

ABSTRACT : Tamakashvâsa as described in Âyurveda is a disease of Prânavaha Srotas (Respiratory system) involving multiple etiopathogenesis. The clinical features are nearly similar to that of Bronchial asthma described in Modern medicine. This study was designed to explore the therapeutic effect and synergistic action (if any) of a plant Tâmalakî (*Phyllanthus fraternus* Webster). Tâmalakî is included in Shvâsahara and Kâsahara groups, used in many formulations prescribed in Shvâsaroga in Âyurveda. Research works suggest its antihistaminic property in experimental model and effective in non bacterial upper respiratory disorders. The present study comprises 3 groups (each 10 patients). Group A was treated with trial drug Ghanasattva of *P. fraternus* Webster, 500mg, thrice daily, orally; while Group B was treated with modern standard drugs (a) Tab. Theo-asthalin, thrice daily, orally and (b) Asthalin inhaler, SOS and Group C as combination of both therapies. Total duration of treatment was 45 days. The observations reveal that, Group A has much better improvement in increasing Jaranashakti ($t=7.57$; $p<0.001$) and Ruchi ($t=9.86$; $p<0.001$) in comparison to Group B and Group C. Moreover, Group C was found more effective in reducing majority of sign-symptoms as such Breathlessness ($t=9.00$; $p<0.001$), Cough ($t=6.47$; $p<0.001$), Expectoration ($t=9.00$; $p<0.001$) Wheezing ($t=7.96$; $p<0.001$), Rhonchi ($t=7.96$; $p<0.001$), Jaranashakti ($t=4.71$; $p<0.01$) and Ruchi ($t=6.68$; $p<0.001$).

Key words : Tâmalakî, *Phyllanthus fraternus* Webster, Ghanasattva, Tamaka Shvâsa, Bronchial asthma, Breathlessness, Jaranashakti.

INTRODUCTION

Tâmalakî is commonly known as 'Bhûmyâmalakî'. In Âyurvedic literatures Tâmalakî is included in many formulations used for the treatment of respiratory diseases^{1, 2, 3, 4}. It is bitter, astringent, sweet, stomachic, febrifuge and antiseptic. It pacifies Pitta -Kapha - Rakta Dosas and is indicated in diseases like Shvâsa, Kâsa, Hikkâ, Kshata, Kshaya, Meha, Mûtraroga etc^{5, 6, 7}. In practice, many species of *Phyllanthus* are used with the name Tâmalakî. In this study *Phyllanthus fraternus* Webster (syn. *Phyllanthus niruri* Linn.) of family Euphorbiaceae is considered as the source plant of Tâmalakî. It is found to have antihistaminic property in experimental model⁸ and effective in non bacterial upper respiratory disorders⁹. Out of 5 types of Shvâsa, Tamaka Shvâsa requires treatment irrespective of its curability or palibility. So the specific etiopathogenesis, clinical manifestations, types and treatment modalities were described separately¹⁰. It simulates with the bronchial asthma. It is defined as a chronic inflammatory disease of airways that is characterized by increased responsiveness of the

tracheobronchial tree to a multiplicity of stimuli. It is manifested physiologically by a widespread narrowing of the air passage, which may be relieved spontaneously or a result of therapy, and clinically by paroxysms of dyspnoea, cough, and wheezing¹¹. In modern medicine, being affords by all means in the treatment of Bronchial asthma no satisfactory result is achieved till date. Prolonged use of agonists, steroids etc. cause the side effects like hypertension, diabetes mellitus, immunosuppression and toxic effects to liver, kidney etc.

In this study, an effort is made to treat the bronchial asthma with an attempt to minimize side effects and toxic effects of modern drugs, and to increase the therapeutic efficacy of trial drug in addition with modern medicine.

MATERIALS AND METHODS

Preparation and Dose of trial drug :

Fresh plants were collected from the surrounding of B.H.U. campus in the months of September -October and were identified by the experts of Department of Dravyaguna and Department of Botany, B.H.U., Varanasi. Then the plant material was cleaned and dried well in shadow, then crushed into yavakûta chûrna and collected into a vessel. Four times water was added & kept for overnight. Next day morning the content was heated slowly till total quantity of content reduced up to

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¼th quantity. The water extract was filtered with cloth for 3 times and then boiled again slowly till its consistency became similar to honey. At this stage vessel was taken out from fire, content was collected into a tray and dispersed uniformly and dried in sunlight for 10 days to get the Ghanasattva. During preparation approximately 500gm of Ghanasattva was obtained from 5kg of crude dried sample. Hence, it can be calculated as:

5000 gm crude drug	=	500 gm Ghanasattva
1gm crude drug	=	100 mg Ghanasattva
5gm crude drug	=	500 mg Ghanasattva

After that capsules were filled in a dose of 500 mg. We have recommended dose of the drug Ghanasattva as 1500 mg per day into three divided doses, which was administered after food with water for a period of 45 days.

