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Kulathadi Kwatha and Talisapatradi Churna In Tamaka Shwasa (Bronchial Asthma) : An Open Label, Single Arm Clinical Study

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ABSTRACT

Background: *Tamaka Shwasa* is a *Pranavaha Sroto Vikara*, with predominant *Dosha*, *Kapha* and *Vata* and the site of origin is *Pittasthana*. The condition has similarity in clinical presentation with Bronchial Asthma. It leads to recurrent episodes of breathlessness, wheezing, cough and tightness of chest. *Shamshodhana* and *Shamshamana* are the two treatment modalities explained in *Tamaka Shwasa*. **Objectives:** To clinically assess the combined effectiveness of *Kulathadi Kwatha* and *Talisapatradi Churna* in *Tamaka Shwasa*. **Materials and methods:** This study was carried out by *Shamanaushadhis* viz; *Kulathadi Kwatha* and *Talisapatradi Churna* in 30 subjects of either sex in between the age 18-40 years, for 30 days, followed by follow up on 45th day. Collected data were tabulated and analysed using SPSS (Statistical package for social sciences) version 20 by using appropriate statistical test. **Results:** There was statistically significant improvement observed in the signs and symptoms of *Tamaka Shwasa* and Peakflow Meter with the P value <0.05. **Conclusion:** The trial drug *Kulathadi Kwatha* and *Talisapatradi Churna* was found beneficial in symptoms of *Tamaka Shwasa*.

Key words: *Tamaka Shwasa*, *Bronchial Asthma*, *Kulathadi Kwatha*, *Talisapatradi Churna*, *Shamana Aushadhis*.

INTRODUCTION

Tamaka Shwasa is *Kapha-Vataja Vikara* and the site of origin is *Pittasthana*. The causative factors responsible for *Tamaka Shwasa* are *Dhuma* (smoke), *Raja* (dust), *Ativyayama* (excessive work/exercise), *Sheetha Sthana Nivasa* (residing in cold areas), *Gurubhojana* (heavy diet), *Sheetha Bhojana* (cold

food/drinks). These factors cause vitiation of *Vata* and *Kapha* leading to vitiation of *Rasa* and impeding the functions of *Pranavata*.^[1]

Tamaka Shwasa has similarity in clinical presentation with Bronchial Asthma characterized by intermittent airflow obstruction, airway inflammation and bronchial hyper responsiveness. Bronchial Asthma manifests with difficulty in breathing, cough, wheezing, and tightness of chest.^[2]

It is estimated that 300 million people worldwide suffer from asthma, among them a tenth of population is living in India. The burden of asthma is immense; the prevalence of asthma has been estimated to range of 2-12% in adults. The world health organization estimated that asthma contributes to the loss of 15 million disability adjusted life.^[3]

Tamaka Shwasa is a *Yapya Vyadhi*. *Kulathadi Kwatha* and *Talisapatradi Churna* have been mentioned in

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Shwasa Chikitsa. As per a clinical trial conducted, *Kulathadi Kwatha* is proven to be an effective *Yoga* which has *Kaphanishteevana Karma* and which significantly reduced the other symptoms of *Tamaka Shwasa* within a stipulated time.^[4] An antioxidant study on *Talisapatradi Churna* has proven its antibacterial and antihistamic activity.^[5] Hence, to evaluate the combined effectiveness of *Kulathadi Kwatha* and *Talisapatradi Churna* and also considering the prevalence recurrence and adverse effect of *Tamaka Shwasa* on the quality of life of the individual, the following study was conducted.

OBJECTIVES

To clinically assess the combined effectiveness of *Kulathadi Kwatha* and *Talisapatradi Churna* in *Tamaka Shwasa* (Bronchial asthma).

MATERIALS AND METHODS

Source of Data

Subjects who attended the Out - Patient Department of Kayachikitsa at Sri Dharmasthala Mnajunatheshwara College of Ayurveda and Hospital, Hassan.

Methods of collection of data

62 subjects were screened and selected based on the screening form prepared.

32 cases were registered and data was collected using specially prepared case report form.

Diagnostic Criteria

Diagnosis was made on basis of signs and symptoms of *Tamaka Shwasa* [Bronchial asthma] viz. Breathlessness (*Shwasakrichratha*), Wheeze (*Gurguratwam*), Cough (*Kasa*) and Expectorations (*Kaphanishteevana*).

Inclusion Criteria

Patients aged between 18-40 years with features of *Tamaka Shwasa* (bronchial asthma - mild to moderate grades as per GINA)^[6] with chronicity < 10 years, either gender and Patient who are willing to sign in informed consent form.

Exclusion Criteria

Patients who are known cases of COPD, Pneumonia, Tuberculosis, Pleural Effusion, Cardiac Pathology, Uncontrolled Diabetes Mellitus, Hypertension, Uremia, Acidosis, Malignancy, Head injuries and pregnant women/lactating mother were excluded.

