the score was 210.53. The percentage improvement was 23.00% which is statistically highly significant (p<0.001).

Table 11 Effect on Laboratory investigations

Clinical Feature	**N**	**Mean Score**		**% Diff.**	**SD ±**	**SE ±**	**'t'**	**P**
		BT	**AT**					
Hbgm%	20	10.98	11.17	1.73	0.49	0.11	-1.73	>0.05
TLC	20	7470	7325	1.94	1058.03	236.58	0.61	>0.05
Neutrophil	20	58.15	60.10	3.35	10.35	2.32	-0.84	>0.05
Lymphocyte	20	35.60	34.85	2.11	9.63	2.15	0.35	>0.05
Monocyte	20	1.40	1.30	7.14	0.79	0.18	0.57	>0.05
Eosinophil	20	5.50	2.45	55.45	4.26	0.95	3.20	<0.01
ESR	20	14.85	11.35	23.57	10.03	2.24	1.56	>0.05
AEC	20	352.00	158.75	54.90	109.16	24.40	7.92	<0.001
TSB	20	0.72	0.73	1.39	0.22	0.05	-0.30	>0.05
SGOT	20	35.95	29.30	18.50	17.98	4.02	1.65	>0.05
SGPT	20	35.20	28.05	20.31	15.82	3.54	2.02	>0.05
Blood urea	20	23.40	25.60	9.40	5.48	1.23	-1.79	>0.05

S/Creatinine	20	0.58	0.64	10.34	0.18	0.04	-1.42	>0.05

Table11 - Except for Eosinophil count and AEC count the hematological parameters were within normal limits both before and after the therapy and statistically insignificant changes ($p>0.05$) were observed in these values after the completion of therapy. The mean score obtained before trial in case of Eosinophil count was 5.50 which after trial was reduced to 2.45. The percentage improvement was 55.45 % which is statistically significant in both the groups ($p<0.01$). The mean score obtained before trial in case of AEC count was 352~~.00~~ which after trial was reduced to 158.75. The percentage improvement was 54.97 % which is highly significant ($p<0.001$).

OVERALL EFFECT OF THERAPY

The result of drug was evaluated on the basis of criteria established for assessment of the results. The patients were categorized into markedly improved, moderately improved, mildly improved and unchanged according to assessment criteria.

Table 12 Overall effect of Therapy

Results	No. of Patients	%age
Markedly Improved	14	70
Moderately improved	6	30
Mildly Improved	0	0
No improvement	0	0

Table 12 - Out of 20 patients 70 % (14) pateints showed marked improvement followed by 30 % (6) patients with moderate improvement.

DISCUSSION ON MODE OF ACTION OF TRIAL DRUG

In *Ayurveda*, bronchial asthma can be correlated with *Tamaka shwas*. It is basically a disease of *Pranavaha srotasa*, involving *Annavaha* and *Udakavaha srotasa*. The *Dosha* involved are mainly *Kapha* and *Vata*, *dushya* involved is *Ras dhatu*.

Charaka samhita has clearly mentioned the guideline for selection of drug or compound in the treatment of *Shwas*. He has emphasized that ideal drug selected should have a prominent quality of pacifying both *Vata* and *Kapha*[5].

The attention is also necessary on other pathogenic components like *Agni*, *Ama*, *Srotasa* and *Dhatus*. So the drugs which have capacity to break the pathogenesis, arrest the progression and also give symptomatic relief in childhood asthma, should be used. The drug which posses properties such as *Vata-kapha shamaka*, *Deepana*, *Pachana*, *Kapha-nissaraka*, *Srotoshodhaka* and *Shothahara* are effective in *Tamaka shwas*.

PROBABLE MODE OF ACTION OF *SHIRISH*

Ayurveda emphasizes on *srotorodha* in the manifestation of *Shwas roga*. *Srotorodha* is the resultant of disturbance in the

equilibrium of *Vata* and *Kapha*. Hence drugs which are beneficial in removing the obstruction and maintain the physiological equilibrium of *Vata* and *Kapha* are useful in this condition.

The pharmacokinetic properties of the drug – *Shirish* as per *Ayurveda* (*Madhura, Tikta, Kashaya rasa, Anushana veerya and Katu vipaka*) will be beneficial in counteracting the exacerbated *Kapha* and *Vata dosha*. By virtue of *Tikta rasa, Katu vipaka* and *Laghu guna* the drug shows *Deepana* and *Pachana* properties. The *Agnideepana* and *Pachana* function boosts the metabolism and diminishes the formation of *Ama*. This property of drug is vital in preventing the disease. *Madhura rasa* is said to increase all the *Sharira dhatus, Mana* and *Indriya*, alleviate *Vata dosha*, increases the vital strength. *Katu vipaka* increases the overall metabolism. This increases the quality of *Rasa dhatu* and their by the entire status of the body[10].

Shirish by virtue of its *Laghu* and *Tikshana guna*, has *Kapha nissaraka* and *Srotoshodhaka* properties, so it decreases the spasm of bronchi. It has property to inhibit histamine release which obstructs the immediate hypersensitive reaction and prevents histamine as well as acetylcholine induced bhronchospasm[11].

The immunomodulator activity of the drug is already described in drug review. As per related study the researchers has concluded that immunomodulatory regimen will play a key role in future therapies for allergic disease. These treatment modalities may not only treat allergic disease, but also be beneficial in reducing morbidity and mortality for which it is responsible[12].

Shirish has *Shothahara, Vishghna, Vedanasthapana* and *Shwasahara* properties which reduces the symptoms of Asthma.

By virtue of its *Vedanasthapana* property it reduces chest pain during coughing. Relief in dyspnoea and wheezing were because of reducing the barrier in the way of *Pranavayu* by *Samakapha*. The probable mode of action of the drug was because of its *Tridoshahar* effect, *Katu vipaka* and *Laghu, Tikshana guna*.

The drug was given with honey which itself has good *Kaphahar* action as per classics. It is one of the best suggested vehicles that have Yogavahi property which does not interfere with drug property and just transports it. The studies indicate its power to enhance the drug action, which is the best quality for *Anupana*.

CONCLUSION

Increasing prevalence of Bronchial Asthma in children is a global issue of concern due to associated long term compromise in the

quality of life. Symptomatology of Bronchial Asthma in children closely resembles with *Tamaka shwasa. Tamak shwas* is a *Kapha-vata* pradhan disease involving *Pranavaha srotas* with some *dushti* of *Annavaha* and *Udakvaha srotas*. Ayurveda can constitute multidimensional approach for the treatment of Bronchial Asthma. The study shows statistically highly significant results in all the clinical features of asthma. Drug was effective with statistically insignificant result. Statistically significant reduction was observed in Absolute Eosinophil count, and PEFR. Research showed long term sustained relief as evident from two month's follow up study. Prolongation of therapy may provide better results. No adverse effects of the study drug were observed during the study.

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