Selection of cases :

The patient of Tamakashvāsa of either sex and different age groups were selected according to diagnostic, inclusion and exclusion criteria from O.P.D. & I.P.D., Department of Dravyaguna, O.P.D. of Department of Medicine, Sir Sundar Lal Hospital, IMS, BHU, Varanasi. Follow-up of the patients was done in regular intervals of 15 days.

Inclusion criteria :

- Age : Patients in between 12-70 years.
- Patient suffering from mild to moderate degree of Tamakashvāsa.

Exclusion criteria :

- Patients of age below 12 and above 70 years.
- Severely malnourished / debilitated patients.
- Restrictive lung diseases (neuronal and skeletal deformity disorders).
- Acute severe asthma (status asthmaticus).
- Cardiac, renal and other type of breathlessness.
- Patients having diabetes mellitus, hypertension, tuberculosis, heart diseases, immuno-suppressive diseases and other chronic illness.

Grouping of patients :

Based on random distribution, 42 patients were registered. Out of them, 34 patients have come for regular follow-up. To prepare the accurate data only 10 patients

in each group were compared. Based on random distribution 30 patients were divided into 3 groups as follows-

- | | | |
|--------------|-------------|---|
| 1. Group - A | 10 patients | Treated with trial drug (Ghanasattva of <i>P. fraternus</i>) |
| 2. Group - B | 10 patients | Treated with Modern standard drugs
(a) Tab. Theo-asthalin (Theophyllin 100mg + Salbutamol 2 mg)
(b) Asthalin inhaler (Salbutamol) SOS |
| 3. Group - C | 10 patients | Treated with combination therapy of above two drugs. |

Parameters for assessment of the drugs response :

Subjective and objective parameters were taken into consideration for assessment of drug response in each follow up of 15 days. The mean scores obtained at the end of 3rd follow up was considered as scores of after treatment (AT), which were compared statistically with scores of before treatment (BT).

Subjective parameters : Breathlessness, Cough, Wheezing, Expectoration, Rhonchi, Jaranashakti and Ruchi.

Objective parameters : Forced Expiratory Volume in 1st second (FEV₁), Forced Vital Capacity (FVC), Peak Expiratory Flow Rate (PEFR), Differential Leucocyte Count for Eosinophil and Absolute Eosinophil Count (AEC) were evaluated.

OBSERVATION AND RESULTS

Therapeutic response on Symptomatic profile :

In group A, statistically highly significant results were found in the symptoms of Breathlessness (t=4.13; p<0.01), Cough (t=9.00; p<0.001), Expectoration (t=4.58; p<0.01), Rhonchi (t=6.13; p<0.001), Jaranashakti (t=7.57; p<0.001) and Ruchi (t=9.86; p<0.001). But statistically significant result was observed in Wheezing (t=3.21; p<0.02).

In group B patient also showed, statistically highly significant results in Breathlessness (t=8.57; p<0.001), Cough (t=4.74; p<0.01), Rhonchi (t=9.00; p<0.001), Wheezing (t=5.01; p<0.01), Jaranashakti (t=3.87; p<0.01) and Ruchi (t=4.74; p<0.01). Statistically non-significant result was observed in Expectoration (t=1.86; p>0.05).

In group C, patient showed statistically highly significant results in reducing almost all the symptomatic profiles. The mean score recorded as Breathlessness ($t=9.00$; $p<0.001$), Cough ($t=6.47$; $p<0.001$), Expectoration ($t=9.00$; $p<0.001$), Wheezing ($t=7.96$; $p<0.001$), Rhonchi ($t=7.96$; $p<0.001$), Jaranashakti ($t=4.71$; $p<0.01$) and Ruchi ($t=6.68$; $p<0.001$).

In intergroup comparison of A vs B showed statistically highly significant results in improving Jaranashakti ($t=3.09$; $p<0.01$) and Ruchi ($t=5.55$; $p<0.001$), and all other profiles were found non-significant ($p>0.05$). Group B vs Group C, showed statistically highly significant result in Cough ($t=3.28$; $p<0.01$), Rhonchi ($t=3.39$; $p<0.01$) and Ruchi ($t=2.91$; $p<0.01$), significant in Breathlessness ($t=2.46$; $p<0.05$), Expectoration ($t=2.33$; $p<0.05$), Wheezing ($t=2.87$; $p<0.02$) and non-significant in Jaranashakti ($t=1.41$; $p>0.05$). Group C vs Group A showed statistically significant effect in Breathlessness ($t=2.41$; $p<0.05$), Cough ($t=2.21$; $p<0.05$) Expectoration ($t=2.47$; $p<0.05$), Wheezing ($t=2.74$; $p<0.02$), Rhonchi ($t=2.15$; $p<0.05$), and Ruchi ($t=2.25$; $p<0.05$) and non-significant in Jaranashakti ($t=1.34$; $p>0.05$).

The statistical data (BT-AT) obtained from the intragroup and intergroup analysis, revealed that trial drug imparts better improvement in symptoms of Jaranashakti and Ruchi than the standard and combination groups. Whereas, the combined group showed better results in all profiles.