Laboratory Investigation

Radiological - Chest X- ray (PA view), Absolute Eosinophil Count and Peak Expiratory Flow Rate.^[7]

Study Design

This study was an open label single arm, clinical study on 30 subjects of *Tamaka Shwasa* (Bronchial Asthma) selected using convenience sampling technique.

Intervention

1. *Kulathadi Kwatha*^[8]
2. *Talisapatradi Churnam*^[9]

Source and authentication of raw drug

Raw drugs were procured and authenticated from GMP certified CKKM Pharmacy Trippunithara, Kochi. *Kulathadi Kwatha* was prepared at Sri Dharmasthala Manjunatheshwara Teaching Pharmacy, Hassan. *Talisapatradi Churna* was purchased from GMP certified Sri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Udupi.

Treatment Plan

Kulathadi Kwatha: 15 ml tid before food

Talisapatradi Churna: 4 grams in 3 divided doses after food with *Madhu* as *Anupana*.^[10]

Duration: 30 days

Follow up during the treatment: follow up was done on 1st, 15th, 30th

Follow up after the treatment: on 45th day

Assessment Criteria

A. Subjective Parameter

The effect of the therapy was assessed on the basis of relief with following signs and symptoms of *Tamaka Shwasa* viz. *Shwasakrichratha*, *Gurguratwam*, *Kasa*,

Kaphanishteevanam, Parshwashoola, Aasinolabate Soukhyam.

B. Objective parameters

Assessment of lung volume was done using GINA Scale and Peak expiratory flow rate.

OBSERVATION

In the present clinical study 32 subjects were registered for observation. Out of 32 subjects 10 subjects were agriculturist, 17 were from rural area., 16 (49.9%) subjects had smoke/dust/perfume, cold drinks and frozen foods, cold climate, physical exertional activities as aggravating factors, 12 had rest, fomentation, change of climate, steam inhalation, expectoration as relieving factor, 18 (56.3%) had *Samagni*, 21 (65.6%) had *Madhyama Koshta*, 29 (90.6%) had disturbed sleep, 9 (28.1%) had a habit of smoking.

Table 1: Baseline distribution of 32 patients of Tamaka Shwasa.

Lakshana	Percent %
Shwasakruchrata	32 (100%)
Gurgurakata	32 (100%)
Kasa	32 (100%)
Kapha Nishteevana	27 (84.4%)
Asinolabhate Soukhyam	28 (87.5%)
Parshwashoola	23 (71.9%)

Results: A total of 32 subjects of *Tamaka Shwasa* were registered for the study; of which 2 dropped out and 30 completed the trial.

Table 2: Effect of therapy on Shwasakruchrata.

Shwasakruchrata	Mean rank	P value
1 st day	3.85	< 0.005
15 th day	2.90	
30 th day	1.60	
45 th day	1.65	
Test: Freidman’s test		

Table 3: Effect of therapy on Shwasakruchrata.

Shwasa kruchrata	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	22	0	8	30	253.00	-4.35	>0.016	S
15 th -30 th day	26	0	0	30	351.00	-4.62	>0.016	S
30-45 th day	8	7	15	30	60.00	.000	>0.016	NS
1 st -45 th day	29	0	1	30	435.00	-4.77	<0.016	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 4: Effect of therapy on Kasa.

Kasa	Mean rank	P value
1 st day	3.88	< 0.005
15 th day	2.85	
30 th day	1.75	
45 th day	1.52	

Table 5: Effect of therapy on Kasa.

Kasa	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	23	0	7	30	276.00	-4.630	<.016	S
15 th -30 th day	21	0	9	30	351.00	-4.347	<0.016	S
30-45 th day	7	1	22	30	60.00	-2.121	>0.016	NS
1 st -45 th day	30	0	0	30	435.00	-4.889	<0.016	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 6: Effect of therapy on Gurgurakata.

Gurgurakata	Mean rank	P value
1 st day	3.65	< 0.005
15 th day	2.87	
30 th day	1.65	
45 th day	1.83	
Test: Freidman's test		

Table 7: Effect of therapy on Gurgurakata.