Response on objective parameters :

Group A showed statistically results in FEV_1 ($t=5.13$; $p<0.01$), FVC ($t=5.11$; $p<0.01$), Eosinophil ($t=3.66$; $p<0.01$) and AEC ($t=7.94$; $p<0.001$), whereas PEFR ($t=2.03$; $p>0.05$) was found non-significant.

In Group B, statistically highly significant results were observed in FEV_1 ($t=19.73$; $p<0.001$), FVC ($t=12.66$; $p<0.001$) and AEC ($t=4.36$; $p<0.01$), whereas significant in Eosinophil ($t=2.60$; $p<0.05$) and PEFR ($t=1.10$; $p>0.05$) was found non-significant.

Group C showed statistically highly significant result in all profiles. FEV_1 ($t=13.09$; $p<0.001$), FVC ($t=11.81$; $p<0.001$), PEFR ($t=4.04$; $p<0.01$), Eosinophil ($t=9.12$; $p<0.001$) and AEC ($t=18.25$; $p<0.001$).

Intergroup comparison of Group A with Group B, showed statistically highly significant in AEC ($t=5.01$; $p<0.001$). The difference of mean (BT-AT) was highest in Group A, signified trial drug more

effective in reducing AEC. The other profiles showed statistically non-significant ($p>0.05$). Group B vs. Group C showed statistically highly significant in Eosinophil ($t=3.88$; $p<0.01$) and AEC ($t=10.27$; $p<0.001$). By observing the differences of mean (BT-AT), Group C was found more effective in both the profiles. FVC ($t=2.87$; $p<0.02$) was found statistically significant and the rest are non-significant ($p>0.05$). Group A vs. Group C were found statistically non-significant ($p>0.05$) in all profiles. The differences of mean (BT-AT) imply that group C imparts better improvement.

DISCUSSION

In the demographic profile, majority of the patients were in age group of 51-60 yrs, male (66.64%), were registered in winter season (46.66%), which shows its aggravation during this period. The 33.33% had addiction of smoking and allergic tendency towards dust, gave the information as one of the causative factors. The 53.33% had chronicity of the disease between 1-5 years.

The assessment of results was based on subjective and objective parameters. From the observations and results, the trial drug in combination with modern drugs was found more effective in reducing majority of sign-symptoms. The trial drug alone showed better improvement in Jaranashakti and Ruchi in comparison to other groups. On this basis the mode of action may be postulated as, in combination they exert synergistic action. The trial drug is Tikta in Rasa predominantly (Tikta is said to have Dīpanīya and Pāchanīya property), so acts at Agni level and stimulates the digestive power and increases the appetite. It pacifies the degree of Breathlessness, Rhonchi, Wheezing, Expectoration, probably due to Ruksha guna (Ruksha guna possesses the best drying up property). It has also antihistaminic property, thus proved effective in reducing Eosinophil and AEC.

CONCLUSION

The effect of therapy after completion of 45 days duration was encouraging. The trial drug alone showed much better result especially in improving Jaranashakti ($t=7.57$; $p<0.001$) and Ruchi ($t=9.86$; $p<0.001$). In combination, it was observed statistically highly significant in reducing Breathlessness ($t=9.00$; $p<0.001$), Cough ($t=6.47$; $p<0.001$), Expectoration ($t=9.00$; $p<0.001$) Wheezing ($t=7.96$; $p<0.001$), Rhonchi ($t=7.96$; $p<0.001$), Jaranashakti ($t=4.71$; $p<0.01$) and Ruchi ($t=6.68$; $p<0.001$), which shows the synergistic effect of trial drug.

Scale of Asthmatic sign-symptoms :

Sign-symptoms	Score	Grade	Grading criteria
Dyspnoea	0	Absent	No breathlessness
	1	Mild	Breathlessness on unaccustomed work
	2	Moderate	Breathlessness on accustomed work
	3	Severe	Breathlessness even at rest
Expectoration	0	Absent	No expectoration
	1	Mild	Occasional scanty expectoration
	2	Moderate	In between 1 and 3
	3	Severe	Copious expectoration
Wheezing	0	Absent	No wheezing
	1	Mild	One or two times per day
	2	Moderate	During night time
	3	Severe	Throughout the day
Rhonchi	0	Absent	Absent on normal breathing, but few on forced breathing
	1	Mild	Few scattered bilateral on normal deep breathing
	2	Moderate	In between Score 1 and Score 3 on normal breathing
	3	Severe	Innumerable high pitched bilateral on normal breathing
<i>Jaranashakti</i> (5 symptoms are Utsāha, Laghutā, Udgāraúuddhi, Kshut-Trishnā pravritti and Yathocita malotsarga)	0	Normal	Presence of 5 symptoms
	1	Mild	Presence of 4 symptoms
	2	Moderate	Presence of 3 symptoms
	3	Severe	Presence of 2/1 symptoms
<i>Ruchī</i>	0	Normal	Equally willing towards all the <i>Āhāra Rasas</i>
	1	Mild	Willing towards some specific <i>Āhāra Rasas</i>
	2	Moderate	Willing towards only one <i>Āhāra Rasa</i>
	3	Severe	Totally unwilling

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