Gurgurakata	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	15	0	15	30	120.00	-3.69	<.016	S
15 th -30 th day	21	1	8	30	242.50	-4.14	<0.016	S
30-45 th day	3	6	21	30	15.00	-1.00	>0.016	NS
1 st -45 th day	26	0	4	30	351.00	-4.61	<0.016	S
Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)								

Table 8: Effect of therapy on Kapha Nishteavana

Kapha Nishteavana	Mean rank	P value
1 st day	3.37	< 0.005
15 th day	2.85	
30 th day	1.88	
45 th day	1.90	
Test: Friedman's test		

Table 9: Effect of therapy on Kaphanishtheavana

Kapha Nishteavana	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	17	6	7	30	197.00	-1.906	<.016	S

15 th -30 th day	17	0	13	30	153.00	-3.945	<0.016	S
30-45 th day	4	4	22	30	18.00	-1.000	>0.016	S
1 st -45 th day	21	0	9	30	231.00	-4.123	<0.016	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 10: Effect of therapy on Muhurmuhur Shwasa

Muhurmuhur Shwasa	Mean rank	P value
1 st day	3.50	< 0.005
15 th day	2.67	
30 th day	1.82	
45 th day	2.02	
Test: Friedman's Test		

Table 11: Effect of therapy on Muhurmuhur Shwasa

Muhurmuhur Shwasa	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	13	0	17	30	91.00	-3.606	<0.016	S
15 th -30 th day	14	1	15	30	112.00	-3.357	<0.016	S
30-45 th day	2	5	23	30	8.00	-1.134	>0.016	NS
1 st -45 th day	22	0	8	30	253.00	-4.600	<0.016	S
Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)								

Table 12: Effect of therapy on GINA assessment severity of Asthma

GINA severity assessment of Asthma	Mean rank	P value
1 st day	3.58	< 0.005
15 th day	3.05	
30 th day	1.63	
45 th day	1.73	
Test: Friedman’s Test		

Table 13: Effect of therapy on GINA assessment severity of Asthma.

GINA severity assessment of Asthma	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	10	0	20	30	91.00	-3.051	<0.016	S
15 th -30 th day	24	0	6	30	112.00	-4.899	<0.016	S
30-45 th day	10	9	11	30	8.00	-.229	>0.016	NS
1 st -45 th day	26	0	4	30	253.00	-4.617	<0.016	S
Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)								

Table 14: Effect of therapy on Assessment of level of asthma control

Assessment of level of asthma control	Mean rank	P value
1 st day	3.57	< 0.005
15 th day	2.98	
30 th day	1.77	
45 th day	1.68	
Test: Friedman’s Test		

Table 15: Effect of therapy on Assessment of level of Asthma control

Assessment of level of asthma control	Ranks				Sum of ranks	Z	P	Remarks
	NR	PR	T	Total				
1-15 th day	12	0	18	30	78.00	-3.464	<0.016	S
15 th -30 th day	21	1	8	30	241.50	-4.264	<0.016	S
30-45 th day	7	5	18	30	45.50	-.577	>0.016	NS
1 st -45 th day	26	0	4	30	351.00	-4.660	<0.016	S
Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)								

Table 16: Effect of therapy on Asinolabate Soukhyam and Parshwashoola

Lakshana	1 st day		15 th day		30 th day		45 th day		P value
	P	A	P	A	P	A	P	A	
Asinolabate Soukhyam	26	4	12	18	1	29	1	29	<0.05
Parshwashoola	21	9	9	21	2	28	0	30	
P - Present, A - Absent									

There was statistically significant difference in Lakshanas like Asinolabate Soukhyam & Parshwashoola with Cochran’s Q test at p<0.05.

Table 17: Effect of therapy on Asinolabate Soukhyam

Asinolabate Soukhyam	1 st day		15 th day		30 th day		45 th day		N	Remarks
	P	A	P	A	P	A	P	A		
	26	4	12	18	1	29	1	29		

P value	0.001	0.001	0.001	>.001		
P - Present, A - Absent, Test: Mc'nemar Test						

Table 18: Effect of therapy on Parshwashoola

Parshwa Shoala	1 st day		15 th day		30 th day		45 th day		N	Remarks
	P	A	P	A	P	A	P	A		
	21	9	9	21	2	28	0	30	30	S
P value	0.008		0.001		0.001		0.001			
P - Present, A - Absent										

Table 19: Effect of therapy on PEF

Parameter PEF	N	Mean	Spericity assumed			Spericity assumed error df	Remarks
			D f	F value	P value		
1 st day	30	.3667	3	16.469	<0.05	27	S
15 th day		.6667					
30 th day		1.1667					
45 th day		1.1667					
Test: Repeated measure ANOVA test							

Table 20: Showing Pair wise comparison

Pairwise Comparisons							Remarks
(I) Factor 1	(J) Factor 1	Mean Difference (I-J)	Std. Error	Sig. ^B	95% Confidence Interval For Difference ^b		
					Lower Bound	Upper Bound	S
1 st Day	15 th Day	-300	.098	<.016	-577	.548	
15 th day	30 th Day	-.500	125		-.853	-.147	
30 th	45 th	.000	136		-.384	.383	

day	Day					
45 th Day	1 st Day	.800	121		.457	1.143
	15 th Day	.500	125		.147	.853
	30 th Day	.000	136		-.384	.384
Repeated measures Anova BT - before treatment, AT - after treatment, Df - degree of freedom						

DISCUSSION

Effect on Shwasakruchrata: Statistically significant improvement was noticed in *Shwasakruchrata* after the treatment. *Shwasakruchrata* is result of *Pranavaha Sroto Sankocha* and *Avarodha*, due to *Vata Prakopa* in *Pranavaha Srotas* & *Vata* being obstructed by *Kapha*. *Kulatha*, *Nagara*, *Vasa*, *Vyaghri* & *Pushkaramula* having *Laghu Ruksha Guna*, *Ushna Veerya* helps in liquefying the *Kapha*, relieves *Srotorodha* and improves breathing. *Talisapatradi Churna* has *Kapha Lekhana* & *Kapha Vatahara* properties. It acts as an expectorant, which helped in reduction of *Shwasakruchrata*.^[18]

Effect on Gurghurukata: *Gurghurukata* was reduced by its mean rank statistically significant improvement was noticed after treatment.

Gurghurukata is due to *Pranavaha Sroto Avarodha* by *Kapha*. It is generated by vibration in the wall of an airway on the point of closure due to smooth muscle contraction.

Talisapatradi Churna possess anti-inflammatory, has bronchodilator and expectorant actions. It can effectively drain out the mucus and reduce airway resistance.^[19]

Effect on Kasa and Kapha Nishteavana: Statistically significant improvement was noticed in *Kasa* and *Kapha Nishteavana* after treatment. *Kasa* is an effort to expel the *Malaroopi Kapha* secreted in the *Pranavaha Srotas*. *Talisapatradi Churna* having *Katu Rasa*, *Laghu Ruksha Guna*, *Ushna Veerya* & *Kapha Vatahara* properties facilitates liquefaction of the mucus and thus helped in reduction of *Kasa* & *Kapha Nishteavana*.^[20]

Effect on Muhurmuhur Shwasa: The symptom was reduced in its mean rank & statistically significant improvement was noticed. Due to *Ruksha Guna, Ushna Veerya* of *Talisapatradi Churna* and *Kulathadi Kwatha*, there was reduction in *Kapha* causing relief in symptom of *Muhurmuhur Shwasa*.^[21]

Effect on Asinolabhate Soukhyam: Statistically significant improvement was noticed in *Asinolabhate Soukhyam* after treatment. An individual suffering with *Tamaka Shwasa* experiences difficulty in breathing in supine position and relief while sitting. This can be explained as the increased broncho constriction due *Kapha Avarodha* causing *Pratilomagati* of *Pranavayu* additional to physiological diaphragmatic pressure on lungs in supine position.

Ushna Teekshna Katu properties of drugs in *Talisapatradi Churna* helps in reduction in production of *Kapha* and increases elimination of *Kapha*. Thus clearing the airway obstruction and *Vata Anulomana* which in turn reduces the broncho constriction and dyspnea.^[22]

Effect on Parshwashoola: Statistically significant improvement was noticed in *Parshwashoola* by its mean after treatment. Due to aggravation in *Vata* and *Kapha*, patient experiences repeated cough and breathing difficulty, in turn causes pain in *Parshwa Bhaga*.

The *Teeksha Guna, Ushna Veerya & Kapha Vata Shamaka* properties of *Talisapatradi Churna* and *Kulathadi Kwatha* helped in reduction of cough, thereby relieved *Parshwashoola*.^[23]

Effect on Gina Assessment Scale: Significant improvement in assessment of level of asthma control and in severity of asthma control was noticed after treatment. *Laghu Ruksha, Teekshna Guna, Ushna Veerya & Kapha Vatahara* properties of *Kulathadi Kwatha* and *Talisapatradi Churna* helped in relieving symptoms of *Tamaka Shwasa*.

Effect on Peak Expiratory Flow Rate: Statistically significant reduction in Peak Expiratory Flow was observed before and after the treatment. *Kapha Vilayana* property of the *Kulathadi Kwatha* and

Talisapatradi Churna enhanced the normal *Gati* of *Vata*. It showed significant reduction in the airway obstruction and relief from symptoms of *Shwasa Kruchrata, Gurghurukata & Kasa*. Thus, there was improvement in the values of peak expiratory flow rate.

CONCLUSION

The trial drug *Kulathadi Kwatha* and *Talisapatradi Churna* was found beneficial in symptoms of *Tamaka Shwasa*. Statistically significant improvement was observed in primary outcome measures like, *Shwasakruchrata, Gurgurata, Kasa, Kaphashteevana, Asinolabhate Soukhyam & Parshwashoola*. The assessment of severity of asthma and level of asthma control as per GINA scale showed marked improvement in all parameters like day time symptoms, exacerbations, nocturnal symptoms and limitations of activities after treatment. Statistically significant improvement was noticed in secondary outcome measures Peak expiratory flow rate.

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